Integrated care pathways for acute stroke: an evaluation of their effects using multiple approaches

Dr Joseph Shiu Kwong Kwan
MB ChB MPhil MRCP

Doctor of Medicine Degree
The University of Edinburgh
2002

CONTENT OF THE THESIS

ABSTRACT

Background

Stroke is common and is associated with high levels of mortality and morbidity. There have been significant advances in acute stroke treatments and stroke rehabilitation in the past few decades. One example is stroke unit care, which has been proven to be effective in reducing death and dependency after stroke. However, there are significant variations in the medical and nursing care of stroke patients in hospital, access to stroke unit care, organisation of care, and clinical outcome. The relationship between these variations is unclear.

In the last twenty years, stroke integrated care pathways (ICPs) have been introduced as a tool to promote organised and efficient patient care that is based on the best-available evidence and clinical guidelines. There are potential advantages and disadvantages with using ICPs, and the evidence to support their widespread use is unclear. ICPs are complex interventions and there are important methodological considerations when conducting evaluation studies – conventional randomised trials are often not possible. Consequently, evaluation of the effects of ICPs may require multiple approaches.

Aims of this thesis

1) To evaluate the effects of ICPs for acute stroke using multiple approaches.
2) To explore the methodological issues concerning the different research designs that are used to evaluate the effects of ICPs for acute stroke.

Methods and results

I sought to evaluate the effects of ICPs for acute stroke using four approaches:

1) ***Assessment of the evidence from previous studies of ICPs for non-stroke conditions.*** I performed a review of the recent literature and found that there were a large number of randomised and non-randomised studies of ICPs for non-stroke conditions. Positive, neutral and negative findings have been reported.

2) ***Assessment of the evidence from previous studies of ICPs for acute stroke.*** I performed a Cochrane systematic review and found three randomised trials and seven non-randomised studies. There were substantial heterogeneity between the studies and most

of the evidence came from non-randomised studies. I found that ICP care may significantly improve the process of care and reduce in-hospital complications, but patient satisfaction and quality of life may be lower.

3) ***Undertaking of two non-randomised studies of the ICP introduced for acute stroke at the Western General Hospital (WGH).*** 1) I performed a before-and-after study (total of 351 patients) to assess the effects of introducing an ICP in a stroke unit. I found that, after its introduction, there were significant improvements in the quality of documentation and certain aspects of patient care, and the risk of urinary tract infection was reduced. However, there was no significant difference in death or discharge destination. 2) I also performed a prospective comparative study (total of 285 patients) to assess the difference in the process of care and outcome between stroke unit care after the introduction of the ICP and general medical ward care. The results were consistent with those of the before-and-after study and previous evidence.

4) ***Undertaking of two questionnaire surveys to assess the experience of the stroke unit staff regarding the use of the ICP for acute stroke at the WGH.*** I found that, when the ICP was first introduced, the staff expected the ICP to improve the process and quality of care, communication and the general working environment. I repeated the survey six months later and found that, although certain aspects of care were felt to have improved, many of the staff's expectations were not realised.

Conclusion

Using these four approaches, I found evidence from previous studies that patient care with a stroke ICP may be associated with both benefit and harm. The non-randomised studies conducted at the WGH confirmed the beneficial effects, but patient satisfaction and quality of life were not assessed. The questionnaire surveys highlighted the importance of being realistic about what an ICP could achieve in clinical practice. The limitations of each of these four approaches are discussed in detail. In summary, the evidence is accumulating that patient care using a stroke ICP may be beneficial, and the beneficial effects may be most apparent in hospitals where the basic structure of the stroke service is in place but the patient care is poorly organised. Further research should provide more information regarding the effects of ICPs on the process of care and outcome. Possible research designs for future studies are discussed.

DECLARATION

I hereby declare that:

- I composed this thesis
- I made a substantial contribution to the work. I planned, designed and undertook the literature review (Chapter 3), the Cochrane systematic review (Chapter 4), the two non-randomised studies (Chapters 5 & 6) and the questionnaire surveys (Chapter 7). I was involved in the design of the database and I collected all the data. I entered much of the data into the database and performed all the data analyses.
- All of the work contributing to this thesis was undertaken whilst I was employed as a research fellow at the Department of Clinical Neurosciences, Western General Hospital, Edinburgh.
- This thesis has not been submitted for any other degree, postgraduate diploma or professional qualification.

Signature: **Date:** 13.11.2002

ACKNOWLEDGEMENTS

I am extremely grateful to the many members of the Department of Clinical Neurosciences who have made this entire research project and thesis possible. My supervisors, Professor Peter Sandercock and Dr Martin Dennis, provided tremendous guidance, encouragement and wisdom. I am indebted to all the staff in the stroke unit who kindly took part in the questionnaire surveys and the stroke patients who allowed us to interview and examine them. Dr Peter Hand assessed many of the patients in my non-randomised studies, and provided great friendship and support. Brenda Thomas and Hazel Fraser from the Cochrane Stroke Group assisted me in performing the Cochrane systematic review. Dr Steff Lewis provided the sound and easy-to-understand statistical advice. Sheila Grant entered much of the data and Vera Soosay managed the database. David Perry provided the essential IT support throughout the two years. I would also like to thank Glaxo Wellcome and The Stroke Association for funding my research fellowship.

Most importantly, a very special thanks to my wife, Beccy, who has been a constant source of enthusiasm, energy, inspiration, prayer and love. I dedicate this thesis to her.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER ONE

INTRODUCTION

1.1 Stroke is a major public health problem

Stroke can be a devastating condition which places a heavy burden on the patient, their family, and the community. Stroke is the second commonest cause of death, accounting for 10 to 12% of all deaths in industrialised countries, and is the leading cause of long-term disability (Bonita 1992; Murray & Lopez 1997a; WHO 1999). Stroke is a growing public health problem as the number of older people in the population increases rapidly (Ostfeld & Wilk 1990; The Office for National Statistics 2001; Help the Aged 2001). In the United Kingdom (UK), the recently published National Service Framework for Older People has highlighted the importance of prevention and treatment of stroke in older people (DoH 2001a).

Stroke is primarily a clinical diagnosis. Stroke can be defined using the World Health Organisation definition: "*a clinical syndrome typified by rapidly developing clinical signs of focal or global disturbance of cerebral functions, lasting more than 24 hours or leading to death, with no apparent causes other than of vascular origin*" (Hatano 1976; WHO 1978). In practice, this definition includes strokes that are due to cerebral infarction, intracerebral haemorrhage and subarachnoid haemorrhage (SAH), but excludes: transient ischaemic attacks (TIAs, which last for less than 24 hours); subdural and extradural haemorrhages; and cerebral infarction or haemorrhage secondary to infection or malignancy (Bonita 1992). More recently, experts have suggested that SAH should not be included in this definition since the management of patients with SAH is quite distinct from those of other forms of stroke (Bamford 2001).

Stroke can be divided into different subtypes. Community-based incidence studies, such as the Oxfordshire Community Stroke Project (OCSP), have found that about 80% of first-ever strokes were due to cerebral infarction, 10% to primary intracerebral haemorrhage (PICH), 5% to SAH, and 5% were of uncertain type (Bamford et al 1990a).

Ischaemic strokes can be further divided into different aetiological subtypes. Proportion of strokes due to each of the aetiological subtype varies widely between different studies (MacKenzie 2000). In general, about 20% of ischaemic strokes are caused by large vessel atherothrombosis (involving the aortic arch, intracranial or extracranial large arteries), 20% by small vessel atherothrombosis, 30% by cardioembolism, 5% by miscellaneous causes (e.g. carotid artery dissection, arteritis, or sudden hypotension), and 25% are of undetermined aetiology (Petty et al 1999; Anon. 1999; Moulin et al 2000; MacKenzie 2000). Since atherothrombotic strokes occur most commonly in older people, and as the number of older people in the population increases, atherothrombotic strokes are likely to account for large proportion of strokes (Ostfeld & Wilk 1990).

Stroke is common

Stroke is a common condition. The prevalence of stroke in the UK was recently estimated to be 17.5 per 1000 people (O'Mahony et al 1999). This means that there are currently over half a million stroke survivors in the UK (Isard & Forbes 1992; Miyai & Reding 1998), and almost one in ten people aged over 75 years has a history of stroke (Geddes et al 1996).

The incidence of first-ever stroke in the UK is 2 to 3 per 1000 people (Bamford et al 1988; Sudlow & Warlow 1997; Wolfe et al 2002). The age-specific incidence rate of first-ever strokes rises exponentially with age for both sexes, such that the incidence rate for people aged over 85 years is about 100 times that for those aged between 35 and 44 years (Bonita et al 1984; Bamford et al 1988; Williams et al 1999). Almost one in four men and one in five women aged 45 years can expect to have a stroke if they live to their 85th year (Bonita et al 1984; Bonita 1992). In the UK, about 130,000 people suffer a stroke each year, nearly three quarters of them occur over the age of 65 and nearly half occur over the age of 75 (Bamford et al 1988; Weir & Dennis 1997). Recurrent strokes account for about 30% of all stroke events, but for patients aged over 75 years, this figure could be as high as 50 to 70% (Bonita 1992; Thorvaldsen et al 1995; Thorvaldsen et al 1999; Williams et al 1999). As the proportion of older people in the population grows rapidly, the absolute numbers of new strokes occurring each year is predicted to rise by as much as a third over the next two decades (Ostfeld & Wilk 1990; Thorvaldsen et al 1999; Wolfe 2000; The Office for National Statistics 2001).

Stroke causes many deaths

About 4.5 million people world-wide die from stroke each year (Murray & Lopez 1997b; Murray & Lopez 1997c). In industrialised countries, stroke accounts for about one in eight of all deaths (Wolfe 2000). Deaths from stroke can be examined in two ways: case fatality rate and stroke mortality rate. Case fatality rate is the proportion of people who die within a specified period after an event (Bonita 1992). In the OCSP, the overall case fatality rate was 19% for the first month and 31% for

the first year (Bamford et al 1990a). Older people and those with recurrent strokes are significantly more likely to die after a stroke (Bamford et al 1990b; Samsa et al 1999).

Stroke mortality rate is the number of deaths caused by stroke in a specified period, which is usually one year (Mas & Zuber 1993). In the UK, the stroke mortality rate rises exponentially with age, from 7 per 100,000 people aged 35 to 44 years to about 1400 per 100,000 people aged over 75 years (WHO 1994). In the UK, as in many other parts of the world such as North America and Western Europe, stroke mortality rate has declined by about 40% in the past 40 years (Khaw 1996; Thorvaldsen et al 1999; Sarti et al 2000). Studies have demonstrated that this fall in mortality could have resulted from either a decline in incidence, a decline in case fatality, or a combination of the two (Broderick et al 1989; Bonita 1992; Bonita & Beaglehole 1996; Thorvaldsen et al 1999; Morikawa et al 2000).

Stroke causes much long-term disability and burden

Stroke is the most common cause of long-term disability in the adult population (Wolfe 2000). Stroke is the sixth leading cause of global disability-adjusted life years in the world; about 9 million people world-wide are estimated to be living with disability as a result of stroke; (Murray & Lopez 1997b; Murray & Lopez 1997c). At one year after stroke, about 40% of the survivors would need regular help from others for activities of daily living (Warlow et al 2000). In the UK, stroke patients occupy about 8% of all hospital bed days and stroke hospital costs account for up to 6% of total hospital costs (Isard & Forbes 1992; Roberts et al 2000). Furthermore, up

to a quarter of nursing home residents are stroke survivors; thus there are about 51,000 stroke survivors in residential or long-term care in the UK (Wade 1994; Bosanquet & Franks 1998).

The total cost of stroke to the NHS and social services has been estimated at £2.3 billion in England in 1995-6, which is equivalent to about 6% of the total NHS and social service expenditure (Bosanquet & Franks 1998). Stroke also results in substantial indirect costs, for example due to loss of earnings by the patient or their carer (about £31 million per year), and the enormous psychological burden on carers and relatives. The total burden and cost of stroke care in industrialised countries has been predicted to rise by 30% to over £3 billion in the year 2023 (Bonita & Beaglehole 1996; Bosanquet & Franks 1998; Di Carlo et al 1999).

1.2 Development of stroke care

I shall briefly describe the development of stroke care (stroke therapy in general, and stroke unit care) in this section. It is not meant to be an exhaustive account but a brief outline.

Development of stroke therapy: a brief history

Acute stroke as a medical condition

Stroke has always existed and the development of stroke care can be traced back to the ancient times. Stroke was first described in ancient Greek medical writing as 'apoplexy' in 400 BC by Hippocrates (Clarke 1963). In the last few centuries, autopsy studies provided physicians with more detailed knowledge about apoplexy, which was later termed 'stroke' in the English language (Schiller 1970). In the 17th century, Johann Wepfer concluded from his autopsy studies on stroke patients that "*apoplexy was produced because the afflux of blood through the arteries is denied to the brain*" (Fraser et al 1999).

Development of stroke rehabilitation

In the fifth century, Caelius Aurelianus suggested treating patients with apoplexy by "*active, assistive and passive motion of the weakened muscles*" (Fraser et al 1999). In the 18th century, Joseph-Clement Tissot wrote a book on therapeutic exercise, suggesting an aggressive approach in mobilising hemiplegic patients (Tissot 1780). Another century passed before Robert Todd emphasised the importance of exercise as a treatment of hemiplegic patients. The first reference to speech and language

therapy was also in the mid-1850's, when Thomas Hun recommended exercises in reading, spelling and repeating words for stroke patients (Kabat 1947). At the end of the 19th century, more and more stroke patients were treated with daily sessions of active exercises as recommended by Sebastian Frenkel, who was later invited to Paris to promote his methods of "*reeducation des movements*", or what is now regard as functional rehabilitation (Frenkel 1890; Fraser et al 1999). However, many physicians were not convinced that patients should receive any form of rehabilitation after stroke. This nihilistic attitude persisted for the next half a century, during which many stroke patients were confined to a bed or chair for the duration of their hospital stay. Enthusiasm was even lower to retrain patients with dysphasia or visual-spatial dysfunction because the rehabilitative process was considered unrewarding.

In the early 1940s, physicians regained their interest in stroke rehabilitation and several new approaches to rehabilitation emerged. Restoring movement and preventing disabling contractures became the primary goals; examples of approaches included those described by Rood, Knott and Kabat, Brunstrom, and Bobath (Rood 1954; Kabat & Knott 1954; Brunstrom 1956; Bobath 1990). Physicians and therapists believed that functional recovery represented neuronal recovery of an injured brain, the mechanisms of which could include the 're-routing' of neuronal pathways, reorganisation of neuronal connections, and even neuronal regrowth (Pomeroy & Tallis 2000; Johansson 2000). Wade recently described rehabilitation as "*an active problem-solving and education process, focused on disability.....and aiming to maximise the patient's participation in society and his or her well-being while reducing stress on the family. In addition to interventions aimed at improving*

function, rehabilitation includes assessment....the setting of goals, and provision of care to maintain the patient's state" (Wade 1999). Rehabilitation therefore became regarded as much more than mobilisation and giving of therapy.

Use of early rehabilitation after acute stroke

At the beginning of the 20th century, Brissaud recommended that stroke patients should perform exercises as soon as possible after the event – during the first week if the medical condition permitted – everyday, twice a day. He suggested that nurses should "*walk the patient and make him use his hand purposefully*" (Fraser et al 1999). However, this approach of early mobilisation was not widely adopted at the time because many physicians thought that it could lead to contractures (Fraser et al 1999).

It was only during the last three or four decades that the role of the therapists (e.g. physiotherapists, occupational therapists, speech therapists) became more prominent. Together with the physicians and nursing staff, they made up the multidisciplinary team. Nowadays, multidisciplinary management by a specialist stroke team is the mainstay of hospital treatment (Miyai & Reding 1998). Despite numerous recent practical innovations, advances in stroke rehabilitation have occurred almost entirely in service delivery and organisation rather than any single treatment (Wade & de Jong 2000).

Development of medical and surgical therapies for stroke

Medical care of stroke patients entered a new era in the 1920s and 1930s, when articles began appearing describing the association between high blood pressure, atherosclerosis and stroke (Fields & Lemak 1989). After the second world war, pharmaceutical companies began developing and testing new pharmacological agents for stroke treatment and prevention. In 1941, Per Hedenius, a Scandinavian, reported the first study of heparin in stroke patients, some of whom had good outcomes (Hedenius 1941). In 1950, Lawrence Craven reported the prophylactic use of aspirin for coronary and cerebral thrombosis and advised his male friends and patients to take one or two aspirin tablets daily (Fields & Lemak 1989). Craven also experimented with administration of dicoumarol to patients who were intolerant of aspirin and found that a small amount of dicoumarol might also be effective in stroke prophylaxis (Fields & Lemak 1989). In 1954, Eastcott performed the first carotid reconstruction operation in St Mary's Hospital, London (Fields 1998). Nowadays, the use of antithrombotics and carotid endarterectomy are the two major strategies for the secondary prevention of ischaemic stroke.

Since the 1950s, physicians became less inclined to use a particular treatment just because it was the norm, and were more likely to be persuaded by evidence from high quality clinical trials; the randomised controlled trial methodology began to be used to evaluate the effects of pharmacological agents. The first (quasi-) randomised trial in acute stroke was of corticosteroids, conducted by Dyken and White in 1956. This trial was important for two reasons: firstly, it was the first randomised trial of a medical therapy for stroke; and secondly, it identified many methodological issues

associated with performing such trials (Warlow et al 2000). The last half a century saw an explosion in the number of clinical trials of acute stroke interventions, with increasing sample sizes, improving methodological quality, and a reduction in delay between stroke onset and patient recruitment (Kidwell et al 2001). The use of trial evidence in the medical care of stroke patients is now well-established (Sackett & Rosenberg 1995).

Development of stroke unit care

Emergence of stroke units from coronary care units

In the USA, organised patient care in stroke units was introduced in the 1960s. This was widely believed to be in response to the perceived success of coronary care units (CCUs) (Blecic & Bogousslavsky 1995; Diez-Tejedor & Fuentes 2001). An understanding of how the CCU evolved and the methods of evaluating CCU care might provide insight into the evolution and evaluation of stroke units. A comparison of the major stages of the development of CCU and stroke unit care is summarised in **Table 1.1**.

The development of the CCU consisted of several key stages. In the 1960s, the mortality for patients with acute myocardial infarction (AMI) was over 30% and almost half of the deaths were primarily due to arrhythmia (Lown et al 1967; Lee & Goldman 1988). At around that time, Lown et al found that refractory arrhythmia could be successfully terminated by electrical cardioversion (Lown et al 1986), and external cardiac massage was found to be effective (Kowenhouven et al 1960). These two important developments were accompanied by the introduction of a specialised

ward to which patients with AMI were admitted for cardiac monitoring and prompt treatment of arrhythmia (Lee & Goldman 1988). The first CCU opened in 1962.

In the 1970s and 1980s, with the introduction of more aggressive treatments for AMI (e.g. intravenous nitroglycerine and thrombolysis, emergency coronary angioplasty) and congestive cardiac failure (e.g. intra-aortic balloon pump), CCUs became more like cardiac intensive care units (Andriange et al 1969; Gialloreto et al 1969; Nager et al 1969). However, the major drawback of CCU care was the high costs. More recently, research has been conducted to find more cost-effective alternatives to CCUs, such as the 'intermediate care unit' (Fineberg et al 1984; Tosteson et al 1996).

Evidence to support the use of coronary care units is weak

Although the number of CCUs grew rapidly across the world, evidence from randomised trials to support its implementation was lacking (Lee & Goldman 1988). The only two randomised controlled trials failed to demonstrate any extra benefit of CCU care over conventional home care (Mather et al 1976; Hill et al 1978). However, both studies excluded the most severe patients and the sample sizes were small (450 and 349 patients respectively). Resistance to perform randomised controlled trials of CCU care grew as evidence of benefit came from several non-randomised studies (MacMillan & Brown 1971; Chia 1982). In 1971, a non-randomised controlled study found that patients with AMI admitted to CCU were less likely to die and more likely to survive a cardiac arrest (MacMillan & Brown 1971). In the 1980s, the support for CCU care was further strengthened by epidemiological studies showing a dramatic decline in in-hospital mortality rates for

AMI by almost a third (Gillum et al 1983). Although the evidence to support the use of CCUs was weak, the justification for its existence was no longer an issue after the publication of large randomised trials of thrombolysis in the late 1980s (GISSI 1986; ISIS-2 1988).

Early development of neurovascular intensive care units

In the USA, early stroke units which were created from the CCU model were known as neurovascular intensive care units (Norris & Hachinski 1976). The aims of such units were broadly similar to those of CCUs, although CCU care was never meant to be multidisciplinary. These intensive stroke units offered comprehensive and early investigations (e.g. brain scan, electroencephalogram, lumbar puncture), one-to-one nursing, and early rehabilitation (Norris & Hachinski 1976). The main objectives were prevention and early treatment of medical complications by concentrating facilities and personnel for optimal care (Millikan 1979).

A few early reports of non-randomised studies showed that care within these units reduced the risk of death and in-hospital complications such as pneumonia and pulmonary embolism (Drake, Jr. et al 1973; Norris & Hachinski 1976). However, other non-randomised studies failed to confirm these positive findings (Kennedy et al 1970; Pitner & Mance 1973). Some physicians also tried combining CCU and stroke unit into one type of specialised unit, known as a 'coronary and cerebrovascular intensive care unit'. Cooper et al described the experience with one of these units and found three specific qualities that could have benefited patient care: a) improved efficiency of care; b) increased staff's interest in stroke; and c) provision of a focal

area for stroke education (Cooper et al 1972). These qualities of the early intensive stroke units continued to be some of the main virtues of the later, less intensive, stroke units.

Due to a lack of evidence of benefit for these intensive stroke units, and the fact that operational costs were very high, efforts were put into developing less intensive units for managing stroke patients (Pitner & Mance 1973; Briggs et al 2001). Nowadays, intensive stroke units only exist in a small number of countries, but the physicians in charge of these units still insist that they are indispensable (Hacke 2000).

Development of less intensive stroke units

As early as the 1950s and 1960s, it was recognised that the care of a stroke patient should be 'organised' (Adams 1974). Feldman published the first randomised trial of a 'system' of stroke rehabilitation in 1962 and reported no significant difference in outcome (Feldman et al 1962). Adams described their experiences before (1948-1956) and after (1956-1958) the introduction of a stroke rehabilitation ward, and found that stroke patients treated in the ward were more likely to be alive at two months and to be discharged home, as compared to those treated before its introduction (Adams 1974). Further small observational studies in the 1960s also reported improvements in outcome with organised stroke care (Waylonis et al 1973; Dow et al 1974).

A move to introduce 'stroke units' in the UK came in the early 1970s. In 1971, the editor of the British Medical Journal urged the physicians to "*accept the lessons*

offered by the transatlantic experience, and to consider the creation of regional stroke units along the lines of the recently developed coronary care units. These units would need both to care for the patients in the acute phase of his illness and to have full rehabilitation services..." (Anon. 1971). However, Isaacs wrote in response to say that, in the UK, stroke rehabilitation units should be "*organised along the lines of a standard geriatric rehabilitation ward, with close collaboration between doctors, nurses, physiotherapists...*" (Isaacs 1971). It was evident that, even three decades ago, different people have different ideas about how stroke units should operate and this debate has continued up to the present time. While Bonner (1973) defined a stroke unit as a specialist team comprising a stroke physician, nurses and therapists who cared for stroke patients around the hospital, others such as Garraway (1980) defined a stroke unit as a special area where stroke patients were cared for by a specialist stroke team (Bonner 1973; Garraway et al 1980a; Wood-Dauphinee 1984).

As stroke units evolved in the 1970s, it became established that most of them were staffed by a specialist multidisciplinary team which usually comprised medical, nursing, therapy (physiotherapy, occupational therapy, speech and language therapy), and social worker staff (Langhorne & Dennis 1998). Some units also involved professionals from other disciplines such as dieticians, psychologists, neurologists, and neurosurgeons (see **Figure 1.1**) (Feigensen et al 1979). The main objectives of stroke rehabilitation unit were to provide coordinated and individualised patient care based on the four following key elements (Garraway 1985):

- Comprehensive assessment of all aspects of the patient's illness and disability;
- Close collaboration between the disciplines;

- Identification and awareness of the objectives of rehabilitation;
- Education and research on stroke disease.

Different styles of stroke units

By the late 1970s and early 1980s, different styles of stroke units became established. When physicians recognised that continuity of care was important, units which combined acute stroke care and rehabilitation were created; patients were admitted soon after stroke onset and remained there for some time during rehabilitation (Garraway et al 1980a; Garraway et al 1980b). Other units were established as purely stroke rehabilitation units, where patients were admitted once they were medically stable – usually one or two weeks after onset (Isaacs 1977; Stevens et al 1984). In the 1980s, other forms of organised stroke care also emerged; one example was mobile stroke teams, which aimed to provide stroke patients with multidisciplinary care wherever the patients were located (Bonner 1973; Wood-Dauphinee et al 1984).

Evidence to support the use of stroke units was strong

From a fairly early stage, stroke units were evaluated by randomised controlled trials, a marked contrast to the evaluation of CCUs. In 1980, Garraway et al published the first large randomised trial and found that patients managed in the stroke rehabilitation unit had better functional outcomes and reduced delay to starting rehabilitative therapy (Garraway et al 1980a; Garraway et al 1980b). As further randomised trials were conducted throughout the next two decades, the Scandinavian countries such as Norway and Sweden were moving rapidly towards a more uniform provision of stroke unit care, whereas such provision was more haphazard in other

countries such as the UK (Indredavik et al 1991; Glader et al 2001). Until 1990, it was believed that although stroke unit care might speed up recovery, it probably could not improve survival or long-term functional outcomes (Langton-Hewer 1990; Ebrahim 1990). However, in 1993, results from the first published systematic review of ten randomised trials (with 1586 patients) suggested that patients managed in a stroke unit were less like to die within the first year (Langhorne et al 1993). This apparent benefit was confirmed in subsequent updates of the systematic review (Stroke Unit Trialists' Collaboration 1997; Stroke Unit Trialists' Collaboration 2002).

Effectiveness of stroke unit care: evidence from a systematic review

It is widely accepted that the highest level of evidence about healthcare interventions is that obtained from a systematic review of well-conducted randomised controlled trials (US DoH & Human Services 1993; Harbour & Miller 2001). Systematic reviews can provide a less biased and more precise estimate of treatment effect, and hence they are generally regarded as the best source of evidence to inform clinical practice (Mulrow 1995).

The Stroke Unit Trialists' Collaboration (SUTC) performed a Cochrane systematic review to assess the effect of stroke unit care compared with conventional medical care (Stroke Unit Trialists' Collaboration 2002). The first review was published in 1997, and the review has since been updated in1998 and 2001. For this review, the reviewers sought all published and unpublished randomised and quasi-randomised trials. "Stroke unit care" was defined simply as "*care coordinated by multidisciplinary team through regular team meetings*" to include stroke units of

different styles. The reviewers then divided the stroke units into three major subtypes:

1. Stroke wards – those that exclusively provided care for stroke patients in a dedicated ward. This category included three sub-divisions:

- *Acute stroke units* (admission of patients acutely), including intensive units
- *Stroke rehabilitation units* (admission of patients for stroke rehabilitation)
- *Comprehensive stroke units* (combined acute stroke and rehabilitation)

2. Mixed rehabilitation wards – those that managed all patients needing rehabilitation and not exclusively stroke patients

3. Mobile stroke teams – a multidisciplinary team providing care in a variety of settings

The control groups were usually patients managed in general medical wards, where there was no specialised stroke care.

Results of the Cochrane systematic review

The Cochrane systematic review was last updated in April 2001 and it now contains the combined data from 23 trials and 4911 patients. Compared with alternative forms of care, stroke unit care:

- significantly reduced the odds of death by the end of follow-up (Odds ratio, OR 0.86, 95% confidence interval, CI 0.71 to 0.94);
- significantly reduced the odds of death or dependency by the end of follow-up (OR 0.78, 95% CI 0.68 to 0.89). See **Figure 1.2**;
- significantly reduced the odds of death or requiring institutional care by the end of follow-up (OR 0.80, 95% CI 0.71 to 0.90). See **Figure 1.3**.

Thus, the number needed to treat (95% CI) to prevent one death is 33 (20-100), to prevent one patient being unable to live at home was 20 (12-50), and to prevent one patient failing to regain independence was 20 (12-50). There was evidence that the benefit was similar among patients of all ages, males and females, and irrespective of stroke severity. The review included five randomised trials that compared different forms of stroke unit care. Three trials found that dedicated stroke rehabilitation units may be more effective than mixed rehabilitation wards in preventing bad outcomes (non-significant trend) (Stevens et al 1984; Kalra et al 1993; Lincoln et al 2000). One UK trial showed that their comprehensive stroke unit was significantly more effective than a mobile stroke team (Kalra et al 2000). Finally, one Finish trial comparing an acute stroke unit with a mixed rehabilitation ward found no significant difference in outcome (Ilmavirta et al 1994).

Recommendation: acute stroke patients should be admitted to a stroke unit

The reviewers concluded by recommending that all acute stroke patients should be offered stroke unit care which includes a substantial period of rehabilitation if required, provided by a coordinated multidisciplinary team. All current UK and European stroke guidelines support this recommendation (SIGN 1997a; Kaste et al 2000; RCP 2001a). In the UK, the Royal College of Physicians (RCP) guidelines also recommend that stroke patients should be the responsibility of a specialist stroke service, which should include the following four elements: a) an inpatient stroke unit; b) a coordinated multidisciplinary stroke team; c) educational programmes for staff, patients and carers; and d) agreed protocols for common problems (RCP 2001b).

Why is stroke unit care effective?

Stroke unit care is different from conventional care

A few studies have suggested that the benefits of stroke unit care may persist for up to ten years (Jorgensen et al 1999; Indredavik et al 1999a; Lincoln et al 2000). However, it remains unclear why stroke unit care is associated with such a significant benefit – is it the result of the whole package of care, or the effects of individual components? (Dennis & Langhorne 1994) The Cochrane systematic review tried to identify the major differences between stroke unit care and conventional care by surveying the trialists' experiences (Stroke Unit Trialists' Collaboration 2002). The following is a summary of the characteristics of a stroke unit which were perceived to be important; whether these characteristics play any role in explaining the apparent beneficial effects remains to be elucidated.

- Care by a coordinated multidisciplinary team
- Routine involvement of carers in management decisions and rehabilitation
- Staffing by medical and nursing staff with an interest in stroke and rehabilitation
- Routine provision of information to patients and carers
- Provision of staff education programmes

So, stroke unit care can perhaps be more appropriately defined according to these five special characteristics. In one randomised study of stroke unit care, Indredavik et al also identified from post-hoc analysis three features of patient care that they felt were related to improved outcome. These were: a) early mobilisation of the acute stroke patient; b) avoidance of dehydration by routine intravenous fluid therapy; and c) monitoring and correction of physiological disturbances (Indredavik et al 1999b).

Observational studies have also highlighted several qualities that were special to stroke unit care, for example, patients in stroke units spent more time out of bed and had more opportunities for independent activities than patients in general medical wards (Pound et al 1999a).

The 'black box' of stroke unit care

The data so far have established that stroke unit care should be well-organised and coordinated by a multidisciplinary team of professional staff who are interested, enthusiastic and knowledgeable about stroke (Dennis & Langhorne 1994), but they do not provide clear guidance on exactly *how* care should be organised or coordinated. Although the beneficial effects of stroke unit care have been shown to be reproducible in the 'usual clinical setting' (Stegmayr et al 1999; Jorgensen et al 2000; Collins et al 2000), some experts suggest that more trials are needed to unpack the 'black box' of stroke unit care and identify the key organisational elements (Stone 1999). However, clinical trials of this kind are difficult to conduct.

Development of acute stroke units

What is an acute stroke unit?

Every stroke unit is unique in style and infrastructure (Sinha & Warburton 2000). Although the Cochrane systematic review found no clear evidence of difference in outcome between the different styles of stroke units, interest in one particular style has recently intensified – the acute stroke unit (Bath et al 1996; Dayno & Mansbach 1999). An acute stroke unit is usually defined as a stroke unit where patients are admitted directly from home, emergency department, or another acute medical

admission unit, and where patient care is often more intensive; patients are usually discharge or transferred out of the unit within one week of admission (Morris et al 1993; Dennis & Langhorne 1994; Stroke Unit Trialists' Collaboration 2002). In the USA, where there are no acute stroke units *per se* – acute stroke patients are admitted to 'stroke centres' (Skolnick 1999). A stroke centre encompasses more than the ward where patients are admitted, but the whole organisational system that is involved in managing the patient. There are national guidelines on the minimal standards for the different components of such centres, for example, in terms of the ward, emergency department, and neuroimaging (Alberts et al 2000; Kareem 2001).

Why are acute stroke units needed?

There are four major reasons to develop acute stroke units (Morris et al 1993; Dayno & Mansbach 1999). Firstly, acute stroke is a complex condition. In order to provide an efficient and effective patient care in the first few hours, complex organisational systems are required; such systems must involve highly trained and enthusiastic healthcare staff. Secondly, acute stroke patients are at high risk of developing neurological, cardiac, metabolic and other complications, each of which may require carefully directed intervention. Thirdly, stroke unit care has been shown to improve outcome, so it is conceivable that acute stroke unit care could do likewise. Lastly, an acute stroke unit may be the ideal setting in which to give treatments that require close monitoring (e.g. thrombolysis) and to perform clinical trials of acute medical treatments (e.g. neuroprotective agents) (Morris et al 1993; Dayno & Mansbach 1999).

A major advantage of caring for patients in an acute stroke unit is that it concentrates patients, healthcare staff, resources, and expertise into one area; this may also facilitate audit and training (Bath & Lees 2000). Dennis and Langhorne stated that "*admitting all patients with acute stroke directly into a unit makes the introduction of assessment protocols easier, allows skills to be focused, and facilitates the large randomised trials of acute treatments...*" (Dennis & Langhorne 1994).

Acute stroke units may be the best place to administer thrombolysis

In the last ten years, thrombolysis using recombinant tissue plasminogen activator (rt-PA) has been introduced to be used for selected groups of patients with ischaemic stroke within the first three hours of onset (Adams, Jr. et al 1996; Wardlaw et al 2002). It is widely accepted that the best place to administer thrombolysis is the acute stroke unit where the patient can be closely monitored by a team of highly trained staff (Koroshetz 1996; Treib et al 2000), and recent European and American recommendations have emphasised this point (Adams, Jr. et al 1996; Hacke et al 2000).

Evidence to support the use of acute stroke units is weak

In the Cochrane systematic review, the difference in the risk of death between stroke unit and the control group is most evident within the first month after stroke (Stroke Unit Trialists' Collaboration 2002). After the first month, further difference in deaths do not emerge. In the OCSP, about two thirds of deaths within the first month after stroke occurred within the first week and deaths were most commonly due to direct neurological sequelae such as trans-tentorial herniation and brainstem compression

(Bamford et al 1990b). After the first week, deaths were usually a result of medical complications such as pneumonia and pulmonary embolism (Bamford et al 1990b).

Sinha and Warburton proposed that a major factor in the success of stroke unit care is the better management of early medical complications (Sinha & Warburton 2000). This argument strengthens the rationale for admitting patients with acute stroke to an acute stroke unit, where medical complications can be detected early and managed appropriately. Dennis and Langhorne suggested that the best model of stroke care is "*one in which patients are admitted into an acute assessment area, either on a medical ward or as part of an acute stroke unit..., and then moved without delay to a stroke rehabilitation unit as soon as they can benefit from that environment*" (Dennis & Langhorne 1994).

Despite the potential benefit of acute stroke unit care, the Cochrane systematic review did not find any clear evidence that it was more effective than alternative forms of care (Stroke Unit Trialists' Collaboration 2002). This conclusion was based on the results of one single randomised trial of 211 patients (Ilmavirta et al 1994). Several other studies have found apparent benefits of acute stroke unit care on patient outcome, but these studies are of less robust research designs (Ronning & Guldvog 1998a; Fagerberg et al 2000).

1.3 Care of an acute stroke patient

In this section, I shall discuss the medical and nursing management of a patient during the acute phase of stroke, which I will arbitrarily define in this thesis as the first one to two weeks after stroke onset. Management thereafter is outside the scope of this thesis. Acute stroke care can be divided into three major components: a) treatment of the cerebral lesion itself; b) general care of the stroke patient; and c) prevention and management of specific complications (Blecic & Bogousslavsky 1995).

Pharmacological treatments of acute ischaemic stroke

Cerebral ischaemia and options for treatment

When a cerebral artery or one of its branches occludes, the area of brain tissue it supplies experiences a sudden fall in cerebral blood flow (CBF) and the tissue becomes ischaemic. Surrounding a core of infarcted tissue that is irreversibly damaged is a rim of tissue called the 'ischaemic penumbra'. The ischaemic penumbra has been documented as a severely hypoperfused, functionally impaired, but still viable area which can regain its function and escape infarction if it is reperfused before a certain time has elapsed (Marchal et al 1996; Baron 2001). CBF within the ischaemic penumbra is typically reduced to 10 to 30ml/100g/min, or about 15 to 40% of normal (Back et al 1998; Fisher 1998; Kaufmann et al 1999).

The ischaemic penumbra exists in a dynamic state and its survival depends on the severity and duration of ischaemia (see **Figure 1.4**) (Fisher 1997). Therefore, the

main targets of pharmacological treatments of acute ischaemic stroke are to restore blood flow and protect vulnerable brain tissue before it becomes infarcted (Lassen 1990; Fisher 1997). There are currently only two pharmacological agents that have been proven to be effective in treating acute ischaemic stroke – thrombolysis and antiplatelet therapy (Hankey 2001). Although various other acute stroke treatment strategies are also used in other countries (e.g. immediate anticoagulation, manipulation of intracranial pressure, surgical decompression), these have not been supported by evidence from large randomised controlled trials.

Thrombolysis for acute ischaemic stroke

Thrombolytic therapy aims to lyse the thrombus or embolus occluding the cerebral artery, hence restoring blood supply to the brain and reduce the volume of brain damaged by ischaemia. In turn, this should improve neurological function and survival (Hacke et al 1995; NINDS 1995; Hacke et al 1998). However, intracranial haemorrhage is a recognised and potentially fatal complication of thrombolytic agents. The most recent Cochrane systematic review of thrombolytic therapy for acute ischaemic stroke included 17 trials with over 5200 patients (Wardlaw et al 2002). Four different thrombolytic agents were evaluated – rt-PA, streptokinase, urokinase and pro-urokinase – but the only one that has a license for clinical use (in certain countries) is rt-PA. The systematic review showed that rt-PA significantly reduced the odds of being dead or dependent (OR 0.79, 95% CI 0.32 to 0.08). In other words, for every 1000 patients treated, there would be 57 more independent survivors. However, rt-PA significantly increased the odds of fatal intracranial haemorrhage (OR 3.2, 95% CI 2.0 to 5.2); this is equivalent to 29 extra fatal

intracranial haemorrhages per 1000 patients treated. Furthermore, the effects of rt-PA may depend on other factors such as the dose (lower doses seemed safer), time from stroke onset to randomisation (rt-PA appeared to be more effective if given earlier), and whether antithrombotic agents were used (co-administration of aspirin or heparin seemed to cause more adverse events). The benefit of rt-PA was also greatest amongst patients randomised within three hours of stroke onset (rather than six hours), where there would be 126 more independent survivors per 1000 patients treated (Wardlaw et al 2002).

Nevertheless, uncertainties remain about which patients should be treated with rt-PA, and which patients should avoid it; consequently, different authors have made different recommendations. Some suggest using rt-PA in routine clinical practice (Adams, Jr. et al 1996; Hacke et al 2000), whereas others suggest using rt-PA only in a clinical trial setting (CAEP Committee on Thrombolytic Therapy for Acute Ischaemic Stroke 2001; RCP 2001b). Further differences in opinion exist in the selection criteria for thrombolytic therapy, for example, age of the patient, neuroimaging findings, stroke severity, and blood pressure (Adams, Jr. et al 1996; Tanne et al 2000; Albers et al 2000; Silver et al 2001; Adams, Jr. 2001). A large-scaled randomised controlled trial called the third International Stroke Trial (IST-3) is being conducted to reliably assess the effects of thrombolysis for acute ischaemic stroke, when given within six hours of onset (Hand et al 2001; Hankey 2001).

Antiplatelet therapy for acute ischaemic stroke

Early antiplatelet therapy may reduce the size of infarcted brain tissue and several mechanisms of action have been proposed, including the prevention of thrombus propagation and re-embolisation, and neuroprotection (e.g. inhibiting the release of thromboxane and glutamate) (De Cristobal et al 2001; Hankey et al 2002). Pharmacological agents with antiplatelet properties include aspirin, dipyridamole, thienopyridine (clopidogrel and ticlodipine) and glycoprotein IIb/IIIa inhibitor, but only aspirin has been shown to be effective when administered in the acute phase of stroke (Gubitz et al 2002). A Cochrane systematic review of antiplatelet therapy for acute ischaemic stroke included eight trials with over 41,000 patients. Antiplatelet therapy significantly reduced the odds of death or dependency (OR 0.94, 95% CI 0.91 to 0.98); this is equivalent to 13 more independent survivors for every 1000 patients treated. Furthermore, antiplatelet therapy increased the odds of making a full recovery (OR 1.06, 95% CI 1.01 to 1.11), which is equivalent to 10 extra fully recovered patients per 1000 treated. However, treatment was associated with a small risk of symptomatic intracranial haemorrhage (OR 1.23, 95% CI 1.0 to 1.5), which is equivalent to 2 extra haemorrhages per 1000 patients treated (Gubitz et al 2002). A detailed individual patient data overview of the two largest randomised trials (International Stroke Trial and the Chinese Acute Stroke Trial) found that the benefits of aspirin were similar in a wide range of patients regardless of age, gender, time from stroke onset to randomisation, presence of atrial fibrillation, and blood pressure (IST 1997; CAST 1997; Chen et al 2000). The current European and UK recommendation is to give 300mg of aspirin to all stroke patients as soon as

intracranial haemorrhage has been excluded, ideally by computed tomography (CT) scanning (SIGN 1997a; Hacke et al 2000; RCP 2001b).

General care of an acute stroke patient

There are very few treatments options available in the acute phase of stroke (Hankey 2001). Trials of many pharmacological agents such as anticoagulants and neuroprotectives have failed to demonstrate significant benefit (Diener et al 2000; Horn & Limburg 2001; STAIR II 2001; Bath et al 2001). There are speculations on the possible reasons for the negative results of these trials, but one reason might be the inconsistent or even poor general care of acute stroke patients in some centres (Blecic & Bogousslavsky 1995).

There are several reports suggesting that the process of acute stroke care might have been gradually improving in different countries, for example, with an increased use of CT scanning (Smith et al 1998; Leys 1999; Widder 2001). Opinions differ on what 'good' acute stroke care should comprise, but there are four aspects that come immediately to mind: a) rapid diagnosis and early transfer of the patient to hospital; b) rapid and accurate assessment of the patient's neurological condition; c) performance of appropriate investigations without delay; and d) rapid transfer of the patient to a stroke unit for specialised multidisciplinary therapy.

Acute stroke is a medical emergency

The concept of treating acute stroke as a medical emergency requiring urgent, coordinated and intensive action has developed rapidly in the past decade (Bath &

Lees 2000; Davenport & Dennis 2000). The acceptance of this status by physicians was helped by the fact that stroke has a rapid onset and poor prognosis, and that thrombolysis is a potentially effective and highly time-dependent treatment (Davenport & Dennis 2000). However, as more patients seek medical attention within the first few hours after stroke onset, differentiation between a TIA and stroke may become more difficult according to their traditional definitions (Bamford 2001).

Hachinski first suggested using the term 'brain attack' to describe an episode of acute neurological deficit of very recent onset, when it is not immediately clear whether the diagnosis might be stroke, TIA, SAH, or something else (Camarata et al 1994; Warlow et al 2000; Bamford 2001). To the public, the term 'brain attack' highlights the similarity between a stroke and a 'heart attack' with respect to the need to seek immediate medical attention (Heros et al 1997; Selman et al 1997). Nowadays, this term is widely used in the USA after the introduction of thrombolysis as a treatment for acute stroke (American Heart Association 1999).

Pre-hospital stroke care

Stroke care starts from the moment the symptoms are first noticed by the patient or a witness. However, many people do not know what the symptoms of stroke are and, even if they do, they do not seek urgent medical help (Pancioli et al 1998; Weltermann et al 2000). UK clinical guidelines state that all suspected stroke patients should be "*promptly admitted to a hospital with a well organised stroke service including a stroke unit...efforts should be made to accelerate hospital admission to minimise delays.*" (RCP 2001a). American guidelines also emphasise the importance

of public education, the need to call an ambulance immediately, and the valuable role of paramedical staff at the point of first contact (Pepe 1996; Zachariah et al 1996; Sayre et al 1996). As new treatments such as thrombolysis are introduced for use within the first six hours of stroke onset, it is all the more important that patients with probable or definite stroke arrive at the hospital as soon as possible (NINDS 1995). However, observational studies have found that more than half of all stroke patients do not arrive at the hospital within six hours (Harper et al 1992; Ferro et al 1994; Kothari et al 1995a; Fogelholm et al 1996; Jorgensen et al 1996; Wang et al 1997). There is a general consensus that efforts should be made to improve the efficiency of transferring patients with suspected stroke to the hospital to receive specialist stroke care. The Helsingborg Declaration (Pan European Consensus Meeting on Stroke Management, November 1995) states that "*stroke is an emergency and all patients should be evaluated in hospital, preferably within six hours of the onset of symptoms.*" (Aboderin & Venables 1996).

When the first medical contact (e.g. a paramedical staff) arrives at the scene of the patient, there are several aspects of care that can be carried out in the emergency situation. They may include: a) assessing the patient's neurological condition by taking an accurate history from the patient and/or a bystander; b) performing a brief physical examination, noting the vital signs (e.g. pulse, blood pressure, oxygen saturation), conscious state and neurological deficits; c) making a diagnosis of brain attack and recognising that the patient may be suitable for thrombolysis; d) providing basic life support (e.g. airway, breathing and circulation) and treating the patient for specific problems (e.g. treatment of convulsions); e) recognising and promptly

treating reversible conditions that can mimic stroke (e.g. hypoglycaemia); and f) notifying the emergency department staff that a patient with brain attack is arriving at the hospital shortly (NSA 1993; Libman et al 1995; Lott et al 1999; Kaste et al 2000; RCP 2001b).

Acute stroke care in hospital

After the patient arrives at the hospital, the care of an acute stroke patient consists of three main elements: a) making a more accurate clinical diagnosis by bedside assessment and investigations; b) nursing care; and c) early rehabilitative therapy. The Helsingborg Declaration recommends that "*patients with persisting impairment should receive a diagnosis, appropriate nursing care, and have their rehabilitation needs assessed and treated*" (Aboderin & Venables 1996). In the UK, the National Service Framework for Older People stresses the importance of making an early diagnosis and providing high quality care in the acute period (DoH 2001a). Each of these three elements are now discussed in turn.

Making an accurate diagnosis of stroke

To make a complete diagnostic evaluation in a patient with suspected stroke or TIA, the following questions need to be answered from the history and physical examination (SIGN 1997b; Warlow et al 2000; Bamford 2001):

- Is it a vascular event?
- Which part of the brain is affected? (anatomy)
- Is the vascular event ischaemic or haemorrhagic? (pathology)
- What is the cause of the vascular event? (mechanism)

- What are the consequences of the vascular event? (impairments, disabilities and handicap) (WHO 1980)
- What other medical problems co-exist?

Some answers would not be available immediately and more information may need to be gathered when the patient is reassessed later. Misdiagnosis of stroke is common even amongst experienced clinicians; observational studies have found that between 5 and 27% of stroke diagnoses were incorrect (Norris & Hachinski 1982; Kothari et al 1995b; Martin et al 1997; Allder et al 1999). The most common conditions that mimic stroke or TIA are epilepsy, migraine, infections (e.g. encephalitis), structural intracranial lesions (e.g. brain tumours), metabolic disturbances (e.g. hypoglycaemia), labyrinthine disorders (e.g. vestibular neuronitis), and demyelination (Libman et al 1995; The Members of the Lille Stroke Program 1997). Medical staff should therefore keep a high index of suspicion for these mimicking conditions in the emergency department.

CT brain scanning is now regarded as a routine investigation in acute stroke (King's Fund 1988; Davis et al 1997; Warlow 1998). CT scanning is a sensitive first-line investigation for excluding intracranial haemorrhage in the acute phase, but its sensitivity declines after the first five days (Adams, Jr. 1997; Wardlaw 2001). By ten days, small haemorrhages may be indistinguishable from infarcts, whereas large haemorrhages may be visible for up to three weeks (Wardlaw 2001). Furthermore, cerebral infarction may not visible until a few hours or even up to a day after stroke, if ever (Wardlaw 2001; Moonis & Fisher 2001). Current UK guidelines state that "*all*

physiotherapist assesses and retrains truncal control and limb function; the speech and language therapist assesses swallowing and communication and provides practical advice in tackling identified problems; and the dietician advises on the nutritional status and ways to prevent or treat under-nutrition (Wojner 1996; Miyai & Reding 1998; Warlow et al 2000). Occupational therapy, however, may be less vital in the acute phase of stroke but early assessment of function and impairment is often helpful in planning treatment (Ballinger et al 1999).

When should physiotherapy begin after stroke? Indredavik et al found that, when patients were treated within the stroke unit, the earlier the patient was mobilised after stroke, the more likely the patient was discharged home (Indredavik et al 1999b). Evidence from other clinical trials also suggests that earlier rehabilitation leads to improved physical and functional outcomes (Hayes & Carroll 1986; Ottenbacher & Jannell 1993). Moreover, some studies have found that more intensive therapy may produce better functional outcome (Kwakkel et al 1997; Kwakkel et al 1999). Current Scottish guidelines recommend that rehabilitative therapy should be started as soon as the patient's condition permits (SIGN 1998). However, many questions remain to be answered, for example, what is the optimal amount, content, and style of rehabilitative therapy? And which patient groups might benefit the most from early rehabilitative therapy? (Shah et al 1990; SIGN 1998).

1.4 Complications after stroke

Complications after stroke can be broadly divided into three categories:

- Consequences of the stroke itself (e.g. immobility, reduced consciousness);
- Secondary medical complications (e.g. pneumonia, deep vein thrombosis);
- Physiological disturbances (e.g. hypertension, hyperglycaemia).

The major complications in each category are summarised in **Table 1.2**.

Medical complications after acute stroke

Reported frequencies of medical complications

Several studies reported the frequencies of a range of medical complications amongst stroke patients admitted to hospital (Kalra et al 1995; Davenport et al 1996a; Johnston et al 1998; Fieschi et al 1998; Tirschwell et al 1999; Langhorne et al 2000a; Roth et al 2001). Several other studies reported the frequencies of single complications (Britton & Roden 1985; Kotila & Waltimo 1992; Davenport et al 1996b; Kotila et al 1998; Brittain et al 1999; Velioglu et al 2001). The reported frequencies of different complications vary considerably because of variations in case ascertainment, definition of complications, method of investigation, characteristics of patient groups, and sample sizes (see **Table 1.3**) (Langhorne et al 2000a). In a prospective Scottish study of 311 consecutive stroke patients, Langhorne et al found that 85% of the patients experienced complications, the most common being urinary tract infection (23%) and chest infection (22%).

Chest infection, which is often caused by aspiration of oropharyngeal content, is responsible for 25 to 30% of deaths after stroke and is the commonest cause of non-neurological death (Johnson et al 1993; Smithard et al 1996; Johnston et al 1998). In the study by Langhorne et al (2000a), very few patients had clinically apparent deep vein thrombosis (2%) and pulmonary embolism (1%), but an unusually high proportion of patients had pressure sores (21%), which were defined as any skin break or necrosis from either pressure or trivial trauma. This finding was very different from other studies, which have rarely found rates higher than 3 to 10% (Kalra et al 1995; Warlow et al 2000; Roth et al 2001).

Medical complications can be iatrogenic, that is, caused by medical or nursing staff themselves or the prescribed medications (see **Table 1.3**). Examples include adverse effects from withholding food (under-nutrition) or medications (e.g. anti-anginal agents), under- or over-hydration, over-sedation, and adverse drug reactions. One retrospective US study of 1029 consecutive stroke patients found that, whilst undergoing rehabilitation, 10% of all patients suffered from dehydration, 10% from adverse drug reactions, and 5% from under-nutrition (Roth et al 2001).

Adverse effects of medical complications on outcome

Medical complications are barriers to recovery after stroke. A prospective study showed that occurrence of serious medical complications was related to worse outcome as measured by the Barthel Index (OR 6.1, 95% CI 2.5 to 15.1), and that half of all deaths may be attributed primarily to medical complications (Johnston et al 1998). Another study found that medical complications were associated with

increased length of hospital stay (Tirschwell et al 1999). The major difficulty with interpreting the results from these studies is that medical complications occur more often in patients with more severe stroke. Any relationship with outcome may therefore be spurious if the results have not been properly adjusted for stroke severity and other factors that could influence outcome (Davenport et al 1996c; Counsell & Dennis 2001).

Evidence from randomised trials of stroke unit care suggests that the deaths that are most likely to be preventable are those resulting from complications of immobility (e.g. pneumonia, deep vein thrombosis) (Langhorne et al 2000a). Prevention, early detection and prompt treatment of these complications could therefore lead to better outcome. Current UK guidelines give clear recommendations on patient positioning, prevention of deep vein thrombosis, and bladder and bowel management after stroke (RCP 2001b). However, many of these recommendations are not based on good quality evidence.

Physiological disturbances after acute stroke

Potential adverse effects of physiological disturbances after acute stroke

The fate of the ischaemic penumbra directly depends on the severity and duration of ischaemia (see **Figure 1.4**). Animal studies have also demonstrated that physiological disturbances such as hyperglycaemia and hypoxia can exacerbate neuronal injury (Greenberg 1998; Busto & Ginsberg 1998). This may cause a worsening of the initial stroke, which is also known as 'stroke progression'. Studies have shown that stroke progression occurs in 26 to 43% of patients, and that about

half of the stroke progressions occur within 24 hours of admission (Britton & Roden 1985; Davalos et al 1990; Jorgensen et al 1994; Toni et al 1995). Stroke progression in turn is strongly correlated with bad functional outcome (Britton & Roden 1985; Jorgensen et al 2001). The International Study of Early/Progressing Stroke (by the European Stroke Database Collaboration and Early/Progressing Stroke Study Group) is an ongoing study of the phenomena of stroke progression (http://www.ncl.ac.uk/stroke-research-unit/posters/epssp.htm).

It therefore appears that the process of secondary neuronal damage can occur very quickly and any attempts to halt the process should be made aggressively and urgently. In an observational study, Langhorne et al found that stroke patients with normal physiological parameters within the first three days (including glucose, temperature, serum osmolarity, and oxygen saturation) had better functional outcomes (Langhorne et al 2000b). The authors concluded that at least some of the neurological impairment occurring in the acute phase of stroke may be reversible and could be exacerbated by physiological abnormalities (Langhorne et al 2000b). Indredavik also commented that "*control of such physiological parameters may be the most important neuroprotective options in acute stroke patients*" (Indredavik 2000). This perhaps forms the basis for a recent trend of increasingly intensive management of physiological disturbances after stroke (Langhorne 1999).

Rationale for actively treating physiological disturbances

The Scandinavian approach to stroke unit care is characterised by early mobilisation, intensive physiological monitoring and correction of abnormal parameters such as

fever, hyperglycaemia, hypoxia, and dehydration (Ronning & Guldvog 1998a; Ronning & Guldvog 1998b; Indredavik et al 1999b). This style of stroke unit care appeared to reduce the number of deaths within the first three weeks from 14% to 8%, and the authors suggested that this might have been a result of preventing stroke progression (Ronning & Guldvog 1998a; Ronning & Guldvog 1998b; Indredavik et al 1999b). In the USA and some countries in Europe, acute stroke care has adopted this style so that intensive physiological monitoring and correction of abnormal parameters are now accepted as routine (Hund et al 1995; Krieger & Hacke 1997; Deibert & Diringer 1999). Such monitoring often detects abnormalities of blood pressure, oxygen saturation, temperature, glucose concentration, and cardiac rhythm (Rem et al 1985; Hacke et al 1994; Davis et al 1999; Bellagamba et al 2001).

In the UK, such intensive physiological monitoring is not widely used; this may be because of a lack of resources, lack of evidence from randomised trials, and the belief by some physicians that a lack of evidence of benefit equates to evidence of lack of benefit (Sandercock & Willems 1992; Wolfe et al 2001). However, there has been a recent call in the UK for a more active approach in managing physiological disturbances after stroke. Wolfe et al wrote, "*the current absence of evidence from randomised trials should not be used as an excuse for neglecting basic care for patients with stroke*" (Wolfe et al 2001). What Wolfe et al meant by "basic care" included active monitoring and treatment of fever, hyperglycaemia, dehydration, hypoxia, as well as ensuring a safe airway (Wolfe et al 2001).

Monitoring of physiological parameters after acute stroke

In conventional intensive care units, control of physiological parameters is usually straightforward since patients are anaesthetised and ventilated, so that invasive monitoring (e.g. intra-arterial lines for continuous blood pressure monitoring) is possible (Indredavik 2000). This model of care is not practical in acute stroke where early mobilisation is one of the main treatment goals (Indredavik et al 1999b; Indredavik 2000; Langhorne et al 2000b).

So is there any direct evidence to show that intensive physiological monitoring and correction of abnormal parameters after acute stroke is feasible and worthwhile? A UK randomised controlled trial tested the hypothesis that acute stroke patients who received augmented care (i.e. 72 hours of continuous physiological monitoring), compared with standard care (i.e. 4-hourly observations), would have a better outcome. The study found that intensive non-invasive physiological monitoring improved the rate of detection and correction of abnormal parameters, and that significantly fewer patients in the augmented care group experienced stroke progression (OR 0.24, 95% CI 0.09 to 0.63) (Davis et al 1999). A non-randomised Italian study also found that non-invasive physiological monitoring and correction of abnormal parameters appeared to improve outcome and also reduce length of stay (Cavallini et al 2001). However, these positive findings were not confirmed by another non-randomised Spanish study (Silva et al 2001). There is currently a ongoing non-randomised controlled trial (the PROCESS trial) that aims to recruit 450 patients to investigate the effectiveness of an acute care protocol with physiological monitoring (Langhorne et al 2001).

Any improvement in patient outcome is unlikely to be due to the physiological monitoring *per se*, but more likely to be due to the corrective measures in response to detecting abnormal parameters (Sinha & Warburton 2000). However, it is unclear how intensive the physiological monitoring needs to be, how long a patient should be monitored, and what 'abnormal' means for each physiological parameter. I shall now discuss four parameters in some detail.

High blood pressure

High blood pressure is common after stroke (Scott & Gray 2000). One study found that almost 70% of patients admitted with stroke had a blood pressure greater than 170/100mmHg (Britton et al 1986). However, a history of high blood pressure is only present in about half of the patients who have a high blood pressure on admission (Sandercock et al 1989). During the first few days after stroke, the blood pressure declines spontaneously in many patients (Britton et al 1986; Harper et al 1994).

High initial blood pressure after stroke may be associated with poor outcome (Choong et al 2000). The recently published Perindopril Protection Against Recurrent Stroke Study (PROGRESS), a multicentre randomised controlled trial which recruited over 6000 patients, has found that blood pressure lowering using a combination of perindopril and indapamide was highly effective in reducing the risk of recurrent stroke or TIA (PROGRESS Collaborative Group 2001). However, the optimal timing of blood pressure lowering after stroke remains unclear because there have been no randomised trials of blood pressure reduction during the acute phase of

stroke (Blood pressure in Acute Stroke Collaboration (BASC) 2002). Current UK guidelines recommend not actively lowering the blood pressure within the first few days after stroke, and keeping the patient well hydrated (SIGN 1997a; RCP 2001b). However, if the patient suffers from hypertensive encephalopathy or acute renal failure resulting from extreme hypertension, blood pressure should be lowered acutely (e.g. using captopril or labetolol) (Hacke et al 2000). For the remaining patients, most experts advise waiting one to two weeks before starting blood pressure lowering therapy (Britton et al 1980; Warlow et al 2000). For patients who are being considered for thrombolytic therapy, current US guidelines state that blood pressure should be below 185/110mmHg *before* treatment, and then kept below 180/105mmHg *during* treatment (Adams, Jr. et al 1996). This recommendation is not based on any randomised trial evidence. Further research is clearly needed to assess the effects of lowering blood pressure during the acute phase of stroke (Blood Pressure in Acute Stroke Collaboration, BASC, 2002).

High body temperture

Fever, which is generally defined as body temperature of above 37.5^0 or 38^0C, is common after stroke. Frequency of occurrence of fever after stroke might vary according to the method of measurement (e.g. oral, rectal, axillary or tympanic) and the characteristics of the patients studied. In the Copenhagen Stroke Study, 25% of stroke patients admitted within six hours of stroke onset had temperature greater than 37.5^0 (Reith et al 1996). In other studies, the frequency varies from 5% to 91% (Georgilis et al 1999; Schwarz et al 2000; Boysen & Christensen 2001). The aetiology of fever after stroke is unclear, but of the stroke patients who develop

fever, may be only 16% have concurrent infection, even though 50% have leucocytosis (Reith et al 1996). Non-infection-related fever may be a result of the cerebral lesion itself, or associated cerebral oedema (Boysen & Christensen 2001).

A systematic review including nine studies and a total of 3790 patients has shown that fever is an independent predictor for higher mortality and morbidity after stroke (OR for mortality 1.19, 95% CI 0.99 to 1.43) (Hajat et al 2000). Furthermore, spontaneous hypothermia after stroke (less than 36.5^0) may be associated with a reduced risk of mortality (Wang et al 2000). The harmful effects of fever have been attributed to increased metabolic demands, changes in the blood-brain-barrier permeability, acidosis, and an increased release of neurotransmitters (Busto & Ginsberg 1998; Dippel et al 2001). However, it is unclear whether fever *per se* causes poor outcome after stroke, or the fact that fever is associated with severe strokes, which in turn is associated with poorer outcome. Boysen and Christensen recently found evidence that the latter may be the case (Boysen & Christensen 2001).

There are two methods of reducing body temperature: mechanically-induced hypothermia and pharmacological treatment of fever. In animal models of focal and global ischaemia, it has been shown that high temperature within the brain (over 39^0) led to increased infarct volume and more severe histological outcome, whereas actively reducing the temperature by mechanical and/or pharmacological means appeared to delay and reduce neuronal injury (Coimbra et al 1996; Busto & Ginsberg 1998; Schmid-Elsaesser et al 1999).

In humans, hypothermia has been used in patients with traumatic head injury and there is some evidence that it may reduce mortality and severe disability (OR 0.39, 95% CI 0.2 to 0.74) (Signorini & Alderson 2002). In stroke, mechanically-induced hypothermia has neither been proven to be easily achieved nor beneficial. Many of the trials employed invasive methods of physiological monitoring (e.g. general anaesthesia and insertion of arterial and central venous catheters) and use of powerful drugs to control shivering (e.g. pethidine) (Kammersgaard et al 2000; Krieger et al 2001). One small randomised trial of 20 consecutive patients with severe stroke found that a combination of anti-inflammatory drug and ice-cooling prevented the development of cerebral oedema (Moriwaki et al 2000). Although some insist that a controlled trial comparing treatment with no treatment of fever is no longer ethical (De Keyser 1998), one such trial has recently been carried out (Dippel et al 2001). In this randomised trial of 75 patients with acute ischaemic stroke, Dippel et al found that treatment with 6g of paracetamol appeared to have reduced body temperature by 0.4^0, even in patients without fever (Dippel et al 2001). However, the study did not investigate the effect of this fall in temperature on functional outcome. One potential adverse effect of prevention or treatment of fever might be a delay in detecting the underlying cause, such as an infection, and hence delaying appropriate treatment. Further randomised studies would be necessary to determine the effects of lowering body temperature after stroke. Current guidelines on the treatment of fever after stroke are imprecise, but they all suggest that treatment should be considered if body temperature rises above 37.5^0 (Adams, Jr. et al 1994; Hacke et al 2000; RCP 2001b).

High blood glucose

Diabetes mellitus has long been known to be an independent modifiable risk factor for both stroke and coronary heart disease; it increases the risk of stroke by two to three fold (Kannel & McGee 1979; Kagan et al 1980; Fuller et al 1983). Between 8 to 20% of stroke patients have a history of diabetes and 5 to 28% may have unrecognised diabetes or impaired glucose tolerance (i.e. those with raised glycosylated haemoglobin concentration, HbA1c) (Scott et al 1999). In 10 to 20% of patients with hyperglycaemia, there is no history of diabetes and HbA1c is normal. In these cases, hyperglycaemia may be a result of raised cortisol level due to stress response after stroke (Scott & Gray 2000). Depending on the definition, hyperglycaemia could be present in over half of all stroke patients (Scott & Gray 2000). This figure is similar to that in patients with acute myocardial infarction (Capes et al 2000).

The relationship between diabetes mellitus, hyperglycaemia, and outcome after stroke is complex and controversial (Counsell et al 1997; Kagansky et al 2001; Counsell & Dennis 2001). Studies of the association between hyperglycaemia and outcome after stroke may vary in their methods of adjusting for outcome, leading to conflicting results. Several studies have found that hyperglycaemia after stroke was an independent prognostic factor for poor outcome, but others did not confirm this (Kiers et al 1992; Counsell et al 1997; Weir et al 1997; Kagansky et al 2001; Wang et al 2001). In animal models of focal and global ischaemia, hyperglycaemia, both during and after the period of ischaemia, has been shown to exacerbate neuronal injury and increase infarct volume (Greenberg 1998). This injury is mainly due to

tissue lactic acidosis, which results in free-radical formation and deterioration of brain energy metabolism (Greenberg 1998; Ginsberg & Busto 1998; Kagansky et al 2001). Other mechanisms may include blood-brain barrier injury and production of glutamate, which is an excitatory amino acid that can eventually lead to cell death (Kagansky et al 2001). More importantly, animal studies have demonstrated that treatment of hyperglycaemia with insulin after ischaemic stroke may be neuroprotective and reduce neuronal damage. However, it remains unclear whether this is due to the direct effect of insulin or the correction of hyperglycaemia (Kagansky et al 2001).

In patients with myocardial infarction and a blood glucose of greater than 11mmol/L, insulin therapy appears to reduce long-term mortality (Malmberg et al 1995; Malmberg 1997). However, no comparable large randomised trial has been completed in patients with acute stroke, though a pilot randomised study (Glucose Insulin in Stroke Trial, GIST) has been performed to assess the safety of 24-hour infusion of glucose, potassium and insulin with the aim of keeping plasma glucose between 7 and 17mmol/L (Scott et al 1999). This pilot study of 25 acute stroke patients showed that this regimen was safe (only one patient required intravenous glucose for symptomatic hypoglycaemia) and effective in achieving the target range (Scott et al 1999). The effect on functional outcome is being assessed in the ongoing GIST study, which aims to recruit 1200 acute stroke patients (Scott et al 2001). Meanwhile, current European guidelines suggest correcting hyperglycaemia with insulin if plasma glucose is above 10 mmol/L, whereas UK guidelines do not recommend any specific treatment (RCP 2001b).

Low blood oxygen concentration

Stroke patients, especially those with hemiparesis and reduced consciousness, are particularly likely to develop abnormal respiratory function and a low oxygen concentration in the blood (hypoxia or hypoxaemia). Impaired chest wall and diaphragm movements, altered central regulation of respiration, sleep apnoea, aspiration, and other complications (e.g. pneumonia, pulmonary embolism, heart failure) can all contribute to hypoxia (Fluck 1966; Roffe et al 2001). One observational study showed that as many as 63% of stroke patients with hemiparesis developed oxygen desaturations to below 96% during the first two days after admission (Sulter et al 2000). Interestingly, in this study, all the patients with a history of cardiac or pulmonary diseases developed oxygen desaturations (Sulter et al 2000). Another study found that a quarter of stroke patients developed oxygen desaturations to below 90% during or after eating (Rowat et al 2000).

Animal studies have shown that hypoxia can increase cerebral damage after stroke and traumatic brain injury (Back et al 1994; Murai et al 1998). In stroke patients, therefore, it may seem sensible to maintain a high level of oxygen saturation (e.g. above 95%) by administering supplemental oxygen and ensuring that the patient is nursed at an appropriate posture (Elizabeth et al 1993; Paczynski et al 1995). 'Airway, breathing and circulation', the three components of basic life support, should apply to every patient with an emergency condition including stroke (Kinsara 2001). However, oxygen itself can be toxic (Beckman 1998). In animal stroke models, excessive oxygen administration can accentuate ischaemic damage (from

free radical production and increased lipid peroxidation) and increase mortality (Mickel et al 1987; Beckman 1998; Sinha & Warburton 2000). In humans, a quasi-randomised trial of 550 acute stroke patients assessed the effects of routinely giving 100% oxygen for 24 hours compared with not giving oxygen (Ronning & Guldvog 1999). The study found that, amongst patients with mild to moderate stroke, routine oxygen therapy appeared to increase the risk of death within one year (Ronning & Guldvog 1999). The authors concluded that stroke patients should not routinely be given oxygen. Producing a clinical guideline for the treatment of this physiological disturbance is therefore difficult and some experts recommend giving supplemental oxygen only when there is evidence of hypoxia (Hacke et al 2000).

1.5 Quality of stroke care

Quality of care is an important public issue

The basis of professional practice is to provide and maintain the highest possible quality of care to patients (GMC 2001). The quality of care that medical professionals provide is now a subject of public debate and hence is under close professional scrutiny (Philip 2000). League tables, such as the *National Performance Indicators*, have been published by the government, ranking the Hospital Trusts and Health Authorities across the UK according to certain clinical indicators of 'quality' (DoH 2002). Hospital Trusts at the top of the league table are praised and those at bottom are encouraged to improve their services. Over the past few years, professional bodies have issued statements highlighting the problems with such league tables, and in particular, whether the league tables truly inform the public about the variations in the quality of care across the UK (BMA 2000; Adab et al 2002).

In the UK, the government has pledged to improve quality of care (DoH 1998; DoH 1999a; DoH 1999b). As a result, regulatory systems such as clinical governance have been introduced with an aim to ensuring a consistently high quality of patient care throughout the NHS (see **Figure 1.5**) (DoH 1998; Scally & Donaldson 1998; Halligan & Donaldson 2001).

What is 'quality'?

Universally accepted definitions of 'quality' have been difficult to achieve, and some have even considered the term too subjective to be useful (Blumenthal 1996a; Scally & Donaldson 1998). Definitions of quality can be divided into two types – generic or disaggregated (Campbell et al 2000). Generic definitions of quality include excellence (RCGP 1994), 'zero defects' (Crosby 1979), and expectations or goals which have been met (Ellis & Whittington 1993). Disaggregated approaches, on the other hand, recognise that quality is complex and multidimensional, and define quality according to individual components or dimensions (Maxwell 1984). The World Health Organisation provides an example of a disaggregated definition of quality. It divides quality into the following four aspects (WHO 1983):

- Professional performance (technical quality);
- Resource use (efficiency);
- Risk management (risk of injury or illness associated with the service provided);
- Patients' satisfaction with the service provided.

These dimensions of quality can therefore be regarded as the attributes of an organisation or service providing a high quality of care.

There are also aspects of quality that may be relevant to the individual groups of stakeholders (Parsley & Corrigan 1999). To the health professionals, a high quality of care should be effective (causing more benefit than harm) and appropriate; to the patient and family, it should be acceptable and accessible; and to the government and funding bodies, it should be cost-effective, equitable, and relevant (Parsley & Corrigan 1999; Dennis 2000). In clinical practice, while the health professional

should be technically excellent, that is 'doing the right thing', he or she should also 'do the right things right', which requires skill, judgement and timeliness of execution (Blumenthal 1996a). Good interpersonal skills are essential if care is to be responsive to the preferences and values of the patient. So, improving the quality of care requires much more than just ensuring the practice is evidence-based and efficient, it must also take the patient's entire experience within a healthcare system into account (Parsley & Corrigan 1999).

Methods of assessing quality of care

Until recently, society has relied primarily on physician's own professional judgement to ensure that patients received high quality care (Brook et al 1996). If, however, the goal is to quantify, compare, and improve the quality of care, then a different approach is needed (Blumenthal 1996b; AHA/ACC 2000). There are now many organisations devoted to supporting research into assessing and improving the quality of care, such as the Agency for Health Care Research and Quality (http://www.ahcpr.gov/), which is part of the US Department of Health.

Donabedian suggested that quality of care can be assessed by examining three main elements: a) structure of service; b) process of care; and c) patient outcome (Donabedian 1988). This three-part approach to quality assessment illustrates the underlying relationships between the three elements: a good structure of service may increase the likelihood of good process of care, which may in turn increase the likelihood of good patient outcome (Donabedian 1988). However, the assessor must

be clear of the relationships between these elements before quality can be assessed effectively (Donabedian 1988).

Structure of service as an indicator of quality of care

Structure of service represents the attributes of the settings within which care occurs. Using stroke as an example, a comprehensive acute stroke service should consist of several essential components such as a stroke unit, CT scanner, and a multidisciplinary team (see **Table 1.4**) (AHA/ACC 2000; Dennis 2000). One method of assessing quality of care is by examining the structure of the service. However, it must be born in mind that the existence of a particular aspect of a service does not necessarily mean that it is carrying out the intended function. For instance, even if there is a CT scanner in the hospital, stroke patients may not have 24-hour access to it (Dennis 2000).

Process of care as an indicator of quality of care

The simplest and hence the most popular method of assessing quality of care is the examination of the process of care (Donabedian 1988; Brook et al 1996). Process of care indicates what is done to the patient, where, when and how (Davies & Crombie 1995). Data on the process of care are relatively easy to collect and can be measured reliably, validly, and mostly without serious bias – so long as the baseline characteristics of the patient groups are properly defined (Davies & Crombie 1995). Furthermore, the use of process measures can quickly identify areas where the service is performing particularly well or poorly.

It has been proposed that measuring an aspect of the process of care is meaningful only if it relates to those factors that are under the control of the healthcare staff (Giuffrida et al 1999). Others have also suggested that it is only appropriate if it relates to interventions that have been proven to be effective (Davies & Crombie 1995). However, Davenport commented that the measurement of the process of care in complex diseases such as stroke is not straightforward, especially when some interventions are poorly defined (e.g. stroke unit care), making it difficult to decide on which processes to measure, and how (Davenport & Dennis 1996). Like all non-randomised studies, audits of the process of care are prone to case selection bias, variation in case-mix, measurement error, and random variation (Chalmers et al 1983; Ebrahim & Harwood 1999; Dennis 2000).

Outcome as an indicator of quality of care

Outcome may be defined according the five 'D's, which focuses on the five types of negative results for the patient – namely, death, disease, disability, discomfort, and dissatisfaction (Orchard 1994). Each of these may be measured as an indicator of outcome. However, measures such as case fatality are dependent on a multitude of factors (e.g. case selection, case mix, play of chance) and are not necessarily indicative of the quality of the service (Anon. 1993; Dennis 2000). Crude hospital statistics, therefore, need to be adjusted for case mix, but identifying and weighting the patient characteristics which affect prognosis are problematical for conceptual, methodological, and practical reasons (Mant & Hicks 1995; Davenport et al 1996c). These include the inherent nature of prognosis itself and the practical difficulties of collecting and quantifying data on the outcomes of interest for specific healthcare

interventions and known risk factors such as severity (Orchard 1994). Orchard has also identified five further problems: a) outcomes are multidimensional; b) many outcomes are qualitative (e.g. satisfaction); c) assessment of outcomes can be affected by timing; d) subgroups of diseases may have differing outcomes; and e) outcomes may not be attributable to quality of care.

With this in mind, small-scale audits of patient outcome are therefore unlikely to yield conclusive results about the quality of care even after adjusting for case-mix (Kassirer 1993; Dennis 2000; Weir & Dennis 2001). However, larger-scale audits of patient outcome, together with an assessment of the process of care and service structure, may be informative and can generate hypotheses for future clinical research (Dennis 2000).

Relationship between process of care and outcome after stroke

Variations in outcome after stroke

There are considerable variations in outcomes after stroke, most notably in case fatality (Thorvaldsen et al 1995; Wolfe et al 1999; Wolfe et al 2000; Brainin et al 2000; Weir et al 2001). In the International Stroke Trial (IST), crude case fatality rates at six months varied from 12% in Sweden to 30% in Poland, and the proportion of patients dead or dependent varied from 42% in Sweden to 60% in Norway (Weir et al 2001). The WHO Monitoring Trends and Determinants in Cardiovascular Disease (MONICA) project also found that the case fatality rates at one month varied from 15 to 49% in men and 18 to 57% in women (Thorvaldsen et al 1995).

The UK appeared to have some of the highest case fatality rates in Europe (Wolfe et al 1999; Wolfe et al 2000; Weir et al 2001). Wolfe et al found in a European study that the adjusted case fatality rate at three months in the UK was 42% (95% CI 35 to 49%), compared with 19% (95% CI 14 to 24%) in France (Wolfe et al 1999). However, a study by Brainin et al did not confirm this finding (Brainin et al 2000). As I have already mentioned, variations in case fatality could be a result of the different methods of case ascertainment, case mix factors (e.g. stroke subtypes), or differences in quality of stroke care (Wolfe et al 1999). In the UK, the apparently high case fatality rates could possibly be due to a combination of these factors.

Variation in the process of stroke care in Europe

Several studies have assessed the management of acute stroke and use of diagnostic procedures between different European countries (Asplund et al 1996; Beech et al 1996; Brainin et al 2000; Weir et al 2001). One consistent finding is that the use of diagnostic procedures is generally higher in France and Germany and lower in the UK. In the European Study of Stroke Care, Beech et al found that in the UK, neuroimaging was performed in 30 to 72%, and carotid duplex in 0 to 23%, of all stroke patients (Beech et al 1996). In France, however, neuroimaging was performed in 97%, and carotid duplex in 82%, of all stroke patients (Beech et al 1996). Furthermore, from the results of the IST, Weir et al found that UK had the second lowest rate of discharging patients with ischaemic stroke on aspirin (54% in the UK compared with 73% in Norway) (Weir et al 2001). The data so far suggest that, in the UK, poor process of care may at least be partially responsible for a higher case fatality after stroke.

Variation in the process of stroke care in the UK

In the past decade, observational studies have found enormous variations in patient care and stroke service provision in the UK (King's Fund 1988; Lindley et al 1995; CSAG 1998; Rudd et al 1999; Ebrahim & Redfern 1999; Roberts et al 2000). The report of the King's Fund Consensus Conference on the Treatment of Stroke was the first to note that stroke services in the UK are *"haphazard, fragmented and poorly tailored to patients' needs"* (King's Fund 1988). The surveys performed by the Clinical Standards Advisory Group (1998), The Stroke Association (1992-1993 and 1998), and the Scottish Stroke Service Audit (1997-1998) confirmed that the organisation of stroke care was poor in many parts of the UK and many hospital Trusts were not meeting the guideline recommendations set out by the Scottish Intercollegiate Guidelines Network (SIGN) (Lindley et al 1995; CSAG 1998; Ebrahim & Redfern 1999; Roberts et al 2000; Roberts 2001).

In the two surveys performed by the Stroke Association five years apart, although improvement in some aspects of acute stroke care was found (e.g. routine aspirin use rose from 39% to 67%), many aspects of acute care remained unsatisfactory (e.g. under half of consultants could get a CT scan the same day or next day) (Lindley et al 1995; Ebrahim & Redfern 1999). Furthermore, only 3% of the physicians caring for stroke patients had a special interest in stroke (Ebrahim & Redfern 1999).

In 1998, the Intercollegiate Stroke Working Party at the Royal College of Physicians (RCP) was commissioned to conduct a national sentinel audit of the organisation and process of care in hospital and during the first six months after discharge (Rudd et al

1999). This was the largest audit of stroke in the UK involving almost 7000 stroke patients, and it used the Intercollegiate Stroke Audit tool, which had been extensively piloted (Hancock et al 1997; Irwin & Rudd 1998; Rudd et al 1999; Irwin et al 2001). Importantly, it showed that 67% of stroke patients spent most of their hospital stay in general medical wards, and that there were large regional variations in both the organisation of care and patient outcome (Rudd et al 1999). A repeat of the national sentinel audit was conducted in 1999 and it found some improvement in certain aspects of stroke care (e.g. proportion of patients managed in stroke units rose from 19% to 26%) but many aspects remained poor (e.g. cognitive and mood assessment) (Rudd et al 2001).

In Scotland, an audit of the process of care and case fatality after stroke in five Scottish hospitals was carried out between 1995 and 1997 (Weir & Dennis 2001). It found significant differences in case fatality rate between different hospitals even after adjusting for case mix. Furthermore, there were major deficiencies in the organisation of care, use of CT scanning, and documentation of care (Weir & Dennis 2001). Similar surveys of general practitioners in the UK have also demonstrated major variations in clinical practice and access to specialist stroke services (Action for Stroke Group 1998; Gibbs et al 2001).

Are variations necessarily undesirable?

Large variations in the access to services are generally regarded as unacceptable, especially those services that have been proven to be beneficial (e.g. stroke units) (Plsek & Wilson 2001). However, variations in clinical practice may be acceptable if

the variations simply reflect a lack of evidence (e.g. artificial feeding after stroke), and this uncertainty may suggest a need for further clinical trials (e.g. Feeding or Ordinary Diet, FOOD, Trial). For interventions that have been proven to be effective (e.g. thrombolysis for AMI), variations in practice may indicate unfamiliarity with clinical guidelines and a lack of training (Awad et al 1999).

So what conclusions can be drawn about quality of care?

The relationship between process of care and outcome is very complex, and conclusions regarding the quality of care cannot easily be drawn. The assessment of this complex relationship is further hampered by the fact that the absolute benefit of most of the processes of care are unknown (e.g. CT scanning, carotid duplex), and the absolute benefit of many acute interventions are very small (e.g. use of aspirin for ischaemic stroke) – hence even large changes in the process of care are unlikely to significantly affect outcome. Planning a 'high quality' stroke service is therefore far from straightforward; it is difficult to decide exactly which process of care should be included and what standard one should aim for, especially if resources are scarce.

Quality of care from the patients' and carers' perspective

Recently, there has been a growing recognition that care must be responsive to the preferences and values of the patient, family and carers, and that their opinion about care are important indicators of its quality, especially regarding interpersonal skills (Donabedian 1988; Blumenthal 1996a). Indeed, the *Report of the Royal Commission on the National Health Service* in 1979 included "*to satisfy reasonable public expectations for health care*" as one of its main objectives (NHS 1979). The

government's efforts to meet this objective, and the focus on the patient as a 'customer' of service, have led to the publication of *The Patient's Charter*, which was later updated as *Your Guide to The NHS* in 2001 (DoH 2001b).

Methods of assessing patients' and carers' views

According to the patient and carer, quality of care may be judged on the following five aspects: competence, respect, choice, accessibility and responsiveness (Larner 1997). For stroke patients, satisfaction has been an outcome of interest in clinical trials only within the past seven years, and many studies have used very similar questionnaires to assess satisfaction (Pound et al 1994; Pound et al 1999b). In a randomised study of early discharge of stroke patients to community therapy, Pound et al found that patients were more likely to be satisfied if they received more therapy, meals-on-wheels, and home help visits (Pound et al 1999b). Furthermore, the study found that satisfaction assessments reflected real differences in the provision of care (Pound et al 1999b).

Another survey of stroke patients' views on their admission to hospital identified four important components that the patients valued: being cared about (psychosocial needs), clinical care, nursing care, and information and advice (Pound et al 1995). The most recent survey of patients' and carers' views on hospital stroke care in Scotland revealed several important aspects of care that were deficient: lack of stroke units, lack of specialist training for staff, poor information provision for patients and carers, no trained liaison person for hospital-home transition, and lack of people to "*talk to*" (CHSS 2001).

Problems with assessing patients' and carers' views

Although patient and carers should be satisfied with their care, the use of their views as indicators of quality of stroke care is controversial. There are three main reasons or this. Firstly, there is no single, agreed, definition of the concept of patient satisfaction (Batchelor et al 1994). Secondly, patients and carers are often not knowledgeable about the medical details, and the measurement of patients' and carers' views may not always be valid or reliable (Blumenthal 1996a). Thirdly, patient satisfaction surveys are prone to methodological problems such as case selection bias (e.g. surveying only the patients who can communicate), variation in case-mix, random error (e.g. small sample size), and non-response to questionnaires (Lin & Kelly 1995). Patients and carers may also be reluctant to reveal their true (especially negative) feeling for fear of offending the healthcare staff (Donabedian 1988). Nevertheless, patient and carer satisfaction will remain an important indicator of stroke care, and further research is needed to improve its evaluation (Lin & Kelly 1995).

Methods of improving quality of stroke care

Many initiatives have been implemented with an aim to improve the quality of care. Examples of these include (Bullivant 1996; Scally & Donaldson 1998; Øvretveit 2000):

- Professional initiatives (e.g. professional self-regulation);
- Promotion of evidence- and guideline-based practice (e.g. integrated care pathways);
- Use of audits (e.g. national sentinel stroke audit);

- Governmental regulation (e.g. clinical governance);
- Total quality management (e.g. European Foundation for Quality Development).

It is beyond the scope of this thesis to discuss all of the above initiatives in detail. Some of these initiatives have been implemented in stroke care, such as the use of audits and the promotion of evidence- and guideline-based practice.

Use of clinical guidelines may improve quality of care

Clinical guidelines are produced by appraising the available research evidence and experience, and converting them into practical recommendations, which are then used to determine what happens to a patient (Thomson et al 1995). They are intended to be a tool to assist the healthcare professional in making clinical decisions (Field & Lohr 1992). Clinical guidelines can either be developed locally (e.g. policy within a hospital or stroke unit) or nationally by consensus panels (e.g. SIGN or RCP stroke guidelines) (Rycroft-Malone 2001). National clinical guidelines can help to define what patients or carers could expect from the healthcare professionals (DoH 2001a; RCP 2001b). Clinical guidelines can also be regarded as a tool to make patient care more consistent and efficient, closing the gap between what the best evidence supports and what healthcare professionals actually do ('the evidence gap') (Woolf et al 1999; Coleman & Nicholl 2001).

In a systematic review to assess the effectiveness of clinical guidelines, Grimshaw and Russell found that explicit clinical guidelines were effective in improving medical practice in the context of effective implementation (Grimshaw & Russell 1993). For that systematic review, a clinical guideline was defined as a

"*systematically developed statement to assist practitioner decisions about appropriate health care for specific clinical circumstances*" (Grimshaw & Russell 1993). Interestingly, none of the 59 studies included in the systematic review examined the effectiveness of stroke guidelines.

The report of the recent Scientific Forum on Assessment of Healthcare Quality in Cardiovascular Disease and Stroke commented that *"although guidelines are designed to suggest diagnostic and therapeutic interventions for most patients in most circumstances, the use of guideline recommendations in an individual patient should be left to the discretion of the professional"* (Hurwitz 1999; AHA/ACC 2000). In other words, the professional is not necessarily in error if a particular guideline recommendation has not been strictly followed (AHA/ACC 2000). This can potentially have important legal and political implications (Hurwitz 1999).

Use of clinical guidelines is not a panacea

The quality of a guideline is directly dependent on the quality of the medical evidence supporting its recommendation(s) (Cluzeau et al 1999; Woolf et al 1999). The problem is that only a small percentage of evidence supporting clinical guidelines comes from randomised controlled trials; the majority comes from 'expert panels' (Bergman 1999). The ability of guidelines to improve clinical practice is also dependent on the level of compliance. In a recent prospective observational study, Duncan et al found that the level of compliance with stroke rehabilitation guidelines was significantly associated with dependency at six months (Duncan et al 2002). The

authors also suggested that compliance with guidelines could be regarded as an indicator of quality of care in stroke rehabilitation.

Physicians' resistance to change their practice

Development of good clinical guidelines does not ensure the recommendations are translated into local clinical practice; physicians are often resistant in changing their practice (Goodpastor & Montoya 1996; Ashford et al 1999; Feder et al 1999). There are at least three possible reasons for this phenomenon (Shekelle 2002):

a) Physicians may not agree with the criteria by which quality is being measured. Many feel that some measures of quality represent misplaced priorities, concentrating on those things that can be easily measured rather than those that are truly important for producing good patient outcomes;
b) Physicians may view quality improvement programmes as an opportunity to blame them for anything bad that may or may not happen to the patient;
c) Physicians have to participate in quality improvement programmes on top of their already very busy schedules.

It may therefore be difficult to gain full co-operation from the physicians unless there is agreement on the measures of quality, a shift from a culture of blame to one of learning from mistakes, and provision of adequate resources for the tasks at hand (Shekelle 2002).

Translating guidelines to clinical practice

Grimshaw and Russell found that successful introduction of guidelines is dependent on many factors including the clinical context and the methods of developing,

disseminating and implementing those guidelines (Grimshaw & Russell 1993). They suggested that passive dissemination of information was generally less effective, whereas patient-specific reminders at the time of consultation (e.g. prescription charts with reminders) were more likely to be effective (Cohen et al 1987; Robie 1988; Schreiner et al 1988; Cummings et al 1989; Grimshaw & Russell 1993). Bero et al also found that 'multifaceted' interventions that involved interaction with the stakeholder (e.g. interactive educational meetings, audit and feedback, local consensus processes, and reminders) might be effective in promoting change in practice (Bero et al 1998).

In clinical practice, however, passive (i.e. the least effective) approaches probably represent the most common approaches adopted by healthcare professionals and policy makers (Bero et al 1998). In Scotland, two studies have highlighted the large variation in the methods of implementing the SIGN guidelines, and no evidence is yet available on the most effective method (Millard 1997; Keaney & Lorimer 1999).

Implementing national guidelines in the local setting

For national guidelines to be relevant in the local setting, they have to be tailored to meet local circumstances. Specific operational details, such as who does what, when and how, should be added where necessary (Feder et al 1999). This adaptation leads to the production of clinical protocols or algorithms (CRAG 1993; Long 1994). Long has proposed a list of desirable characteristics that guidelines and protocols should possess (see **Table 1.5**) (Long 1994). For acute stroke care, protocols and algorithms are more likely to be acceptable and followed if all the members of the

multidisciplinary team are involved in their design and implementation, or in other words, if every person has a sense of 'ownership' (Conroy & Shannon 1995; Langley et al 1998; Adams et al 1999).

Integrated care pathways can promote evidence- and guideline-based stroke care

Many interventions have been shown to reduce the risk of stroke, but the full benefits of these interventions are not realised at the current levels of utilisation because nearly all the evidence-based and guideline-endorsed stroke treatment strategies are underused (Holloway et al 2000). Integrated care pathways are organisational interventions that can promote evidence- and guideline-based care, improve the organisation and efficiency of care, and reduce cost (Sulch et al 2000) It is a potentially effective tool in managing patients admitted with acute stroke.

1.6 Objectives of this thesis

In this thesis, I sought to explore in detail two major issues concerning the use of integrated care pathways for acute stroke:

1. Should integrated care pathways be used to manage stroke patients?

- Amongst patients admitted to hospital with an acute stroke, is there any evidence of significant difference in patient care and outcome between management with an integrated care pathway as compared to conventional care?
  - What is the evidence from previous studies?
  - At the Western General Hospital, did the introduction of an integrated care pathway in the acute stroke unit influence patient care and outcome?
  - At the Western General Hospital, what did the stroke unit staff think were the effects of introducing the ICP?

2. How should the effects of integrated care pathways for acute stroke be evaluated?

- What are the methodological considerations when evaluating the effects of integrated care pathways?
- What are the strengths and weaknesses of the research designs used to evaluate the integrated care pathway for acute stroke in the Western General Hospital?
- Is there an ideal research design that should be used to evaluate the effects of integrated care pathways for acute stroke?

1.7 Summary of this chapter

- Stroke is an important public health problem. It is common, causes many deaths and much long-term disability, and is associated with a substantial burden on society. The burden of stroke is likely to rise over the next decade as the proportion of older people in the population rises.
- Diagnostic and therapeutic nihilism about the management of stroke should be a thing of the past. Admission to a stroke unit leads to substantial improvements in outcome.
- Acute stroke care can be divided into three main components: treatment of the cerebral lesion itself; general care of a stroke patient; and management of specific complications.
- Worsening of the initial stroke is common and may be exacerbated by physiological disturbances. There is evidence that intensive physiological monitoring and correction of abnormal physiological parameters may improve outcome after stroke.
- Quality of stroke care can be defined and assessed according to the structure of service, process of care, and patient outcome. The quality of stroke care varies between and within countries. In the UK, it appears that many patients are receiving inconsistent and often low standards of care.
- Clinical guidelines have the potential to improve patient care and standardise practice. Guideline recommendations need to be tailored to meet local circumstances. Some strategies, such as patient-specific reminders, are more likely to be effective in changing practice.

- Integrated care pathways are an organisational intervention that aims to promote evidence- and guideline-based care, improve the organisation and efficiency of care, and reduce cost. It is a potentially effective tool in managing stroke patients.
- In this thesis, I sought to explore two major issues concerning the use of integrated care pathways for acute stroke: a) should integrated care pathways be used to manage patients with acute stroke? and b) how should the effects of integrated care pathways for acute stroke be evaluated?

Table 1.1 Major stages in the development of CCU and stroke unit care. Adapted from Lee et al (1988) & Langhorne & Dennis (1998).

Period From	CCU Development	Stroke Unit Development
1960s	First CCU opened in 1962. Objective of CCU admission was to recognise and treat arrhythmia early after an acute myocardial infarction.	Introduction of 'organised stroke rehabilitation'. First randomised trial of a system of stroke rehabilitation.
1970s	Development of aggressive treatments for acute myocardial infarction and congestive heart failure. CCUs became coronary intensive care units. Two randomised trials failed to show benefit.	Neurovascular intensive care units introduced in the USA but were unpopular and expensive. Less intensive stroke units were developed.
1980s	Increased use of thrombolysis and emergency angioplasty for acute myocardial infarction. CCU care became more expensive.	First large-scale randomised trial showing benefit of stroke unit care with rehabilitation. Other forms of organised stroke care, e.g. mobile stroke team, were also developed.
1990s to now	Attempts to limit cost of CCU care, e.g. developing criteria for CCU admission and more cost-effective alternatives such as 'intermediate care units'.	Systematic reviews of randomised trials showing stroke unit care was beneficial. Introduction of thrombolysis for acute ischaemic stroke. Development of acute stroke units.

Table 1.2 Major complications after stroke. Adapted from Warlow et al (2001).

Consequences of stroke

- Reduced consciousness
- Breathing difficulty
- Weakness, gait problem
- Sensory impairment
- Visual impairment
- Visual-spatial impairment
- Communication problem
- Dysphagia
- Urinary/faecal incontinence
- Headache
- Nausea & vomiting
- Stroke progression
- Emotional disturbance
- Epilepsy
- Cognitive impairment
- Spasticity, contracture
- Swollen & cold limb
- Painful shoulder
- Central post-stroke pain

Medical complications

- Pneumonia
- Urinary tract infection
- Deep vein thrombosis
- Pulmonary embolism
- Pressure sore
- Malnutrition
- De-/over-hydration
- Over-sedation
- Adverse drug reactions
- Falls & fractures
- Withholding drugs e.g. anti-anginal Rx
- Co-existing problems e.g. angina, asthma

Physiological disturbances

- Hypertension
- Hypotension
- Hyperglycaemia
- Hypoglycaemia
- Fever
- Hypoxia
- Syndrome of inappropriate ADH secretion
- Irregular breathing
- Electrolyte imbalance
- Bradycardia
- Tachyarrhythmia

Table 1.3 Reported frequencies of medical complications in hospitalised stroke patients. These data came from 23 studies included in a literature review performed by Langhorne (2000a).

Complication	Range of frequencies (%) from 6 retrospective studies	Range of frequencies (%) from 17 prospective studies
Neurological		
Recurrent stroke	5	18
Epileptic seizure	2-5	3
Medical		
Urinary infection	7 – 25	11 – 28
Chest infection	7 – 21	10 – 20
Other infection	4	4 – 31
Pressure sore	3 – 18	-
Fall (all)	22 – 25	-
Deep vein thrombosis	1 – 3	1 – 2
Pulmonary embolism	2 – 18	0 – 1
Shoulder pain	4	27
Depression	5 – 33	1 – 50
Anxiety	7	8
Confusion	5	3 – 40
Other complications	32	-
Any complication	**40 – 96**	**63 – 95**

Table 1.4 Components of a comprehensive acute stroke service. Adapted from Dennis (2000).

Facilities	Healthcare Personnel
▪ Ambulance service	▪ Paramedical staff
▪ Emergency department	▪ Emergency medical & nursing staff
▪ Acute stroke unit	▪ Stroke physician
▪ CT or MRI scanner	▪ Multidisciplinary team
▪ Carotid duplex scanner	▪ Neurology support
▪ ECG and echocardiography	▪ Neurosurgery support
▪ Laboratory for blood tests	▪ Cardiology support

Table 1.5 Desirable characteristics that clinical guidelines and protocols should possess. Adapted from Long (1994).

- Outcome focused
- Based on the best available evidence and professional judgement
- Reflective of the patient's perspective
- Valid
- Reliable
- Representative of all relevant disciplines and stakeholders
- Clinically applicable
- Clinically flexible
- Unambiguous
- Well documented
- Widely used
- Easy to evaluate
- Regularly updated

Figure 1.1 Multidisciplinary team approach in acute stroke care. Other professionals can also be involved but have not been shown here.

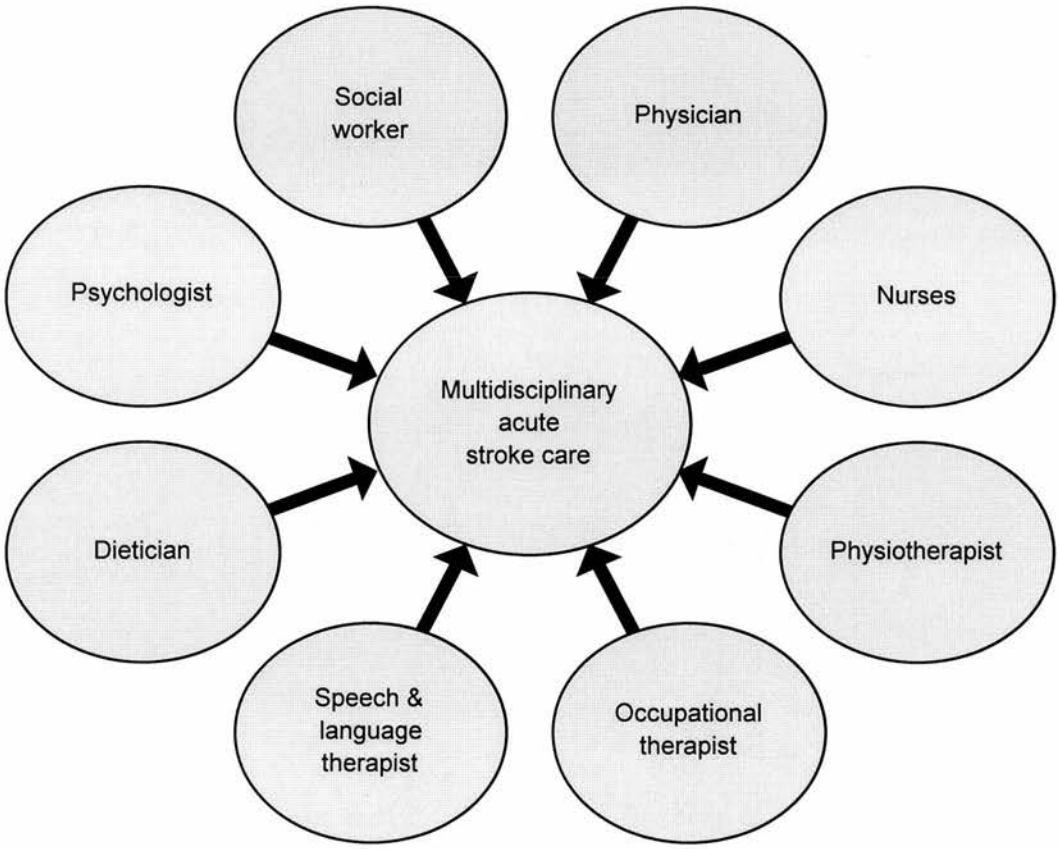


Figure 1.2 Results from the Cochrane systematic review: stroke unit care vs alternative forms of care. Death or dependency by the end of follow-up. Reproduced with permission.

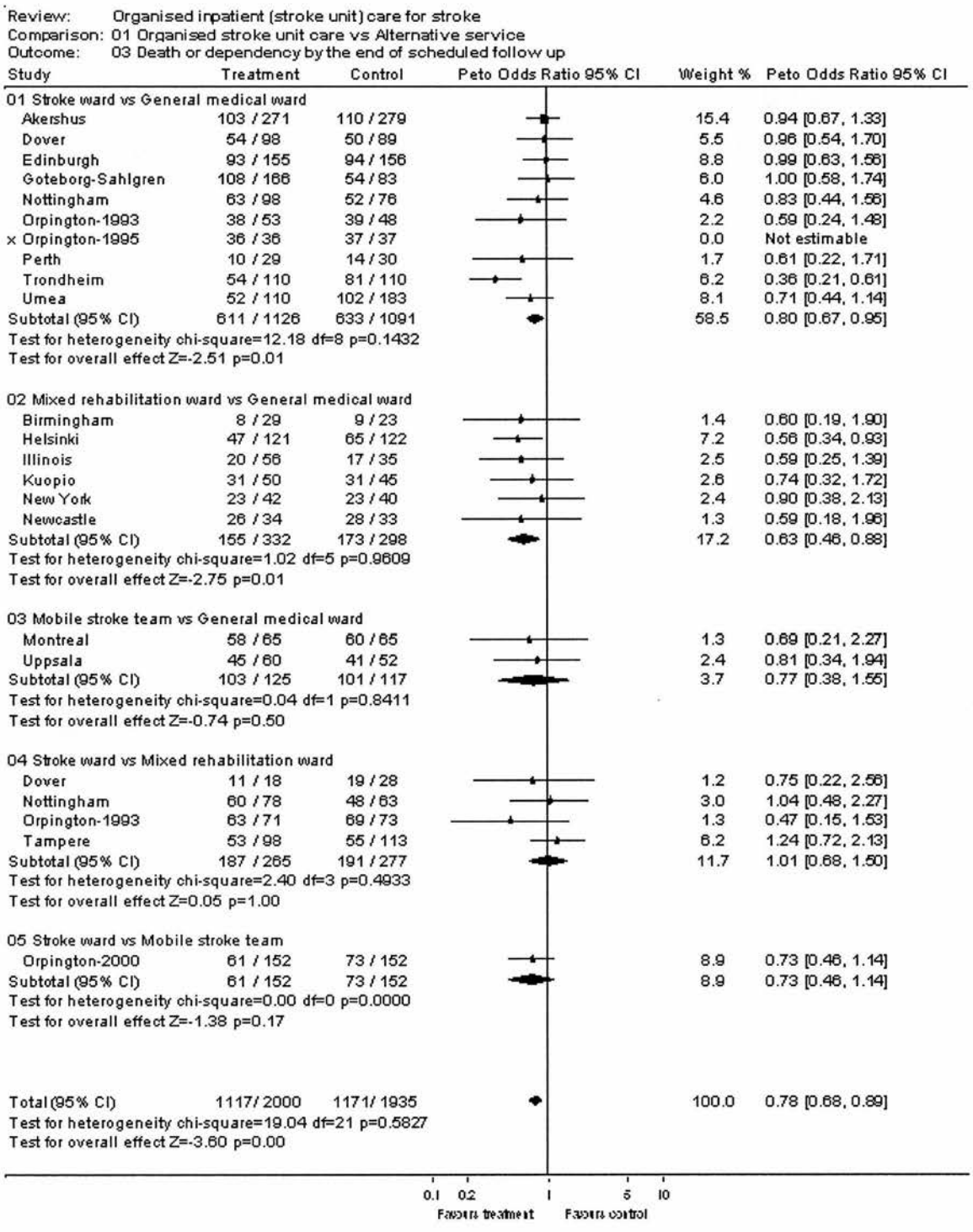


Figure 1.3 Results from the Cochrane systematic review: stroke unit care vs alternative forms of care. Death or institutionalisation by the end of follow-up. Reproduced with permission.

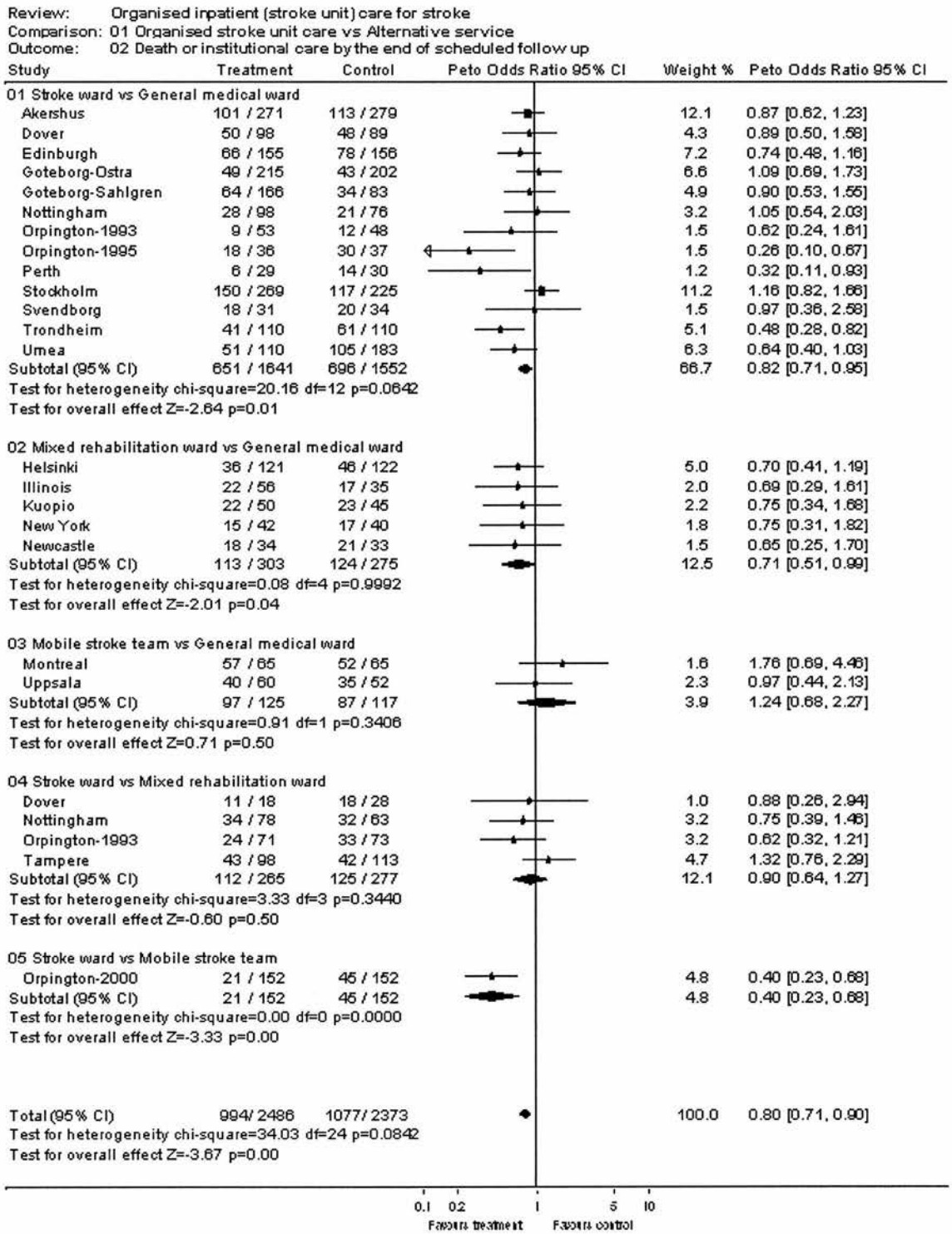


Figure 1.4 Survival of the brain tissue after ischaemic stroke depends on the severity (i.e. level of cerebral blood flow) and duration of ischaemia. This is an original drawing. Definition of the ischaemic penumbra is given in the main text.

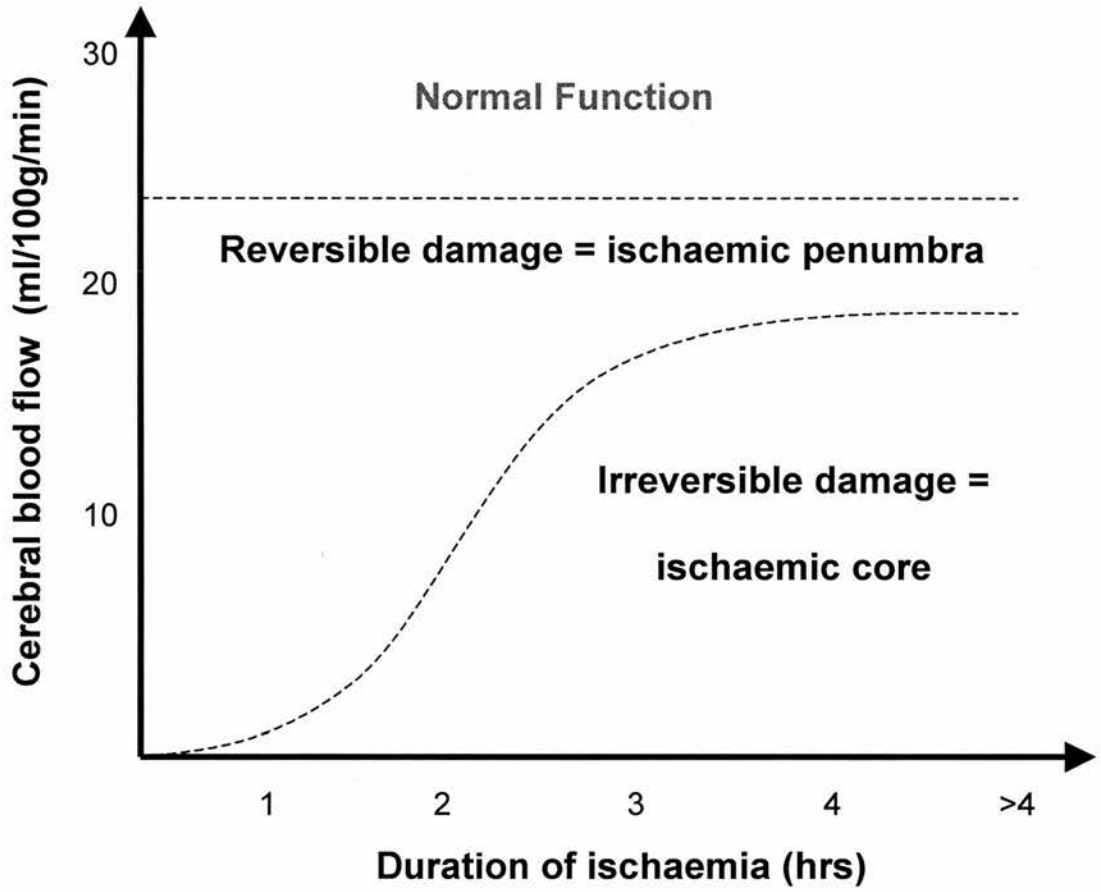
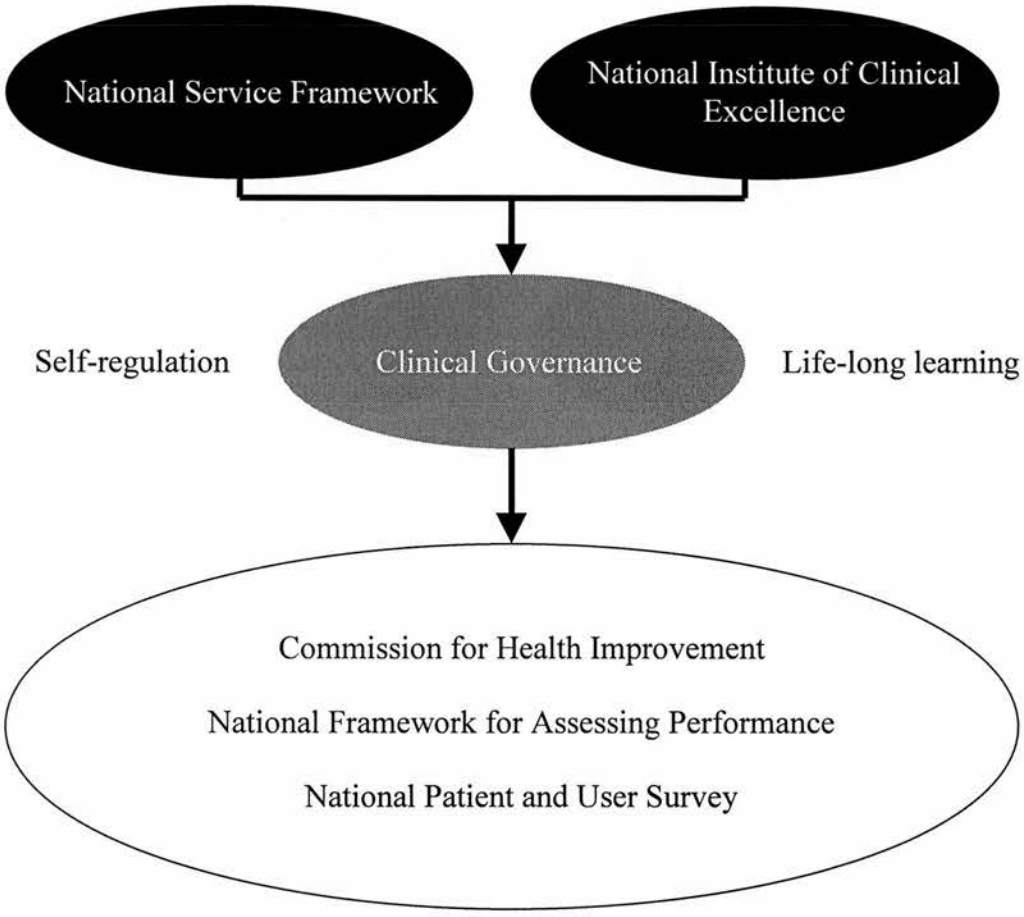


Figure 1.5 A new national system to improve quality of care across the UK.



Black oval text box: The National Service Framework sets out common standards across the country for the treatment of particular conditions. The National Institute of Clinical Excellence acts as a national-wide appraisal body for new and existing treatments, and disseminates consistent advice on what works and what does not.

Grey oval text box: Clinical governance is a system to ensure that national quality standards are applied locally.

White oval text box: Standards are monitored through three systems: the Commission for Health Improvement, National Framework for Assessing Performance, and National Survey of Patient and User Experience. These aim to identify and spread best practice and reduce poor performance (DoH 1998).

References for Chapter 1

Anonymous (1971) Examination of the unconscious patient. *The BMJ.* 4:313-314.

Anonymous (1993) Dicing with death rates (editorial). *Lancet.* 341:1183-1184.

Anonymous (1999) Epidemiology of stroke. *Cerebrovasc Dis.* 9(Suppl 4):7-13.

Aboderin I, Venables G. (1996) Stroke management in Europe. Pan European consensus meeting on stroke management (Helsingborg Declaration). *J Intern Med.* 240(43):173-180.

Action for Stroke Group. (1998) *Results of a GP survey on the management of stroke.* London: The Stroke Association.

Adab P, Rouse AM, Mohammed MA et al. (2002) Performance league tables: the NHS deserves better. *The BMJ.* 324(7329):95-98.

Adams GF. (1974) Prognosis and prospects of strokes. In: *Cerebrovascular disability and the ageing brain.* Edinburgh: Churchill Livingstone.

Adams HP, Jr. (1997) Management of patients with acute ischaemic stroke. *Drugs.* 54 Suppl 3:60-69.

Adams HP, Jr. (2001) Treatment of acute ischemic stroke: selecting the right treatment for the right patient. *Eur Neurol.* 45(2):61-66.

Adams HP, Jr., Brott TG, Crowell RM et al. (1994) Guidelines for the management of patients with acute ischemic stroke. A statement for healthcare professionals from a special writing group of the Stroke Council, American Heart Association. *Circulation.* 90(3):1588-1601.

Adams HP, Jr., Brott TG, Furlan AJ et al. (1996) Guidelines for thrombolytic therapy for acute stroke: a supplement to the guidelines for the management of patients with acute ischemic stroke. A statement for healthcare professionals from a special writing group of the Stroke Council, American Heart Association. *Stroke.* 27(9):1711-1718.

Adams JL, Fitzmaurice DA, Heath CM et al. (1999) A novel method of guideline development for the diagnosis and management of mild to moderate hypertension. *Br J Gen Pract.* 49(440):175-179.

AHA/ACC. (2000) Measuring and improving quality of care. A report from the American Heart Association/American College of Cardiology first scientific forum on assessment of healthcare quality in cardiovascular disease and stroke. Quality of Care and Outcomes Research in CVD and Stroke Working Groups. *Stroke.* 31(4):1002-1012.

Albers GW, Alberts M, Broderick J et al. (2000) Recent advances in stroke management. *J Stroke Cerebrovasc Dis.* 9(3):95-105.

Alberts MJ, Hademenos G, Latchaw RE et al. (2000) Recommendations for the establishment of primary stroke centers (The Brain Attack Coalition). *JAMA.* 283(23):3102-3109.

Allder S, Moody AR, Martel AL et al. (1999) Limitations of clinical diagnosis in acute stroke. *Lancet.* 354:1532.

American Heart Association. (1999) *1999 annual report.* American Heart Association.

Andriange M, Lisin N, Calay G et al. (1969) First record of a coronary intensive care unit. *Rev Med Liege.* 24(9):369-376.

Ashford J, Eccles M, Bond S et al. (1999) Improving health care through professional behaviour change: introducing a framework for identifying behaviour change strategies. *Br J Clin Governance.* 4(1):14-23.

Asplund K, Rajakangas AM, Kuulasmaa K et al. (1996) Multinational comparison of diagnostic procedures and management of acute stroke. The WHO MONICA Study. *Cerebrovasc Dis.* 6:66-74.

Awad IA, Fayad P, Abdulrauf SI. (1999) Protocols and critical pathways for stroke care. *Clin Neurosurg.* 45:86-100.

Back T, Kohno K, Hossmann KA. (1994) Cortical negative DC deflections following middle cerebral artery occlusion and KCl-induced spreading depression: effect on blood flow, tissue oxygenation, and electroencephalogram. *J Cereb Blood Flow Metab.* 14(1):12-19.

Back T, Nedergaard M, Ginsberg MD. (1998) The ischaemic penumbra: pathophysiology and relevance of spreading depression-like phenomena. In: Ginsberg MD & Bogousslavsky J (ed.). *Cerebrovascular Disease. Pathophysiology, diagnosis, and management.* Malden, MA: Blackwell Science, 276-286.

Ballinger C, Ashburn A, Low J et al. (1999) Unpacking the black box of therapy - a pilot study to describe occupational therapy and physiotherapy interventions for people with stroke. *Clin Rehabil.* 13(4):301-309.

Bamford J. (2001) Assessment and investigation of stroke and transient ischaemic attack. *J Neurol Neurosurg Psychiatry.* 70(Suppl 1):i3-i6.

Bamford J, Dennis M, Sandercock P et al. (1990b) The frequency, causes and timing of death within 30 days of a first stroke: the Oxfordshire Community Stroke Project. *J Neurol Neurosurg Psychiatry.* 53(10):824-829.

Bamford J, Sandercock P, Dennis M et al. (1990a) A prospective study of acute cerebrovascular disease in the community: the Oxfordshire Community Stroke Project - 1981-86. 2. Incidence, case fatality rates and overall outcome at one year of cerebral infarction, primary intracerebral and subarachnoid haemorrhage. *J Neurol Neurosurg Psychiatry.* 53(1):16-22.

Bamford J, Sandercock P, Dennis M et al. (1988) A prospective study of acute cerebrovascular disease in the community: the Oxfordshire Community Stroke Project 1981-86. 1. Methodology, demography and incident cases of first-ever stroke. *J Neurol Neurosurg Psychiatry.* 51(11):1373-1380.

Baron JC. (2001) Perfusion thresholds in human cerebral ischemia: historical perspective and therapeutic implications. *Cerebrovasc Dis.* 11:Suppl-8.

Batchelor C, Owens DJ, Read M et al. (1994) Patient satisfaction studies: methodology, management and consumer evaluation. *Int J Health Care Qual Assur.* 7(7):22-30.

Bath P, Butterworth RJ, Soo J et al. (1996) The King's College Hospital acute stroke unit. *J R Coll Physicians Lond.* 30(1):13-17.

Bath PM, Lees KR. (2000) ABC of arterial and venous disease. Acute stroke. *The BMJ.* 320(7239):920-923.

Bath PMW, Lindenstrom E, Boysen G et al. (2001) Tinzaparin in acute ischaemic stroke (TAIST): a randomised aspirin-controlled trial. *Lancet.* 358:702-710.

Beckman JS. (1998) Interactions of oxidants, nitric oxide, and antioxidant defenses in cerebral ischaemia and injury. In: Ginsberg MD & Bogousslavsky J (ed.). *Cerebrovascular Disease. Pathophysiology, diagnosis, and management.* Malden: Blackwell Science, 455-470.

Beech R, Ratcliffe M, Tilling K et al. (1996) Hospital services for stroke care. A European perspective. European Study of Stroke Care. *Stroke.* 27(11):1958-1964.

Bellagamba G, Assouad C, Balestrini F et al. (2001) Stroke unit: a cardio-cerebral approach. *Clin Exp Hypertens.* 23(1-2):167-175.

Bergman DA. (1999) Evidence-based guidelines and critical pathways for quality improvement. *Pediatrics.* 103(1 Suppl E):225-232.

Bero LA, Grilli R, Grimshaw JM et al. (1998) Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. The Cochrane Effective Practice and Organization of Care Review Group. *The BMJ.* 317(7156):465-468.

Bisnaire D. (1998) Nursing research in stroke. A review. *Axone.* 20(1):10-13.

Blecic S, Bogousslavsky J. (1995) Current management of acute stroke. In: Fisher M (ed.). *Stroke therapy.* Newton: Butterworth-Heinemann, 247-266.

Blood Pressure in Acute Stroke Collaboration (BASC). (2002) Interventions for deliberately altering blood pressure in acute stroke (Cochrane Review). In: *The Cochrane Library, Issue 2, 2002.* Oxford: Upsate Software.

Blumenthal D. (1996a) Quality of health care. Part 1: Quality of care - what is it? *N Engl J Med.* 335(12):891-894.

Blumenthal D. (1996b) Quality of health care. Part 4: The origins of the quality-of-care debate. *N Engl J Med.* 335(15):1146-1149.

BMA – British Medical Association (2000) *Clinical indicators (league tables) - a discussion paper.* London: British Medical Association.

Bobath B. (1990) *Adult hemiplegia: evaluation and treatment.* London: Heinemann.

Bonita R. (1992) Epidemiology of stroke. *Lancet.* 339:342-344.

Bonita R, Beaglehole R. (1996) The enigma of the decline in stroke deaths in the United States. The search for an explanation. *Stroke.* 27:370-372.

Bonita R, Beaglehole R, North JD. (1984) Event, incidence and case-fatality rates of cerebrovascular disease in Auckland, New Zealand. *Am J Epidmiol.* 120:236-243.

Bonner CD. (1973) Stroke units in community hospitals: a "how-to" guide. *Geriatrics.* 28(4):166.

Bosanquet N, Franks P. (1998) *Stroke care: reducing the burden of disease.* London: The Stroke Association.

Boysen G, Christensen H. (2001) Stroke severity determines body temperature in acute stroke. *Stroke.* 32(2):413-417.

Brainin M, Bornstein N, Boysen G et al. (2000) Acute neurological stroke care in Europe: results of the European Stroke Care Inventory. *Eur J Neurol.* 7(1):5-10.

Briggs DE, Felberg RA, Malkoff MD et al. (2001) Should mild or moderate stroke patients be admitted to an intensive care unit? *Stroke.* 32(4):871-876.

Brittain KR, Peet SM, Potter JF et al. (1999) Prevalence and management of urinary incontinence in stroke survivors. *Age Ageing.* 28(6):509-511.

Britton M, Carlsson A, de Faire U. (1986) Blood pressure course in patients with acute stroke and matched controls. *Stroke.* 17(5):861-864.

Britton M, de Faire U, Helmers C. (1980) Hazards of therapy for excessive hypertension in acute stroke. *Acta Med Scand.* 207(4):253-257.

Britton M, Roden A. (1985) Progression of stroke after arrival at hospital. *Stroke.* 16(4):629-632.

Broderick JP, Phillips SJ, Whisnant JP. (1989) Incidence rates of stroke in the eighties. *Stroke.* 20:577-582.

Brook RH, McGlynn EA, Cleary PD. (1996) Quality of health care. Part 2: Measuring quality of care. *N Engl J Med.* 335(13):966-970.

Brunstrom S. (1956) Associated reactions of the upper extremity in adult patients with hemiplegia. An approach to training. *Phys Ther.* 45:17-32.

Bullivant JR. (1996) Benchmarking in the UK National Health Service. *Int J Health Care Qual Assur.* 9(2):9-14.

Busto R, Ginsberg MD. (1998) The influence of altered brain temperature in cerebral ischaemia. In: Ginsberg MD & Bogousslavsky J (ed.). *Cerebrovascular Disease. Pathophysiology, diagnosis, and management.* Malden: Blackwell Science, 287-307.

CAEP Committee on Thrombolytic Therapy for Acute Ischaemic Stroke. (2001) Thrombolytic therapy for acute ischaemic stroke (positional statement). *Can J Emerg Med.* 3(1):8-12.

Camarata PJ, Heros RC, Latchaw RE. (1994) "Brain attack": the rationale for treating stroke as a medical emergency. *Neurosurgery.* 34(1):144-157.

Campbell SM, Roland MO, Buetow SA. (2000) Defining quality of care. *Soc Sci Med.* 51(11):1611-1625.

Capes SE, Hunt D, Malmberg K et al. (2000) Stress hyperglycaemia and increased risk of death after myocardial infarction in patients with and without diaetes: a systematic overview. *Lancet.* 355:773-778.

CAST – Chinese Acute Stroke Trial. (1997) CAST: randomised placebo-controlled trial of early aspirin use in 20,000 patients with acute ischaemic stroke. Chinese Acute Stroke Trial Collaborative Group. *Lancet.* 349(9066):1641-1649.

Cavallini A, Micieli G, Zambrelli E et al. (2001) Role of continuous physiological monitoring in the acute phase of stroke [abstract]. *Cerebrovasc Dis.* 11(Suppl 4):117.

Chalmers TC, Celano P, Sacks H et al. (1983) Bias in treatment assignment in controlled clinical trials. *N Engl J Med.* 309:1358-1361.

Chen ZM, Sandercock P, Pan HC et al. (2000) Indications for early aspirin use in acute ischemic stroke : A combined analysis of 40,000 randomized patients from the chinese acute stroke trial and the international stroke trial. On behalf of the CAST and IST collaborative groups. *Stroke.* 31(6):1240-1249.

Chia BL. (1982) The current status of coronary care units in the treatment of acute myocardial infarction. *Ann Acad Med Singapore.* 11(3):382-388.

Choong PF, Langford AK, Dowsey MM et al. (2000) Clinical pathway for fractured neck of femur: a prospective, controlled study. *Medical Journal of Australia.* 172(9):423-426.

CHSS – Chest, Heart, Stroke Scotland. (2001) *Improving stroke services. Patients' and carers' views. A report commissioned by Chest, Heart & Stroke Scotland and Scottish Asssociation of Health Councils.* Edinburgh: Chest, Heart & Stroke Scotland.

Clarke E. (1963) Apoplexy in Hippocratic writings. *Bull Hist Med.* 31:301.

Cluzeau FA, Littlejohns P, Grimshaw JM et al. (1999) Development and application of a generic methodology to assess the quality of clinical guidelines. *Int J Qual Health Care.* 11(1):21-28.

Cohen SJ, Christen AG, Katz BP et al. (1987) Counseling medical and dental patients about cigarette smoking: the impact of nicotine gum and chart reminders. *Am J Public Health.* 77(3):313-316.

Coimbra C, Drake M, Boris-Moller F et al. (1996) Long-lasting neuroprotective effect of postischemic hypothermia and treatment with an anti-inflammatory/antipyretic drug. Evidence for chronic encephalopathic processes following ischemia. *Stroke.* 27(9):1578-1585.

Coleman P, Nicholl J. (2001) Influence of evidence-based guidance on health policy and clinical practice in England. *Qual Health Care.* 10(4):229-237.

Collins D, McConaghy D, McMahon A et al. (2000) An acute stroke service: potential to improve patient outcome without increasing length of stay. *Ir Med J.* 93(3):84-86.

Conroy M, Shannon W. (1995) Clinical guidelines: their implementation in general practice. *Br J Gen Pract.* 45(396):371-375.

Cooper SW, Olivet JA, Woosley FM. (1972) Establishment and operation of combined intensive care unit for patients with cardiac and cerebrovasular disorders. *NY State J Med.* 72:2215-2220.

Counsell C, Dennis M. (2001) Systematic review of prognostic models in patients with acute stroke. *Cerebrovasc Dis.* 12(3):159-170.

Counsell C, McDowall M, Dennis M. (1997) Hyperglycaemia after acute stroke. Other models find that hyperglycaemia is not independent predictor. *The BMJ.* 315(7111):810.

CRAG – Clinical Resource and Audit Group. (1993) *Clinical guidelines*. Edinburgh:

Crosby PB. (1979) *Quality is free - the art of making quality certain.* New York: McGraw Hill.

CSAG – Clinical Standards and Audit Group. (1998) *Report on clinical effectiveness using stroke care as an example*. London: Stationery Office.

Cummings SR, Richard RJ, Duncan CL et al. (1989) Training physicians about smoking cessation: a controlled trial in private practice. *J Gen Intern Med.* 4(6):482-489.

Davalos A, Cendra E, Teruel J et al. (1990) Deteriorating ischemic stroke: risk factors and prognosis. *Neurology.* 40(12):1865-1869.

Davenport R, Dennis M. (2000) Neurological emergencies: acute stroke. *J Neurol Neurosurg Psychiatry.* 68(3):277-288.

Davenport RJ, Dennis M, Warlow C. (1996c) Effect of correcting outcome data for case mix: an example from stroke medicine. *The BMJ.* 312:1503-1505.

Davenport RJ, Dennis M, Wellwood I et al. (1996a) Complications after acute stroke. *Stroke.* 27:415-420.

Davenport RJ, Dennis MS. (1996) Assessing the quality of care. Measuring the process of care is not always straightforward. *The BMJ.* 312(7024):185.

Davenport RJ, Dennis MS, Warlow CP. (1996b) Gastrointestinal hemorrhage after acute stroke. *Stroke.* 27(3):421-424.

Davies HT, Crombie IK. (1995) Assessing the quality of care. *The BMJ.* 311(7008):766.

Davis M, Hollyman C, McGiven M et al. (1999) Physiological monitoring in acute stroke. *Age Ageing.* 28(Suppl 1):45-45.

Davis SM, Rosen D, Donnan G. (1997) Acute stroke management around the world. In: *In: Acute stroke treatment.* London: Martin Dunitz Ltd, 1-14.

Dayno JM, Mansbach HH. (1999) Acute stroke units. *J Stroke Cerebrovasc Dis.* 8(3):160-170.

De Cristobal J, Moro MA, Davalos A et al. (2001) Neuroprotective effect of aspirin by inhibition of glutamate release after permanent focal cerebral ischaemia in rats. *J Neurochem.* 79(2):456-459.

De Keyser J. (1998) Antipyretics in acute ischaemic stroke. *Lancet.* 352(9121):6-7.

Deibert E, Diringer M. (1999) Intensive care management of acute ischaemic stroke. *The Neurologist.* 5:313-325.

Dennis M. (2000) Stroke services: the good, the bad and the... *J R Coll Physicians Lond.* 34(1):92-96.

Dennis M, Langhorne P. (1994) So stroke units save lives: where do we go from here? *The BMJ.* 309(6964):1273-1277.

Di Carlo A, Lamassa M, Pracucci G et al. (1999) Stroke in the very old : clinical presentation and determinants of 3-month functional outcome: A European perspective. European BIOMED Study of Stroke Care Group. *Stroke.* 30(11):2313-2319.

Diener HC, Cortens M, Ford G et al. (2000) Lubeluzole in acute ischemic stroke treatment: a double-blind study with an 8-hour inclusion window comparing a 10-mg daily dose of lubeluzole with placebo. *Stroke.* 31(11):2543-2551.

Diez-Tejedor E, Fuentes B. (2001) Acute care in stroke: do stroke units make the difference? *Cerebrovasc Dis.* 11(Suppl 1):31-39.

Dippel DWJ, van Breda EJ, van Gemert HMA et al. (2001) Effect of paracetamol (acetaminophen) on body temperature in acute ischemic stroke: a double-blind, randomized phase II clinical trial. *Stroke.* 32(7):1607-1612.

DoH – Department of Health. (1998) *A first class service: quality in the new NHS.* London: The Stationery Office.

DoH – Department of Health. (1999b) *Making a difference.* London: The Stationery Office.

DoH – Department of Health. (1999a) *Saving lives: uur healthier nation.* London: The Stationery Office.

DoH – Department of Health. (2001a) *National Service Framework for Older People.* London: The Stationery Office.

DoH – Department of Health. (2001b) *Your guide to the NHS.* London: The Stationery Office.

DoH – Department of Health. (2002) *NHS Performance Indicators: National Figures, February 2002.* Department of Health.

Donabedian A. (1988) The quality of care. How can it be assessed? *JAMA.* 260(12):1743-1748.

Dow RS, Dick HL, Crowell FA. (1974) Failures and successes in a stroke program. *Stroke.* 5(1):40-47.

Drake WE, Jr., Hamilton MJ, Carlsson M et al. (1973) Acute stroke management and patient outcome: the value of neurovascular care units (NCU). *Stroke.* 4(6):933-945.

Duncan PW, Horner RD, Reker DM et al. (2002) Adherence to postacute rehabilitation guidelines is associated with functional recovery in stroke. *Stroke.* 33(1):167-178.

Ebrahim S. (1990) *Clinical epidemiology of stroke.* Oxford: Oxford University Press.

Ebrahim S, Harwood R. (1999) *Stroke. Epidemiology, evidence, and clinical practice.* Oxford: Oxford University Press.

Ebrahim S, Redfern J. (1999) *Stroke care - a matter of chance: a national survey of stroke services.* London: The Stroke Association.

Elizabeth J, Singarayar J, Ellul J et al. (1993) Arterial oxygen saturation and posture in acute stroke. *Age Ageing.* 22(4):269-272.

Ellis R, Whittington D. (1993) *Quality assurance in health care - a handbook.* London: Arnold.

Fagerberg B, Claesson L, Gosman-Hedstrom G et al. (2000) Effect of acute stroke unit care integrated with care continuum versus conventional treatment: A randomized 1-year study of elderly patients: the Goteborg 70+ Stroke Study. *Stroke.* 31(11):2578-2584.

Feder G, Eccles M, Grol R et al. (1999) Clinical guidelines: using clinical guidelines. *The BMJ.* 318(7185):728-730.

Feigensen JS, Gitlow HS, Greenberg SD. (1979) The disability orientated rehabilitation unit - a major factor influencing stroke outcome. *Stroke.* 10:5-8.

Feldman DJ, Lee PR, Untertrecker J. (1962) A comparison of functionality oriented medical care and formal rehabilitation in the management of patients with hemiplegia due to cerebrovascular disease. *J Chron Dis.* 15:297-310.

Ferro JM, Melo TP, Oliveira V et al. (1994) An analysis of the admission delay of acute strokes. *Cerebrovasc Dis.* 4:72-75.

Field MJ, Lohr KN. (1992) *Guidelines for clinical practice: from development to use.* Washington DC: National Academy Press.

Fields WS. (1998) Historic introduction. In: Ginsberg MD & Bogousslavsky J (ed.). *Cerebrovascular Disease. Pathophysiology, diagnosis, and management.* Malden: Blackwell Science, 827-833.

Fields WS, Lemak NA. (1989) *A history of stroke. Its recognition and treatment.* Oxford: Oxford University Press.

Fieschi C, Argentino C, Fiorelli M et al. (1998) Frequency and conquences of medical complications of ischaemic stroke. *Lancet.* 352(Suppl 4):27.

Fineberg HV, Scadden D, Goldman L. (1984) Care of patients with a low probability of acute myocardial infarction. Cost effectiveness of alternatives to coronary-care-unit admission. *N Engl J Med.* 310(20):1301-1307.

Fisher M. (1997) Characterizing the target of acute stroke therapy. *Stroke.* 28(4):866-872.

Fisher M. (1998) Anti-ischaemic stroke therapy. In: Ginsberg MD & Bogousslavsky J (ed.). *Cerebrovascular Disease. Pathophysiology, diagnosis, and management.* Malden, MA: Blackwell Science, 1878-1886.

Fluck DC. (1966) Chest movements in hemiplegia. *Clin Sci.* 31(3):383-388.

Fogelholm R, Murros K, Rissanen A et al. (1996) Factors delaying hospital admission after acute stroke. *Stroke.* 27(3):398-400.

Fraser HW, Ersoy Y, Bowman F et al. (1999) The development of stroke services: entering the new millennium. *Scot Med J.* 44:166-170.

Frenkel HS. (1890) Die Therapie atactischer Bewegunstbrungen. *Mfinchen Med Wcshcr.* 37:917.

Fuller JH, Shipley MJ, Rose G et al. (1983) Mortality from coronary heart disease and stroke in relation to degree of glycaemia: the Whitehall study. *Br Med J (Clin Res Ed).* 287(6396):867-870.

Garraway M. (1985) Stroke rehabilitation units: concepts, evaluation, and unresolved issues. *Stroke.* 16(2):178-181.

Garraway WM, Akhtar AJ, Hockey L et al. (1980a) Management of acute stroke in the elderly: follow-up of a controlled trial. *The BMJ.* 281(6244):827-829.

Garraway WM, Akhtar AJ, Prescott RJ et al. (1980b) Management of acute stroke in the elderly: preliminary results of a controlled trial. *The BMJ.* 280(6220):1040-1043.

Geddes JML, Fear J, Tennant A et al. (1996) Prevalence of self-reported stroke in a population in Northern England. *J Epidemiol Community Health.* 50:140-143.

Georgilis K, Plomaritoglou A, Dafni U et al. (1999) Aetiology of fever in patients with acute stroke. *J Intern Med.* 246(2):203-209.

Gialloreto O, Samuel T, Gelinas M et al. (1969) Coronary intensive care unit: results and considerations of a new diagnostic-therapeutic intensive care unit. *Can Med Assoc J.* 100(12):547-553.

Gibbs RGJ, Newson R, Lawrenson R et al. (2001) Diagnosis and initial management of stroke and transient ischemic attack across UK health regions from 1992 to 1996: experience of a national primary care database. *Stroke.* 32(5):1085-1090.

Gillum RF, Folsom A, Luepker RV et al. (1983) Sudden death and acute myocardial infarction in a metropolitan area, 1970-1980. The Minnesota Heart Survey. *N Engl J Med.* 309(22):1353-1358.

Ginsberg MD, Busto R. (1998) Small-animal models of global and focal cerebral ischaemia. In: Ginsberg MD & Bogousslavsky J (ed.). *Cerebrovascular Disease. Pathophysiology, diagnosis, and management.* Malden: Blackwell Science, 14-35.

GISSI. (1986) Effectiveness of intravenous thrombolytic treatment in acute myocardial infarction. Gruppo Italiano per lo Studio della Streptochinasi nell'Infarto Miocardico (GISSI). *Lancet.* 1(8478):397-402.

Giuffrida A, Gravelle H, Roland M. (1999) Measuring quality of care with routine data: avoiding confusion between performance indicators and health outcomes. *The BMJ.* 319(7202):94-98.

Glader E-L, Stegmayr B, Johansson L et al. (2001) Differences in Long-Term Outcome Between Patients Treated in Stroke Units and in General Wards: A 2-Year Follow-Up of Stroke Patients in Sweden. *Stroke.* 32(9):2124-2130.

GMC – General Medical Council. (2001) *Good medical practice.* London: General Medical Council.

Goodpastor WA, Montoya ID. (1996) Motivating physician behaviour change: social influence versus financial contingencies. *Int J Health Care Qual Assur.* 9(6):4-9.

Greenberg JH. (1998) Glucose and oxygen metabolism in ischaemia. In: Ginsberg MD & Bogousslavsky J (ed.). *Cerebrovascular Disease. Pathophysiology, diagnosis, and management.* Malden: Blackwell Science, 227-248.

Grimshaw JM, Russell IT. (1993) Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet.* 342:1317-1322.

Gubitz G, Sandercock P, Counsell C. (2002) Antiplatelet therapy for acute ischaemic stroke (Cochrane systematic review). In: *The Cochrane Library, Issue 2, 2002.* Oxford: Update Software.

Hacke W. (2000) *Critical care of stroke (teaching course).* World Stroke Congress, Melbourne.

Hacke W, Kaste M, Fieschi C et al. (1995) Intravenous thrombolysis with recombinant tissue plasminogen activator for acute hemispheric stroke. The European Cooperative Acute Stroke Study (ECASS). *JAMA.* 274(13):1017-1025.

Hacke W, Kaste M, Fieschi C et al. (1998) Randomised double-blind placebo-controlled trial of thrombolytic therapy with intravenous alteplase in acute ischaemic stroke (ECASS II). Second European-Australasian Acute Stroke Study Investigators. *Lancet.* 352(9136):1245-1251.

Hacke W, Kaste M, Skyhoj OT et al. (2000) Acute treatment of ischemic stroke. European Stroke Initiative (EUSI). *Cerebrovasc Dis.* 10 Suppl 3:22-33.

Hacke W, Schwab S, De Georgia M. (1994) Intensive care of acute ischaemic stroke. *Cerebrovasc Dis.* 4:385-392.

Hajat C, Hajat S, Sharma P. (2000) Effects of poststroke pyrexia on stroke outcome: a meta-analysis of studies in patients. *Stroke.* 31(2):410-414.

Halligan A, Donaldson L. (2001) Implementing clinical governance: turning vision into reality. *The BMJ.* 322(7299):1413-1417.

Hancock RJT, Oddy M, Saweirs WM et al. (1997) The RCP stroke audit package in practice. *J R Coll Physicians Lond.* 31(1):74-78.

Hand P, Lindley RI, Wardlaw J et al. (2001) The third International Stroke Trial (IST-3). *Cerebrovasc Dis.* 11(Suppl 4):35.

Hankey GJ. (2001) New drugs, or new trials of current drugs, for the treatment of acute ischaemic stroke? *Lancet.* 258:684-685.

Hankey GJ, Sudlow CL, Dunbabin DW. (2002) Thienopyridine derivatives (ticlopidine, clopidogrel) versus aspirin for preventing stroke and other serious vascular events in high vascular risk patients (Cochrane review). In: *Cochrane Library, Issue 2, 2002.* Oxford: Update Software.

Harbour R, Miller J. (2001) A new system for grading recommendations in evidence based guidelines. *The BMJ.* 323(7308):334-336.

Harper G, Castleden CM, Potter JF. (1994) Factors affecting changes in blood pressure after acute stroke. *Stroke.* 25(9):1726-1729.

Harper GD, Haigh RA, Potter JF et al. (1992) Factors delaying hospital admission after stroke in Leicestershire. *Stroke.* 23(6):835-838.

Hatano S. (1976) Experience from a multicentre stroke register: a preliminary report. *Bull World Health Organ.* 54:541-553.

Hayes SH, Carroll SR. (1986) Early intervention care in the acute stroke patient. *Arch Phys Med Rehabil.* 67(5):319-321.

Hedenius P. (1941) The use of heparin in internal diseases. *Acta Med Scand.* 107:170-177.

Help the Aged. (2001) *The Older Population (Report).* London: Help the Aged.

Heros RC, Camarata PJ, Latchaw RE. (1997) Brain attack. Introduction. *Neurosurg Clin N Am.* 8(2):135-144.

Hill JD, Hampton JR, Mitchell JR. (1978) A randomised trial of home-versus-hospital management for patients with suspected myocardial infarction. *Lancet.* 1(8069):837-841.

Holloway RG, Benesch C, Rush SR. (2000) Stroke prevention: narrowing the evidence-practice gap. *Neurology.* 54(10):1899-1906.

Horn J, Limburg M. (2001) Calcium Antagonists for Ischemic Stroke : A Systematic Review. *Stroke.* 32(2):570-576.

Hund E, Grau A, Hacke W. (1995) Neurocritical care for acute ischemic stroke. *Neurol Clin.* 13(3):511-527.

Hurwitz B. (1999) Legal and political considerations of clinical practice guidelines. *The BMJ.* 318(7184):661-664.

Ilmavirta M, Frey H, Erila T et al. (1994) *Stroke outcome and outcome of brain infarction. A prospective randomised study comparing the outcome of patients with acute brain infarction treated in a stroke unit and in an ordinary neurological ward [academic dissertation]. Volume 410 (Series A). Tampere, Finland.* Tampere: University of Tampere Faculty of Medicine.

Indredavik B. (2000) Association between physiological homeostasis and early recovery after stroke. *Stroke.* 31:-2527.

Indredavik B, Bakke F, Slordahl SA et al. (1999a) Stroke unit treatment. 10-year follow-up. *Stroke.* 30(8):1524-1527.

Indredavik B, Bakke F, Slordahl SA et al. (1999b) Treatment in a combined acute and rehabilitation stroke unit: which aspects are most important? *Stroke.* 30(5):917-923.

Indredavik B, Bakke F, Solberg R et al. (1991) Benefit of a stroke unit: a randomized controlled trial. *Stroke.* 22(8):1026-1031.

Irwin P, Rudd A. (1998) Casemix and process indicators of outcome in stroke. The Royal College of Physicians minimum data set for stroke. *J R Coll Physicians Lond.* 32(5):442-444.

Irwin P, Rutledge Z, Rudd A. (2001) The feasibility of a national audit of stroke. *Br J Clin Governance.* 6(1):27-33.

Isaacs B. (1971) Stroke units. *The BMJ.* 4(785):492.

Isaacs B. (1977) Five years experience of stroke unit. *Health Bull (Edinburgh).* 35:93-98.

Isard PA, Forbes JF. (1992) The cost of stroke to the National Health Service in Scotland. *Cerebrovasc Dis.* 2:47-50.

ISIS-2 (Second International Study of Infarct Survival) Collaborative Group. (1988) Randomised trial of intravenous streptokinase, oral aspirin, both, or neither among 17,187 cases of suspected acute myocardial infarction: ISIS-2. *Lancet.* 2(8607):349-360.

IST (International Stroke Trial) Collaborative Group. (1997) The International Stroke Trial (IST): a randomised trial of aspirin, subcutaneous heparin, both, or neither among 19,435 patients with acute ischaemic stroke. *Lancet.* 349(9065):1569-1581.

Johansson BB. (2000) Brain plasticity and stroke rehabilitation: the Willis lecture. *Stroke.* 31(1):223-230.

Johnson ER, McKenzie SW, Sievers A. (1993) Aspiration pneumonia in stroke. *Arch Phys Med Rehabil.* 74(9):973-976.

Johnston KC, Li JY, Lyden PD et al. (1998) Medical and neurological complications of ischemic stroke: experience from the RANTTAS trial. *Stroke.* 29(2):447-453.

Jorgensen HS, Kammersgaard LP, Houth J et al. (2000) Who benefits from treatment and rehabilitation in a stroke Unit? A community-based study. *Stroke.* 31(2):434-439.

Jorgensen HS, Kammersgaard LP, Nakayama H et al. (1999) Treatment and rehabilitation on a stroke unit improves 5-year survival. A community-based study. *Stroke.* 30(5):930-933.

Jorgensen HS, Nakayama H, Raaschou HO et al. (1994) Effect of blood pressure and diabetes on stroke in progression. *Lancet.* 344(8916):156-159.

Jorgensen HS, Nakayama H, Reith J et al. (1996) Factors delaying hospital admission in acute stroke. The Copenhagen Stroke Study. *Neurology.* 47:383-387.

Jorgensen HS, Reith J, Nakayama H et al. (2001) Potentially reversible factors during the very acute phase of stroke and their impact on the prognosis: is there a large therapeutic potential to be explored? *Cerebrovasc Dis.* 11(3):207-211.

Kabat H. (1947) Studies on neuromuscular dysfunction. IX. New principles of neuromuscular reeducation. *Permanente Found Med Bull.* 5:3.

Kabat H, Knott M. (1954) Proprioceptive facilitation therapy for paralysis. *Physiotherapy.* 40:171-176.

Kagan A, Popper JS, Rhoads GG. (1980) Factors related to stroke incidence in Hawaii Japanese men. The Honolulu Heart Study. *Stroke.* 11(1):14-21.

Kagansky N, Levy S, Knobler H. (2001) The role of hyperglycaemia in acute stroke. *Neurological Review.* 58:1209-1212.

Kalra L, Dale P, Crome P. (1993) Improving stroke rehabilitation: a controlled study. *Stroke.* 24:1462-1467.

Kalra L, Evans A, Perez I et al. (2000) Alternative strategies for stroke care: a prospective randomised controlled trial. *Lancet.* 356(9233):894-899.

Kalra L, Yu G, Wilson K et al. (1995) Medical complications during stroke rehabilitation. *Stroke.* 26(6):990-994.

Kammersgaard LP, Rasmussen BH, Jorgensen HS et al. (2000) Feasibility and safety of inducing modest hypothermia in awake patients with acute stroke through surface cooling: a case-control study: the Copenhagen stroke study. *Stroke.* 31(9):2251-2256.

Kannel WB, McGee DL. (1979) Diabetes and cardiovascular disease. The Framingham study. *JAMA.* 241(19):2035-2038.

Kareem MZ. (2001) Guidelines for stroke center development. *Stroke.* 32:816.

Kassirer JP. (1993) The quality of care and th equality of measuring it. *N Engl J Med.* 329:1263-1265.

Kaste M, Skyhoj OT, Orgogozo J et al. (2000) Organization of stroke care: education, stroke units and rehabilitation. European Stroke Initiative (EUSI). *Cerebrovasc Dis.* 10 Suppl 3:1-11.

Kaufmann AM, Firlik AD, Fukui MB et al. (1999) Ischemic core and penumbra in human stroke. *Stroke.* 30(1):93-99.

Keaney M, Lorimer AR. (1999) Auditing the implementation of SIGN (Scottish Intercollegiate Guidelines Network) clinical guidelines. *Int J Health Care Qual Assur Inc Leadersh Health Serv.* 12(6-7):314-317.

Kennedy FB, Pozen TJ, Gabelman EH et al. (1970) Stroke intensive care - an appraisal. *Am Heart J.* 80(2):188-196.

Khaw KT. (1996) Epidemiology of stroke. *J Neurol Neurosurg Psychiatry.* 61:333-338.

Kidwell CS, Liebeskind DS, Starkman S et al. (2001) Trends in acute ischemic stroke trials through the 20th century. *Stroke.* 32(6):1349-1359.

Kiers L, Davis SM, Larkins R et al. (1992) Stroke topography and outcome in relation to hyperglycaemia and diabetes. *J Neurol Neurosurg Psychiatry.* 55(4):263-270.

King's Fund. (1988) King's Fund Consensus Conference. Treatment of stroke. *The BMJ.* 297(6641):126-128.

Kinsara AJ. (2001) 2000 Guidelines for Cardiopulmonary Resuscitation Emergency Cardiovascular Care. *Circulation.* 104(9):E45.

Kirkevold M. (1997b) The role of nursing in the rehabilitation of acute stroke patients: toward a unified theoretical perspective. *Advances in Nurs Sci.* 19(4):55-64.

Kirkevold M. (1997a) The role of nursing in the rehabilitation of acute stroke patients: toward a unified theoretical perspective. *ANS Adv Nurs Sci.* 19(4):55-64.

Koroshetz W. (1996) *Acute stroke management: hospital stroke expertise. Proceedings of a national symposium on rapid identification and treatment of acute stroke.* National Institute of Neurological Disorders and Stroke.

Kothari R, Barsan W, Brott T et al. (1995a) Frequency and accuracy of prehospital diagnosis of acute stroke. *Stroke.* 26(6):937-941.

Kothari RU, Brott T, Broderick JP et al. (1995b) Emergency physicians. Accuracy in the diagnosis of stroke. *Stroke.* 26(12):2238-2241.

Kotila M, Numminen H, Waltimo O et al. (1998) Depression after stroke: results of the FINNSTROKE study. *Stroke.* 29(2):368-372.

Kotila M, Waltimo O. (1992) Epilepsy after stroke. *Epilepsia.* 33(3):495-498.

Kowenhouven WB, Jude JR, Knickerbocker GG. (1960) Closed chest cardiac massage. *JAMA.* 173:1064-1067.

Krieger D, Hacke W. (1997) Intensive care treatment of ischaemic stroke. In: *In: Acute stroke treatment.* London: Martin Dunitz Ltd, 79-108.

Krieger DW, De Georgia MA, Abou-Chebl A et al. (2001) Cooling for acute ischemic brain damage (COOL AID): an open pilot study of induced hypothermia in acute ischemic stroke. *Stroke.* 32(8):1847-1854.

Kwakkel G, Wagenaar RC, Koelman TW et al. (1997) Effects of intensity of rehabilitation after stroke. A research synthesis. *Stroke.* 28(8):1550-1556.

Kwakkel G, Wagenaar RC, Twisk JW et al. (1999) Intensity of leg and arm training after primary middle-cerebral-artery stroke: a randomised trial. *Lancet.* 354(9174):191-196.

Langhorne P. (1999) Measures to improve recovery in the acute phase of stroke. *Cerebrovasc Dis.* 9 Suppl 5:2-5.

Langhorne P, Dennis M. (1998) *Stroke units: an evidence based approach.* London: BMJ Books.

Langhorne P, Fraser P, Wright F et al. (2001) Evaluation of an acute care protocol for stroke patients: a controlled clinical trial [abstract]. *Cerebrovasc Dis.* 11(Suppl 4):35.

Langhorne P, Li BPT, Stott DJ. (2000b) Association between physiological homeostasis and early recovery after stroke. *Stroke.* 31:2526-2527.

Langhorne P, Stott DJ, Robertson L et al. (2000a) Medical complications after stroke: a multicenter study. *Stroke.* 31(6):1223-1229.

Langhorne P, Williams BO, Gilchrist W et al. (1993) Do stroke units save lives? *Lancet.* 342(8868):395-398.

Langley C, Faulkner A, Watkins C et al. (1998) Use of guidelines in primary care - practitioners' perspectives. *Fam Pract.* 15(2):105-111.

Langton-Hewer R. (1990) Rehabilitation after stroke. *Q J Med.* 76:659-674.

Larner S. (1997) Quality rehabilitation - oasis or mirage? *Int J Health Care Qual Assur Inc Leadersh Health Serv.* 10(4-5):192-196.

Lassen NA. (1990) Pathophysiology of brain ischemia as it relates to the therapy of acute ischemic stroke. *Clin Neuropharmacol.* 13:Suppl-8.

Lee TH, Goldman L. (1988) The coronary care unit turns 25: historical trends and future directions. *Ann Intern Med.* 108(6):887-894.

Leys D. (1999) Seven reasons for hospitalizing stroke patients in special treatment units. *Presse Med.* 28(4):181-183.

Libman RB, Wirkowski E, Alvir J et al. (1995) Conditions that mimic stroke in the emergency department. Implications for acute stroke trials. *Arch Neurol.* 52(11):1119-1122.

Lin B, Kelly E. (1995) Methodological issues in patient satisfaction surveys. *Int J Health Care Qual Assur.* 8(6):32-37.

Lincoln NB, Husbands S, Trescoli C et al. (2000) Five year follow up of a randomised controlled trial of a stroke rehabilitation unit. *The BMJ.* 320(7234):549.

Lindley RI, Amayo EO, Marshall J et al. (1995) Hospital services for patients with acute stroke in the United Kingdom: the Stroke Association Survey of consultant opinion. *Age Ageing.* 24(6):525-532.

Long AF. (1994) Guidelines, protocols and outcomes. *Int J Health Care Qual Assur.* 7(5):4-7.

Lott C, Hennes HJ, Dick W. (1999) Stroke - a medical emergency. *J Accid Emerg Med.* 16(1):2-7.

Lown B, Amarasingham R, Neuman J. (1986) New method for terminating cardiac arrhythmias. Use of synchronized capacitor discharge. *JAMA.* 256(5):621-627.

Lown B, Fakhro AM, Hood WB, Jr. et al. (1967) The coronary care unit. New perspectives and directions. *JAMA.* 199(3):188-198.

MacKenzie JM. (2000) Are all cardio-embolic strokes embolic? An autopsy study of 100 consecutive acute ischaemic strokes. *Cerebrovasc Dis.* 10:289-292.

MacMillan RL, Brown KW. (1971) Comparison of the effects of treatment of acute myocardial infarction in a coronary unit and on a general medical ward. *Can Med Assoc J.* 105(10):1037-1040.

Malmberg K. (1997) Prospective randomised study of intensive insulin treatment on long term survival after acute myocardial infarction in patients with diabetes mellitus. DIGAMI (Diabetes Mellitus, Insulin Glucose Infusion in Acute Myocardial Infarction) Study Group. *The BMJ.* 314(7093):1512-1515.

Malmberg K, Ryden L, Efendic S et al. (1995) Randomized trial of insulin-glucose infusion followed by subcutaneous insulin treatment in diabetic patients with acute myocardial infarction (DIGAMI study): effects on mortality at 1 year. *J Am Coll Cardiol.* 26(1):57-65.

Mant J, Hicks N. (1995) Detecting differences in quality of care: the sensitivity of measures of process and outcome in treating acute myocardial infarction. *The BMJ.* 311(7008):793-796.

Marchal G, Beaudouin V, Rioux P et al. (1996) Prolonged persistence of substantial volumes of potentially viable brain tissue after stroke: a correlative PET-CT study with voxel-based data analysis. *Stroke.* 27(4):599-606.

Martin PJ, Young G, Enevoldson TP et al. (1997) Overdiagnosis of TIA and minor stroke: experience at a regional neurovascular clinic. *Q J Med.* 90(12):759-763.

Mas JL, Zuber M. (1993) Epidemiology of stroke. *J Neuroradiol.* 20:85-101.

Mather HG, Morgan DC, Pearson NG et al. (1976) Myocardial infarction: a comparison between home and hospital care for patients. *The BMJ.* 1(6015):925-929.

Maxwell RJ. (1984) Quality assessment in health. *The BMJ.* 288:1470-1472.

Mickel H, Vaishnav Y, Kempski O et al. (1987) Breathing 100% oxygen after global brain ischemia in Mongolian Gerbils results in increased lipid peroxidation and increased mortality. *Stroke.* 18(2):426-430.

Millard A. (1997) Evidence-based clinical guidelines - implementation plans in Scotland. *Int J Health Care Qual Assur Inc Leadersh Health Serv.* 10(6-7):236-240.

Millikan CH. (1979) Stroke intensive care units. Objectives and results. *Stroke.* 10(3):235-237.

Miyai I, Reding MJ. (1998) Stroke recovery and rehabilitation. In: Ginsberg MD & Bogousslavsky J (ed.). *Cerebrovascular Disease. Pathophysiology, diagnosis, and management.* Malden: Blackwell Science, 2043-2056.

Moonis M, Fisher M. (2001) Imaging of acute stroke. *Cerebrovasc Dis.* 11(3):143-150.

Morikawa Y, Nakagawa H, Naruse Y et al. (2000) Trends in Stroke Incidence and Acute Case Fatality in a Japanese Rural Area : The Oyabe Study. *Stroke.* 31(7):1583-1587.

Moriwaki H, Nagatsuka K, Miyashita K et al. (2000) Antipyretic therapy prevents the development of cerebral edema in acute ischaemic stroke: a pilot study using serial CT examinations. *Stroke.* 31(1):-313.

Morris AD, Grosset DG, Squire IB et al. (1993) The experiences of an acute stroke unit - implications for multicentre acute stroke trials. *J Neurol Neurosurg Psychiatry.* 56(4):352-355.

Moulin T, Tatu L, Vuillier F et al. (2000) Role of a stroke data bank in evaluating cerebral infarction subtypes: patterns and outcome of 1,776 consecutive patients from the Besançon stroke registry. *Cerebrovasc Dis.* 10(4):261-271.

Mulrow C. (1995) Rationale for systematic reviews. In: Chalmers I & Altman DG (ed.). *Systematic reviews.* Plymouth: BMJ Publishing Group, 1-8.

Murai H, Nakamura M, McIntosh TK. (1998) Ischaemia complicating traumatic brain injury. In: Ginsberg MD & Bogousslavsky J (ed.). *Cerebrovascular Disease. Pathophysiology, diagnosis, and management.* Malden: Blackwell Science, 176-189.

Murray CJ, Lopez AD. (1997a) Mortality by cause for eight regions of the world: Global Burden of Disease Study. *Lancet.* 349(9061):1269-1276.

Murray CJ, Lopez AD. (1997b) Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. *Lancet.* 349(9064):1498-1504.

Murray CJ, Lopez AD. (1997c) Global mortality, disability, and the contribution of risk factors: Global Burden of Disease Study. *Lancet.* 349(9063):1436-1442.

Nager F, Rosli R, Albert H et al. (1969) Treatment of acute myocardial infarct in a coronary intensive care unit. Experiences with 260 patients. *Schweiz Med Wochenschr.* 99(10):309-317.

NHS. (1979) *Report of the Royal Commission on the National Health Service.* London: HMSO.

NINDS (The National Institute of Neurological Disorders and Stroke) rt-PA Stroke Study Group. (1995) Tissue plasminogen activator for acute ischemic stroke. *N Engl J Med.* 333(24):1581-1587.

Norris J, Hachinski V. (1976) Intensive care management of stroke patients. *Stroke.* 7(6):573-577.

Norris JW, Hachinski VC. (1982) Misdiagnosis of stroke. *Lancet.* 1(8267):328-331.

NSA – National Stroke Association. (1993) Stroke: the first six hours. Emergency evaluation and treatment. National Stroke Association consensus statement. *J Stroke Cerebrovasc Dis.* 3:133-143.

O'Mahony PG, Thomson RG, Dobson R et al. (1999) The prevalence of stroke and associated disability. *J Public Health Med.* 21(2):166-171.

Orchard C. (1994) Comparing healthcare outcomes. *The BMJ.* 308(6942):1493-1496.

Østfeld AM, Wilk E. (1990) Epidemiology of stroke, 1980-1990: a progress report. *Epidemiologic Reviews.* 12:253-256.

Ottenbacher KJ, Jannell S. (1993) The results of clinical trials in stroke rehabilitation research. *Arch Neurol.* 50(1):37-44.

Øvretveit J. (2000) Total quality management in European healthcare. *Int J Health Care Qual Assur Inc Leadersh Health Serv.* 13(2):74-79.

Paczynski RP, Diringer MN, Hsu CY. (1995) Experimental therapies to improve delivery of oxygen and substrate in acute stroke. *Curr Opin Neurol.* 8(1):6-14.

Pancioli AM, Broderick J, Kothari R et al. (1998) Public perception of stroke warning signs and knowledge of potential risk factors. *JAMA.* 279(16):1288-1292.

Parsley K, Corrigan P. (1999) *Quality improvement in healthcare: putting evidence into practice.* Cheltenham: Stanley Thornes Ltd.

Pepe PE. (1996) *The initial links in the chain of recovery for brain attack: access, prehospital care, notification, and transport. Proceedings of a national symposium on rapid identification and treatment of acute stroke.* National Institute of Neurological Diseases and Stroke.

Petty GW, Brown RD, Jr., Whisnant JP et al. (1999) Ischaemic stroke subtypes. A population-based study of incidence and risk factors. *Stroke.* 30(12):2513-2516.

Philip I. (2000) Measuring quality of care. *Age Ageing.* 29:95-96.

Pitner SE, Mance CJ. (1973) An evaluation of stroke intensive care: results in a municipal hospital. *Stroke.* 4(5):737-741.

Plsek PE, Wilson T. (2001) Complexity, leadership, and management in healthcare organisations. *The BMJ.* 323(7315):746-749.

Pomeroy VM, Tallis RC. (2000) Need to focus research on stroke rehabilitation. *Lancet.* 355:836-837.

Pound P, Bury M, Gompertz P et al. (1995) Stroke patients' views on their admission to hospital. *The BMJ.* 311(6996):18-22.

Pound P, Ebrahim S. (1997) Redefining 'doing something': health professionals' views on their role in the care of stroke patients. *Physiother Res Int.* 2(2):12-28.

Pound P, Gompertz P, Ebrahim S. (1994) Patients' satisfaction with stroke services. *Clin Rehab.* 8:7-17.

Pound P, Sabin C, Ebrahim S. (1999a) Observing the process of care: a stroke unit, elderly care unit and general medical ward compared. *Age Ageing.* 28(5):433-440.

Pound P, Tilling K, Rudd AG et al. (1999b) Does patient satisfaction reflect differences in care received after stroke? *Stroke.* 30(1):49-55.

PROGRESS Collaborative Group. (2001) Randomised trial of a perindopril-based blood-pressure-lowering regimen among 6105 individuals with previous stroke or transient ischaemic attack. *Lancet.* 358:1033-1041.

RCGP. (1994) Samuel, O., Gant, J., and Irvine, D. (ed.). *Quality and audit in general practice: meanings and definitions.* London: Royal College of General Practitioners.

RCN. (2000) *Guideline for assessment and prevention of pressure ulcers. ttp://www.rcn.org.uk/ services/promote/clinical/clinical_guidelines.htm#8.* London: Royal College of Nursing.

RCP. (2001a) Consensus conference on stroke treatment and service delivery. *Proceedings of the Royal College of Physicians of Edinburgh.* 31(Supplement 8).

RCP. (2001b) *National Clinical Guidelines for Stroke.* Royal College of Physicians.

Reith J, Jorgensen HS, Pedersen PM et al. (1996) Body temperature in acute stroke: relation to stroke severity, infarct size, mortality, and outcome. *Lancet.* 347(8999):422-425.

Rem J, Hachinski V, Boughner D et al. (1985) Value of cardiac monitoring and echocardiography in TIA and stroke patients. *Stroke.* 16(6):950-956.

Roberts MA. (2001) *Scottish Stroke Service Audit. Report of an audit on the organisation of services for stroke patients, 1997-1998.*

Roberts MA, Allen A, Langhorne P et al. (2000) Organisation of services for acute stroke in Scotland - report of the Scottish stroke services audit. *Health Bull (Edinburgh).* 58(2):87-95.

Robie PW. (1988) Improving and sustaining outpatient cancer screening by medicine residents. *South Med J.* 81(7):902-905.

Roffe C, Sills S, Wilde K et al. (2001) Effect of hemiparetic stroke on pulse oximetry readings on the affected side. *Stroke.* 32(8):1808-1810.

Ronning OM, Guldvog B. (1998a) Stroke unit versus general medical wards, II: neurological deficits and activities of daily living: a quasi-randomized controlled trial. *Stroke.* 29(3):586-590.

Ronning OM, Guldvog B. (1998b) Stroke units versus general medical wards, I: twelve- and eighteen-month survival: a randomized, controlled trial. *Stroke.* 29(1):58-62.

Ronning OM, Guldvog B. (1999) Should stroke victims routinely receive supplemental oxygen? A quasi-randomized controlled trial. *Stroke.* 30(10):2033-2037.

Rood MS. (1954) Neurophysiological reactions as a basis for physical therapy. *Phys Ther Rev.* 34:444-449.

Roth EJ, Lovell L, Harvey RL et al. (2001) Incidence of and risk factors for medical complications during stroke rehabilitation. *Stroke.* 32(2):523-529.

Rowat AM, Wardlaw JM, Dennis MS et al. (2000) Does feeding alter arterial oxygen saturation in patients with acute stroke? *Stroke.* 31(9):2134-2140.

Rudd A, Lowe D, Irwin P et al. (2001) National stroke audit: a tool for change? *Quality in Health Care.* 10:141-151.

Rudd AG, Irwin P, Rutledge Z et al. (1999) The national sentinel audit for stroke: a tool for raising standards of care. *J R Coll Physicians Lond.* 33(5):460-464.

Rycroft-Malone J. (2001) Formal consensus: the development of a national clinical guideline. *Qual Health Care.* 10(4):238-244.

Sackett DL, Rosenberg WM. (1995) The need for evidence-based medicine. *J R Soc Med.* 88(11):620-624.

Samsa GP, Bian J, Lipscomb J et al. (1999) Epidemiology of recurrent cerebral infarction: a medicare claims-based comparison of first and recurrent strokes on 2-year survival and cost. *Stroke.* 30(2):338-349.

Sandercock P, Willems H. (1992) Medical treatment of acute ischaemic stroke. *Lancet.* 339(8792):537-539.

Sandercock PA, Warlow CP, Jones LN et al. (1989) Predisposing factors for cerebral infarction: the Oxfordshire community stroke project. *The BMJ.* 298(6666):75-80.

Sarti C, Rastenyte D, Cepaitis Z et al. (2000) International Trends in Mortality From Stroke, 1968 to 1994. *Stroke.* 31(7):1588-1601.

Sayre MR, Swor R A, Honeycutt L K. (1996) *Prehospital identification and treatment. Proceedings of a national symposium on rapid identification and treatment of acute stroke.* National Institute of Neurological Diseases and Stroke.

Scally G, Donaldson LJ. (1998) The NHS's 50 anniversary. Clinical governance and the drive for quality improvement in the new NHS in England. *The BMJ.* 317(7150):61-65.

Schiller F. (1970) Concepts of stroke before and after Virchow. *Med Hist.* 14(2):115-131.

Schmid-Elsaesser R, Hungerhuber E, Zausinger S et al. (1999) Combination drug therapy and mild hypothermia: a promising treatment strategy for reversible, focal cerebral ischemia. *Stroke.* 30(9):1891-1899.

Schreiner DT, Petrusa ER, Rettie CS et al. (1988) Improving compliance with preventive medicine procedures in a house staff training program. *South Med J.* 81(12):1553-1557.

Schwarz S, Hafner K, Aschoff A et al. (2000) Incidence and prognostic significance of fever following intracerebral hemorrhage. *Neurology.* 54(2):354-361.

Scott JF, Gray CS. (2000) Cerebral and systemic pathophysiological responses to acute stroke [In Process Citation]. *Age Ageing.* 29(3):197-202.

Scott JF, Robinson GM, French JM et al. (1999) Glucose potassium insulin infusions in the treatment of acute stroke patients with mild to moderate hyperglycemia: the Glucose Insulin in Stroke Trial (GIST). *Stroke.* 30(4):793-799.

Scott JF, Robinson GM, French JM et al. (2001) Blood pressure response to glucose potassium insulin therapy in patients with acute stroke with mild to moderate hyperglycaemia. *J Neurol Neurosurg Psychiatry.* 70(3):401-404.

Selman WR, Tarr R, Landis DM. (1997) Brain attack: emergency treatment of ischemic stroke. *Am Fam Physician.* 55(8):2655-2656.

Shah S, Vanclay F, Cooper B. (1990) Efficiency, effectiveness, and duration of stroke rehabilitation. *Stroke.* 21(2):241-246.

Shekelle PG. (2002) Why don't physicians enthusiastically support quality improvement programmes? *Qual Saf Health Care.* 11:6.

SIGN. (1997a) *Management of patients with stroke: I. Assessment, investigation, immediate management and secondary prevention.* Edinburgh: Scottish Intercollegiate Guidelines Network.

SIGN. (1997b) *Management of patients with stroke: II. Management of carotid stenosis and carotid endarterectomy.* Edinburgh: Scottish Intercollegiate Guidelines Network.

SIGN. (1998) *Management of patients with stroke: IV. Rehabilitation, prevention and management of complications, and discharge planning.* Edinburgh: Scottish Intercollegiate Guidelines Network.

Signorini DF, Alderson P. (2002).Therapeutic hypothermia for head injury (Cochrane systematic review). In: *The Cochrane Library, Issue 2, 2002.* Oxford: Update Software.

Silva Y, Serena J, Castellanos M et al. (2001) Stroke units: the effects of continuous monitoring on clinical outcome. *Cerebrovasc Dis.* 11(Suppl 4):112.

Silver B, Demaerschalk B, Merino JG et al. (2001) Improved outcomes in stroke thrombolysis with pre-specified imaging criteria. *Can J Neurol Sci.* 28(2):113-119.

Sinha S, Warburton EA. (2000) The evolution of stroke units - towards a more intensive approach. *Q J Med.* 93:633-638.

Skolnick BE. (1999) Guidelines for acute stroke treatment centers. *Phys Med Rehabil Clin N Am.* 10(4):801-813.

Smith MA, Shahar E, Doliszny KM et al. (1998) Trends in medical care of hospitalized stroke patients between 1980 and 1990: the Minnesota stroke survey. *J Stroke Cerebrovasc Dis.* 7(1):76-84.

Smithard DG, O'Neill PA, Parks C et al. (1996) Complications and outcome after acute stroke. Does dysphagia matter? *Stroke.* 27(7):1200-1204.

STAIR II (Stroke Therapy Academic Industy Roundtable II). (2001) Recommendations for Clinical Trial Evaluation of Acute Stroke Therapies. *Stroke.* 32(7):1598-1606.

Stegmayr B, Asplund K, Hulter-Asberg K et al. (1999) Stroke units in their natural habitat: can results of randomized trials be reproduced in routine clinical practice? Riks-Stroke Collaboration. *Stroke.* 30(4):709-714.

Stevens RS, Ambler NR, Warren MD. (1984) A randomized controlled trial of a stroke rehabilitation ward. *Age Ageing.* 13(2):65-75.

Stone S. (1999) Stroke units: more trials needed. *Age Ageing.* 28(2):95-97.

Stroke Unit Trialists' Collaboration. (1997) How do stroke units improve patient outcomes? A collaborative systematic review of the randomized trials. *Stroke.* 28(11):2139-2144.

Stroke Unit Trialists' Collaboration. (2002) Organised inpatient (stroke unit) care for stroke (Cochrane Review). In: *The Cochrane Library, Issue 1, 2002.* Oxford: Update Software.

Sudlow CL, Warlow C. (1997) Comparable studies of the incidence of stroke and its pathological types. Results from an international collaboration. *Stroke.* 28(3):491-499.

Sulch D, Perez I, Melbourn A et al. (2000) Randomized controlled trial of integrated (managed) care pathway for stroke rehabilitation. *Stroke.* 31(8):1929-1934.

Sulter G, Elting JW, Stewart R et al. (2000) Continuous pulse oximetry in acute hemiparetic stroke. *J.Neurol Sci.* 179(S 1-2):65-69.

Tanne D, Gorman MJ, Bates VE et al. (2000) Intravenous tissue plasminogen activator for acute ischemic stroke in patients aged 80 years and older: the tPA stroke survey experience. *Stroke.* 31(2):370-375.

The Members of the Lille Stroke Program. (1997) Misdiagnoses in 1,250 consecutive patients admitted to an acute stroke unit. *Cerebrovasc Dis.* 7:284-288.

The Office for National Statistics. (2001) *Social trends*. London: The Stationery Office.

Thomson R, Lavender M, Madhok R. (1995) How to ensure that guidelines are effective. *The BMJ.* 311(6999):237-242.

Thorvaldsen P, Asplund K, Kuulasmaa K et al. (1995) Stroke incidence, case fatality, and mortality in the WHO MONICA project. *Stroke.* 26(3):361-367.

Thorvaldsen P, Davidsen M, Bronnum-Hansen H et al. (1999) Stable stroke occurrence despite incidence reduction in an ageing population. Stroke trends in the Danish Monitoring Trends and Determinants in Cardiovascular Disease (MONICA) population. *Stroke.* 30(12):2529-2534.

Tirschwell DL, Kukull WA, Longstreth WT. (1999) Medical complications of ischaemic stroke and length of hospital stay: experience in Seattle, Washington. *J Stroke Cerebrovasc Dis.* 8(5).

Tissot CL. (1780) *Gymnastique Medicinale et Chirurgicale.* Paris:

Toni D, Fiorelli M, Gentile M et al. (1995) Progressing neurological deficit secondary to acute ischemic stroke. A study on predictability, pathogenesis, and prognosis. *Arch Neurol.* 52(7):670-675.

Tosteson AN, Goldman L, Udvarhelyi IS et al. (1996) Cost-effectiveness of a coronary care unit versus an intermediate care unit for emergency department patients with chest pain. *Circulation.* 94(2):143-150.

Treib J, Grauer MT, Woessner R et al. (2000) Treatment of stroke on an intensive stroke unit: a novel concept. *Intensive Care Med.* 26(11):1598-1611.

US DoH & Human Services. (1993) *Agency for Health Care Policy and Research. Acute pain management: operative or medical procedures and trauma. (Clinical practice guideline No 1. AHCPR publication 92-0023).* Rockville: AHCPR.

Velioglu SK, Ozmenoglu M, Boz C et al. (2001) Status epilepticus after stroke. *Stroke.* 32(5):1169-1172.

Wade D. (1999) Rehabilitation therapy after stroke. *Lancet.* 354(9174):176-177.

Wade DT. (1994) Stroke. In: Stevens A & Raftery J (ed.). *Health care needs assessment.* Oxford: Radcliff Press.

Wade DT, de Jong BA. (2000) Recent advances in rehabilitation. *The BMJ.* 320(7246):1385-1388.

Wang XD, Guo H, Zhang XY et al. (1997) An observation on the time of hospital arrival and correct diagnosis with CT in acute cerebral stroke patients. *Cerebrovasc Dis.* 7:89-93.

Wang Y, Lim LL, Levi C et al. (2000) Influence of admission body temperature on stroke mortality. *Stroke.* 31(2):404-409.

Wang Y, Lim LLY, Levi C et al. (2001) Influence of hyperglycaemia on stroke mortality. *J Stroke Cerebrovasc Dis.* 10(1):11-18.

Wardlaw JM. (2001) Radiology of stroke. *J Neurol Neurosurg Psychiatry.* 70(Suppl 1):-i7.

Wardlaw JM, del Zoppo G, maguchi T. (2002) Thrombolysis for acute ischaemic stroke (Cochrane systematic review). In: *The Cochrane Library, Issue 2, 2002.* Oxford: Update Software.

Warlow C. (1998) Epidemiology of stroke. *Lancet.* 352 (Suppl 3):1-4.

Warlow C, Dennis M, van Gijn J et al. (2000) *Stroke. A practical guide to management.* Malden: Blackwell Science.

Warner R. (2000) The effectiveness of nursing in stroke units. *Nurs Stand.* 14(25):32-35.

Waylonis GW, Keith MW, Aseff JN. (1973) Stroke rehabilitation in a midwestern county. *Arch Phys Med Rehabil.* 54:151-155.

Weir CJ, Murray GD, Dyker AG et al. (1997) Is hyperglycaemia an independent predictor of poor outcome after acute stroke? Results of a long-term follow up study. *The BMJ.* 314(7090):1303-1306.

Weir N, Dennis MS. (2001) Towards a national system for monitoring the quality of hospital-based stroke services. *Stroke.* 32(6):1415-1421.

Weir NU, Dennis MS. (1997) Meeting the challenge of stroke. *Scott Med J.* 42:145-147.

Weir NU, Sandercock PAG, Lewis SC et al. (2001) Variations between countries in outcome after stroke in the International Stroke Trial (IST). *Stroke.* 32(6):1370-1377.

Weltermann BM, Rogalewski A, Homann J et al. (2000) Knowledge about stroke among the German population. *Dtsch Med Wochenschr.* 125(14):416-420.

WHO. (1978) *Cerebrovascular disorders: a clinical and research classification.* Geneva: World Health Organisation. Offset Publication No 43.

WHO. (1980) *International classification of impairments, disabilities and handicaps: conference papers.* Geneva, Switzerland: World Health Organisation.

WHO. (1983) *The principles of quality assurance. A report of a WHO meeting.* Copenhagen, Denmark: World Health Organisation.

WHO. (1994) *World Health Statistics Annuals 1982-1994.* Geneva: World Health Organisation.

WHO. (1999) *World Health Report 1999 - Making a Difference.* Geneva, Switzerland: World Health Organisation.

Widder B. (2001) Acute therapy of stroke. With these basic measures prognosis can be improved. *MMW Fortschr Med.* 143(11):28-32.

Williams RG, Jiang JG, Matchar DB et al. (1999) Incidence and occurrence of total (first-ever and recurrent) stroke. *Stroke.* 30(12):2523-2528.

Wojner AW. (1996) Optimizing ischemic stroke outcomes: an interdisciplinary approach to poststroke rehabilitation in acute care. *Crit Care Nurs Q.* 19(2):47-61.

Wolfe C, Rudd A, Dennis M et al. (2001) Taking acute stroke care seriously. In the absence of evidence we should manage acute stroke as a medical emergency. *The BMJ.* 323(7303):5-6.

Wolfe CD. (2000) The impact of stroke. *Br Med Bull.* 56(2):275-286.

Wolfe CD, Giroud M, Kolominsky-Rabas P et al. (2000) Variations in stroke incidence and survival in 3 areas of Europe. *Stroke.* 31(9):2074-2079.

Wolfe CD, Rudd AG, Howard R et al. (2002) Incidence and case fatality rates of stroke subtypes in a multiethnic population: the South London Stroke Register. *J Neurol Neurosurg Psychiatry.* 72(2):211-216.

Wolfe CD, Tilling K, Beech R et al. (1999) Variations in case fatality and dependency from stroke in western and central Europe. The European BIOMED Study of Stroke Care Group. *Stroke.* 30(2):350-356.

Wood-Dauphinee S. (1984) Team care following stroke; what does it accomplish? *Physiother Can.* 36(1):17-22.

Wood-Dauphinee S, Shapiro S, Bass E et al. (1984) A randomized trial of team care following stroke. *Stroke.* 15(5):864-872.

Woolf SH, Grol R, Hutchinson A et al. (1999) Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines. *The BMJ.* 318(7182):527-530.

Zachariah BS, Dunford J, Van Cott C C. (1996) *Dispatch life support and the acute stroke patient: making the right call. Proceedings of a national symposium on rapid identification and treatment of acute stroke* National Institute of Neurological Diseases and Stroke.

CHAPTER TWO

INTEGRATED CARE PATHWAYS: THEIR NATURE, ORIGIN AND METHODS OF EVALUATION

2.1 Introduction

Integrated care pathways (ICPs) are increasingly being implemented across many countries with an aim to improve patient care (NHS Wales 1999). Unlike other forms of treatments (especially pharmacological agents), this relatively new organisational tool is being developed and implemented in many UK hospitals with very little debate about what it is and what its effects are (Norris 1998; de Luc 2000). This relaxed approach might be because ICPs are generally regarded as harmless and, in the current political climate of the NHS, policy makers may adopt an 'anything to improve patient care is worth a try' attitude.

In my opinion, ICPs should be regarded as an organisational intervention that requires a proper definition and evaluation. Thus, before introducing an ICP, physicians and policy makers should first determine: a) what an ICP is; b) how an ICP operates in the local setting; c) what are the effects of its introduction on the process of care and patient outcome; and d) whether it is acceptable and feasible to the staff using it.

2.2 What is an integrated care pathway?

Common definitions of an integrated care pathway

'Integrated care pathway' is a fluid term. The medical literature is abundant with articles that praise the tool and describe the many identified benefits of its implementation (de Luc 2000). Hale argued that the multitude of benefits ascribed to ICPs is partly due to a lack of conceptual clarity surrounding the term, what it is, and what it does (Hale 2002).

There are many common definitions for ICPs – the majority of them are vague and they all differ slightly. As a result, there is no universally accepted or standard definition for an ICP (Field & Lohr 1992; Campbell et al 1998; Overill 1998). The Department of Health in the UK defined an ICP as "*a systematically developed statement which assists the practitioner and patient in making decisions about appropriate healthcare for specific clinical conditions*" (DoH 1996). Compton defined an ICP as "*an abbreviated version of the multidisciplinary processes which need to occur in a timely and sequential manner to achieve quality outcomes*" (Compton et al 1995). In the USA, Hofmann described an ICP as a tool that "*co-ordinates the delivery of patient care for a particular condition. It is a guide to usual treatment patterns, providing a visualisation of the big picture*" (Hofmann 1993).

Others such as Overill have tried to define an ICP by describing its aims and functions: "*an ICP determines locally agreed, multidisciplinary practice based on guidelines and evidence ... it forms all or part of the clinical record, documents the*

care given and facilitates the evaluation of outcomes for continuous quality improvement" (Overill 1998). Nelson, on the other hand, was more precise in stating that an ICP "*specifies key events, tests and assessments occurring in a timely fashion to produce the best prescribed outcomes, within the resources and activities available...*" (Nelson 1995). This type of definition, which is more explicit, is more likely to be useful in everyday practice.

Other terms used to mean an integrated care pathway

ICPs are known by many other names, such as clinical pathways, critical pathways, patient pathways, care path method, anticipatory recovery pathways, multidisciplinary pathways of care, and CareMaps™ (Hunter & Fairfield 1997; de Luc 2000). In fact, there are probably over 20 terms used to denote an integrated care pathway (Bridge 1997). Although many of these names are often used interchangeably, they may in fact be describing different concepts in different settings. In the UK, it is common to use the term 'integrated care pathway' since it emphasises the integration between different disciplines in caring for patients (Norris 1998).

Operation of an integrated care pathway

ICPs are designed to be used as a structured clinical record by every member of the multidisciplinary team, so that it may be easier to find information and communicate with the other members (Quigley et al 1998). The format of ICPs varies widely; some ICPs are printed versions of clinical guidelines that are available for reference on the ward, some are protocols or algorithms that outline the care that the patient

should receive, while others are computer programs that guide the healthcare professional through each step of the patient's management (Yandell 1995). In the UK, ICPs are most commonly pre-printed care plans that contain detailed checklists of recommended treatments for the different aspects of patient care from day to day (Campbell et al 1998). The recommendations are usually based on the best available evidence or clinical guidelines (Bridge et al 1997). The size of the ICP depends on the complexity of the condition and the level of detail of the included information (see **Table 2.1**); an ICP can therefore be a very small (e.g. a one-page checklist) or a very large document (e.g. more than 50 pages long). In certain specialities such as day surgery, where there is relatively little variation in the timing of patient outcome (e.g. being pain-free, length of stay), the ICP can also indicate the time by which certain outcomes are to be expected. I have summarised the four major aims of using ICPs in **Table 2.2**.

Some ICPs have an in-built system to assess clinical outcomes and monitor practice variation. The latter process is known as variance reporting or tracking (Schriefer 1995; Brown & Nemeth 1998). This system aims to gather information on the occasions when the recommended care strategy has not been carried out (i.e. a variance). This enables the evaluation of any divergence from the anticipated plan of care or outcome, and informs on the possible ways of improving the process. However, it is extremely time-consuming and is often poorly documented, especially in complex medical conditions such as stroke (Anon. 1995).

Overall, ICPs seem to be different from other forms of information provision systems that aim to assist healthcare professionals with clinical decision-making, such as guidelines, standards and policies (see **Table 2.3**). Furthermore, ICPs are usually multi-faceted, which means that they are different from mono-faceted tools (e.g. diagnostic algorithms, protocol for thrombolysis). Thus, ICPs are usually applicable to more than one aspect of care, for example, emergency assessment plus diagnosis, or diagnosis plus acute treatment, etc.

What are the potential benefits of using an integrated care pathway?

There are many potential benefits of using an ICP (Pearson et al 1995; Campbell et al 1998). However, whether these potential benefits become reality would depend on the way that it is designed and implemented in the local setting (de Luc 2000). Like clinical guidelines, the potential benefits of using ICPs can be divided into three main categories (Thomson et al 1995): benefits to the patient; benefits to the healthcare professional; and benefits to the healthcare system.

Benefits to the patient

A potential benefit to the patient is that the ICP may promote the use of those treatments that are supported by good evidence and endorsed by national guidelines (SIGN 1997; Campbell et al 1998; NHS Wales 1999). This could in theory improve clinical outcome (e.g. by reducing the occurrence of complications). Management with an ICP could improve the thoroughness of patient care and reduce variation in clinical practice, unnecessary investigations, and practical errors (e.g. wrong dosage of medications). If ICPs improve communication between the disciplines and the

quality of information written in the patient record, patient care may be more organised and efficient, and patient-staff communication may also improve (Ayestas et al 1995; Hajewski et al 1998). This might in turn enhance patient satisfaction and reduce the number of complaints and litigation claims (Nolin 1995).

Benefits to the healthcare professional

Members of one discipline are often unaware of the other disciplines' input into patient care (Riches et al 1994). Multidisciplinary team meetings are therefore commonly used as a forum to communicate, chart the patient's progress, define future goals, and plan treatment strategies. ICPs may potentially help to improve documentation and multidisciplinary communication, and make team meetings more effective and efficient. Furthermore, it could make 'hand-overs' between healthcare professionals (e.g. between early and late shifts of nurses) easier and more informative (Zander 1988; Walsh 1997). One observational study showed that nurses spent an average of 27% of their time documenting and only 28% of their time providing direct patient care (Short 1997). By using a checklist-and-tickbox format, ICPs have the potential to streamline and standardise documentation and hence reduce the amount of time spent on paperwork (Campbell et al 1998). Since each item of the checklist should be signed by the person carrying out the task, it is clear who is accountable for each task. This might make it easier to respond to patient complaints (Woodyard & Sheetz 1993). Lastly, ICPs could act as a training tool for medical students, nursing students, and junior staff; any improvement in staff training might in turn have a positive impact on job satisfaction (Abbot et al 1994; Overill 1998).

Observational studies have shown that doctors and nurses do not document the care they deliver adequately (Gabbay & Layton 1992; Stone & Whincup 1994; Short 1997; Rudd et al 1999). In particular, there may be a substantial delay before an event is documented (or it may be omitted altogether), and the language used can often be repetitive and inconsistent. The United Kingdom Central Council (UKCC) has therefore produced specific guidelines for record keeping (see **Table 2.4**) (UKCC 1998). Other nursing experts have recommended 'charting by exception', which is a non-traditional, but legal, approach of documenting care by recording only unexpected events (Grant et al 1995; Short 1997). The General Medical Council (GMC) has also issued some general guidelines in medical record keeping for doctors (GMC 2001). More recently, tools such as pre-printed clerking proforma and unitary patient records (i.e. combining medical, nursing and therapists' notes) have been used with some success to improve the quality of documentation (Davenport et al 1995; Goodyear & Lloyd 1995; Kidd & Stout 1996; Morrison et al 2001). An ICP can be designed to be both a clerking proforma and a unitary patient record, hence it may improve multidisciplinary communication, reduce duplication of effort, and make it easier to find information (Parsley & Corrigan 1999).

Benefits to the healthcare system

Clinical governance requires the clinician to demonstrate his or her ability to consistently deliver patient care that is safe, well-considered, and of high quality (Scally & Donaldson 1998; Ellis & Johnson 1999). ICPs could potentially support the administration of clinical governance in a number of ways, for example, by encouraging individual clinicians to adhere to evidence- and guideline-based

practice, and by improving documentation and facilitating audit, which is an essential component of clinical governance (Ellis & Johnson 1999). The process of designing and introducing the ICP may also be beneficial to the team, for example, by encouraging collaboration between the members of the team (de Luc 2000).

The process of variance reporting could inform the healthcare staff on the possible reasons why certain aspects of care may be sub-substandard (Crombie & Davies 1993; Johnson 1997), or not cost-effective (e.g. using proprietary rather than generic drugs) (Riches et al 1994). Taking action to address the identified problems may help to improve quality of care and to minimise hospital cost (Odderson 1996).

What are the potential concerns of using an integrated care pathway?

The most commonly voiced concern about using ICPs is that they may reduce the level of autonomy that healthcare professionals exert over patient care (Pearson et al 1995; Sutton et al 2000). Some have used the term 'cookbook medicine' to describe the use of ICPs (Harding 1994; Bertram et al 1996; Wilson 1999), while others disagree (O'Malley 1997).

The use of ICPs generates two interesting paradoxes. The first one is this: on the one hand, ICPs aim to standardise patient care (*low* autonomy); on the other hand, ICPs are only meant to be 'templates' to assist clinical decision-making – the final decision of whether or not to use specific treatment strategies should rest with the professionals themselves (*high* autonomy) (Campbell et al 1998). Putting ICPs into practice may generate a second, legal, paradox. On the one hand, evaluation

processes such as variance reporting can identify the individuals who have deviated from a pre-printed care plan (successful lawsuits *likely*); on the other hand, healthcare professionals are meant to be free to exercise their clinical judgement when using ICPs (successful lawsuits *less likely*) (Nolin 1995). An ICP may also raise the expectation of the patients and relatives (especially when they can read the document); this may be problematic if there is any deviation from the recommended care plan.

Although ICPs aim to streamline patient care, reduce paperwork, and lower costs, the reverse can potentially occur. ICPs can turn a routine and simple task into a complicated and labour-intensive plan, with more paperwork to complete (Hunter & Fairfield 1997). This may in turn leave little time for other aspects of patient care. Alternatively, ICPs may over-simplify patient care, and healthcare professionals may not think about clinical problems or treatments that are not mentioned in the ICP. Junior doctors or nurses who use ICPs might become less inclined to use their own initiative to select the most appropriate investigations and treatments according to clinical need. Consequently, the unthinking use of all pre-stated investigations and treatments in all patients may increase rather than cut costs (Wee et al 2000). Over time, this might also lead to 'de-skilling' of staff. Conflicts may also arise when there are discrepancies between the ICP protocol and the wishes of the patients and relatives (Hunter & Fairfield 1997).

There is also concern that, even though patients might be discharged earlier when ICPs are used (if care is more efficient and organised), some observational studies

have found that patients might be more likely to be readmitted to hospital or require institutional care. Thus, patients are discharged 'quicker but sicker'. This could in turn increase the overall cost of care (Hale 1995; Cardozo & Aherns 1999).

The process of design, implementation, and local evaluation of ICPs can take a great deal of time, effort and resource. Since these indirect costs are difficult to quantify, assessing the cost-effectiveness of an ICP in a given setting may therefore be problematic (Hale 1995).

2.3 Developing a working definition of an integrated care pathway

Problems caused by having no standard definition of an integrated care pathway

Are all the organisations that are developing ICPs actually developing the same tool? The answer to this question must be 'no' (de Luc 2000). It therefore seems that different people are calling different models of ICP-like interventions by different names. This poses several major problems. Firstly, it may be difficult to implement an intervention that is difficult to define and understand because one cannot be sure whether it could be applicable to one's local setting. Secondly, it is difficult to evaluate the evidence from different studies since one cannot be sure whether the interventions being studied are similar. So, investigators should ideally define their intervention clearly, giving a detailed description of what the intervention is, how it operates, and the local circumstances within which the intervention has been implemented. Thirdly, it is difficult to design research studies for an intervention that is poorly defined, variable and unstructured.

Integrated care pathway is a complex intervention

According to the Medical Research Council, complex interventions are those that consist of a number of components which can act both independently and inter-dependently (Medical Research Council 2000). It is not easy to precisely define the 'active ingredients' of a complex intervention, or how they relate to each other. For example, stroke unit care may be regarded as a complex intervention since it is difficult to determine the 'active ingredients' that make it effective. Is it the physical

set-up? The mix of care providers? The skills of the providers? The technology available? The organisational arrangements? In practice, it is important to establish why or how a complex intervention works because it may enable others to draw inferences about whether the intervention can be put into operation in other contexts (Medical Research Council 2000).

ICP, like stroke unit care, is a complex intervention (Campbell et al 2000). Patient care with an ICP can vary in terms of organisation, management, location, format and design of the ICP, process of development and implementation, nature of the healthcare staff (skill mix, number and disciplines), and the local circumstances within which they operate. The Medical Research Council proposed that, before any clinical trial is undertaken on a complex intervention, it is essential to: a) establish a working definition for the intervention; and b) determine the probable active components of the intervention (Medical Research Council 2000). For an ICP, it may be possible to establish a working definition by stating the essential elements.

A working definition of an integrated care pathway

From examining the medical literature, and in my opinion, the essential elements of an ICP could include the following:

- An ICP is a plan of care (written or computerised);
- An ICP is developed and used by a multidisciplinary team (i.e. a team of members from more than one discipline);
- An ICP is applicable to more than one aspect of care (i.e. assessment, diagnosis, investigation, treatment).

Many 'experts' in the field of ICP development may also add other elements to this list, such as variance reporting or the application of evidence-based guidelines. In my opinion, although some of these other elements may be important for certain ICPs, they are not *essential* for every ICP.

I therefore propose that an ICP can be defined as a plan of care that is developed and used by members from more than one discipline, and is applicable to more than one aspect of care. This simple, working, definition will be used in the rest of this thesis. To my knowledge, no one else has used this definition of ICP before. The closest definition to this one is by Wigfield and Boon, who stated that "*care maps are a multidisciplinary team approach to assessing, planning, implementing, monitoring and evaluating care in collaboration with the patient*" (Wigfield & Boon 1996).

2.4 The origin of integrated care pathways

Organisational tools used in non-healthcare industries

In 1958, the US Navy planned to build the Polaris submarine. Due to the enormous complexity of the project and the huge number of contractors involved, a new method was developed to assist with the planning and scheduling of the project. This new method was called the Programme Evaluation and Review Technique (PERT) (Woolf et al 1968). PERT was used to define the tasks to be performed and the length of time necessary to accomplish them (Modell 1996). At about the same time, DuPont company and Remington Rand Corporation developed a similar tool, called the Critical Path Method (CPM), to assist with the scheduling of the shutdown of DuPont chemical plants (Landry 2001). The term 'critical' referred to the fact that the path consisted of steps that took the longest time, so that any delay in completing any of the steps would delay the entire project (Landry 2001). Over the next ten years or so, these two organisational tools became widely used in non-healthcare industries (Luttman et al 1995).

Managed care in the USA

Historically, healthcare in the USA has been provided on a fee-for-service basis. In the 1930s, managed care emerged as an alternative to fee-for-service (Hunter 2000). Doctors approached industries and proposed that the industry should pay a group of doctors a fixed sum of money to provide healthcare for its employees, and it was the doctors' responsibility to provide the appropriate healthcare within the total sum agreed (Scofield 1997). The underlying principle of managed care was this: for any

common clinical scenario, there were numerous but predictable elements of care which needed to be delivered on time and in the correct order. Managed care aimed to define what these elements should be, how they may be applied and by whom, and in some cases, the expected outcome (Fairfield et al 1997; Ellis 1997). This method of treatment was initially resisted, especially by the American medical profession. However, it was encouraged by the Nixon administration in the early 1970s and the use of managed care became widespread (Scofield 1997). Nowadays, managed care functions as an organisational process which seeks to deliver high-quality and efficient patient care whilst controlling costs (Wigfield & Gale 1998).

Case management and integrated care pathways in the USA

It was soon realised that managed care was not feasible in practice without two things: a person (or a group of people) in charge of the process and a tool to facilitate the process. This led to the development of: a) the case manager; and b) the ICP (Wigfield & Boon 1996; Smith 1998). In brief, a case manager was the person who co-ordinated the individual patient's overall care and ensured that the patient achieved the pre-specified outcomes (Ayestas et al 1995; Compton et al 1995). The case manager would be responsible for the continuity and consistency of care across all the clinical settings and sectors (e.g. primary and secondary sectors) (Lee et al 1998). It was thought that the nursing profession was best placed to undertake the function of a case manager since they often have the most intimate knowledge of the patients (Smith 1998).

ICPs were originally developed from the organisational tools used in non-healthcare industries (e.g. PERT and CPM). Case managers used ICPs to determine whether high-quality care was being delivered in a timely and cost-effective manner (Crummer & Carter 1993). The use of ICPs by case managers to deliver the aims of managed care is also known as 'case management'. Other organisational initiatives such as 'disease management', 'integrated care', 'transitional care' and 'home hospital programmes' are variants of the same theme (Hunter 2000; Boult et al 2000).

ICPs were originally developed for medical conditions or surgical procedures that were common, 'simple' (i.e. single pathology with little variation in practice) and costly (Nelson 1995; Bailey et al 1998). Later, the use of ICPs for more complex medical conditions (e.g. acute stroke, diabetes, psychiatric conditions) became more widespread – see **Chapter 3**. Freeland et al were the first to report the use of an ICP for inpatient rehabilitation for patients with arthritis (Freeland et al 1986). The first ICP to be used in acute stroke was at the New England Medical Centre, Boston (Zander 1988).

Integrated care pathways in the UK

In the UK, where the state pays for healthcare (largely through taxation), the government has attempted to control the costs of the NHS by the introduction of the 'internal market' (DoH 1989). Accordingly, and in contrast to the USA, the UK approach to quality and cost-effective patient care has involved large-scaled structural changes, such as those heralded by the White Papers *Working for Patients*

and *Health of the Nation* (DoH 1989; DoH 1992; DoH 1998). These mainly legislative approaches have been supplemented by other initiatives such as risk management and clinical governance.

However, while these initiatives are all concerned with quality and performance, the very essence of ICPs, there has been little official recognition in the UK of ICPs or case management as a co-ordinated approach to high quality and cost-effective care (Norris 1998). Although government publications such as the *New NHS: Modern, Dependable* and *A First Class Service: Quality in The New NHS* have promoted 'patient-focused care' and 'integrated care', none of them have specifically recommended the use of ICPs (DoH 1997; DoH 1998). Possible reasons may include: a) a lack of a clear definition of what an ICP is; b) a lack of evidence that ICPs are beneficial; and c) a lack of evidence that ICPs are cost-effective (Walsh 1997; Ellis & Johnson 1999).

From the early 1990s, however, many Health Trusts began implementing ICPs, chiefly within the surgical specialities (NHS Wales 1999). In contrast to the US, the primary objective of using ICPs in the UK was not to contain cost, but to assist the healthcare professionals in making evidence-based clinical decisions, with prompts from local protocols and national guidelines (Campbell et al 1998; Riley 1998; Kitchiner & Bundred 1999).

The total number of Health Trusts using ICPs is difficult to estimate since new ones are constantly being implemented and current ones are abandoned (Bridge et al 1997;

Riley 1998). In 1998, a UK-wide survey found that 86% of all hospital Trusts (over 250 in total) were using at least one ICP in delivering patient care (Currie 1998). Currently, ICPs are used in a huge variety of medical and surgical conditions (Campbell et al 1998; Bryson & Browning 1999; NHS Wales 1999). In 1997, the National Pathway Association carried out a postal questionnaire survey of its 157 UK members, with a 64% response rate. The survey found that ICPs were most commonly used in orthopaedic surgery, general surgery, and general and geriatric medicine (Riley 1998). In this survey, a third of respondents were using ICPs that involved general practitioners or social services, and a quarter were using ICPs that involved more than one hospital Trust (Riley 1998).

Integrated care pathways are one of many organisational tools to improve the quality of stroke care

Apart from ICPs, the endeavour to improve the quality of stroke care has led to the development of other organisational tools such as treatment algorithms (Effeney et al 1983; Caplan 1994; Karanjia et al 1997), 'stroke education record' (Evans 1998), 'comprehensive assessment toolbox' (Duncan et al 1999), and various 'stroke programmes' (Dignan et al 1986). A recent systematic review has also identified several interventions that had been introduced to overcome specific barriers to efficient acute stroke care (Sandercock et al 2001). These included: educational programmes for the public and healthcare professionals (Alberts et al 1992; Barsan et al 1994); training programmes for the paramedical staff to improve the accuracy of diagnosis (Kidwell et al 1998; Smith et al 1999); and re-organisation of in-hospital

systems to streamline acute care (e.g. 'code stroke' system) (Gomez et al 1994; Englander et al 1998).

2.5 Methodological considerations when evaluating the effects of integrated care pathways

The number of publications in the medical literature on ICP or case management has grown dramatically over the last few years. In 1996, the NHS Wales estimated that there were about 4000 published reports (NHS Wales 1999). I also tried to estimate this number by searching the MEDLINE, EMBASE, CINAHL, CancerLit and ClinPSYC databases, using "*critical pathways*" and "*case management*" as the only two search terms. In October 2001, this search retrieved 12,994 reports. Despite this large number of reports, it is believed that only a very small proportion of them are likely to be controlled clinical trials (Hale 1995; Campbell et al 1998). If this were true, what are the possible reasons why the effects of ICPs may be difficult to evaluate using conventional trial designs?

General problems with evaluating the effects of integrated care pathways

Compared with trials of pharmacological agents or surgical procedures, the evaluation of a health service intervention such as an ICP is more complex. In practice, ICPs are variable in their nature and their operation depends greatly on the local circumstances. Consequently, the results generated by studies of ICPs may have questionable internal validity (i.e. the extent to which differences between the study groups are real rather than a product of bias) and/or external validity (i.e. the extent to which trial results can be generalised to a wider population) (Medical Research Council 2000; Juni et al 2001).

Since an ICP can contain a large number of elements, each of these elements may contribute towards the effects of the ICP. Furthermore, each of the elements (e.g. organisation of the multidisciplinary team) may itself be complex and so they can all increase the overall complexity of the ICP (Medical Research Council 2000).

Randomised controlled trials are usually the gold standard for evaluating interventions

It is widely accepted that the most effective method to evaluate a therapeutic intervention is by comparing two groups of patients who are so similar at baseline that their outcomes only differ by chance, or because one group received an effective or harmful therapeutic intervention (Collins & MacMahon 2001). The best way to construct such groups is by random allocation without the treating clinician being able to predict which group a patient is going to be in; this is the basis of randomised controlled trials (RCTs) (Barton 2000). Well-designed, large scale RCTs should, therefore, minimise the effects of bias and provide the most accurate estimate of effect for an intervention (Peto & Baigent 1998; Pocock & Elbourne 2000). There is also some weak evidence that the process of performing an RCT *per se* might have a positive effect on the outcome of the participants, regardless of the effectiveness of the intervention (Braunholtz et al 2001). This 'trial effect' may be due to changes in the clinicians' behaviour within a trial environment, or the fact that clinicians who recruit patients into trials may be 'better' clinicians (Braunholtz et al 2001).

Problems with randomised controlled trials

Despite the superiority of RCTs over other trial designs, there may be occasions when performing an RCT (i.e. randomising at the patient level) is not feasible (Medical Research Council 2000). For complex interventions such as ICPs, the performance of RCTs can be associated with many methodological difficulties. Here are several examples.

The control intervention may also be complex

In addition to the aforementioned complexity of an ICP, the control intervention (e.g. 'standard' medical care) may be equally as, if not more, complex. This would further increase the difficulty in interpreting and generalising the results of the trial.

Getting large numbers of patients may be challenging

Since the treatment effects of ICPs may only likely to be moderate, very large numbers of patients would be needed to provide adequate power to detect a significant difference in outcome (Peto & Baigent 1998). Getting large numbers of patients would require substantial resources, time and effort.

Healthcare professionals may not want to take part

To many people, the theory behind the use of ICP seems so sensible (de Luc 2000). Hence, many healthcare professionals may have a pre-formed opinion that ICPs are beneficial, and may therefore be reluctant to recruit patients into the trial.

Patients and carers may not give consent

ICPs are generally regarded as a safe intervention, and many patients and carers may therefore believe that anything to improve patient care must be better than none. It may therefore be difficult to obtain informed consent for a controlled trial where the control is 'standard' medical care. Furthermore, trial results would be less generalisable if it only recruits a very low proportion of eligible patients (Medical Research Council 2000).

Lack of blinding is a source of bias

The purpose of blinding is to minimise bias resulting from the expectations of the patient or caregivers regarding outcomes (Day & Altman 2000). A lack of blinding might therefore influence outcomes of a trial; for example, patients in the standard medical care group might be managed less intensively than usual if the caregivers believe that the intervention is beneficial. In trials of ICPs, due to practical reasons, it would be very difficult to blind the patient, caregivers, and assessor of outcomes to treatment allocation.

Cross-contamination of interventions

Randomisation of individual patients to ICP or standard medical care would only be meaningful if the two types of care is comparable in every way except for the use of the ICP. If randomisation takes place within one ward, the healthcare staff from that ward would have to 'switch' between using an ICP and not using one. This is difficult to achieve in practice without 'cross-contamination' of treatment. Moreover, if patients are randomised to be managed in different wards (e.g. one ward using the

ICP and another not using the ICP), then patient care is likely to be significantly different; this would also confound the results of the trial. The consequence of cross-contamination may be the rejection of an effective intervention as ineffective because the observed effect size is statistically non-significant (i.e. a type II error) (Torgerson 2001).

Other, less common, confounders

Randomisation depends on the statistical power of chance to evenly distribute potential confounding factors among the trial arms. Where confounders are minimal and participant numbers are high, this method should be adequate. However, if a confounding factor is common, it may end up being more prevalent in one trial arm over the other (Medical Research Council 2000).

Choice of outcome measures

It may be difficult to agree on the appropriate and meaningful outcome measures. Some outcome measures such as patient satisfaction are also difficult to quantify and interpret, whereas functional outcome such as mortality may not be realistic. Furthermore, some outcomes can only be measured in certain groups of patients (e.g. communication difficulty is usually an exclusion criteria for assessments of quality of life).

Problems with multicentre trials

The inclusion of many centres to recruit patients can boost the sample size of the trial and improve the precision of the results. However, as I have already mentioned, ICPs

can differ significantly in their nature between hospitals, and hence the results of such multicentre trials would have to be interpreted with a high level of caution, taking into account the variations in the nature of the ICPs and local circumstances. One possible way of tackling this problem is by standardising the ICPs so that they mainly consist of just the 'essential' elements. However, this approach may make it more difficult to generalise the trial results to the wider health service.

Problems with cluster randomised trials

Cluster randomised trials, where groups of patients rather than individuals are randomised, are often advocated to minimise cross-contamination between treatments when trial patients are managed within the same setting (Torgerson 2001). Cluster randomised trials are increasingly being used in health service research where randomising at the patient level is often not feasible (Campbell & Grimshaw 1998). In such cases, cluster randomisation at the level of the healthcare professional or organisation is necessary.

However, cluster randomised trials are associated with methodological problems. The major consequence of clustering is that the outcome of each patient can no longer be assumed to be independent of that of any other patient. Patients within a location are therefore more likely to be similar than different, and certain types of patients or conditions may be more prevalent in certain locations. This can significantly reduce the statistical power of the study, and hence the sample size of cluster randomised trials would have to be much larger than individually randomised trials (Campbell & Grimshaw 1998; Kerry & Bland 1998).

From an ethical point of view, cluster randomisation implies that an intervention (e.g. implementing an ICP or not) is imposed on a hospital or group of hospitals; this raises questions about the autonomy of individual patients within each cluster (e.g. how can they give their consent to treatment?) (Edwards et al 1999). Moreover, since the implementation of an ICP requires time, effort and plenty of enthusiasm from all the members of the team, an imposition of such an intervention may be unacceptable to the people involved in its implementation. This may in turn introduce bias into the study.

Does this mean that randomised controlled trials could not be used to evaluate integrated care pathways?

Randomisation remains the best method to minimise bias in a trial, but there are many methodological pitfalls that must be born in mind when planning and conducting such a trial. In my opinion, even a well designed and large scale RCT is unlikely to be able to obtain a precise estimate of effect of an ICP – the results would always be influenced by bias and confounding factors.

How might one evaluate the effects of integrated care pathways?

When RCTs are not feasible, one might have to gather evidence using multiple approaches. This could include: a) examining the evidence from previous studies; b) conducting non-randomised quantitative studies; and c) conducting surveys and qualitative studies. Evidence from each approach can be considered as one piece of the jigsaw puzzle, and when they are interpreted together, they may provide a more

complete picture about an intervention. This approach is known as 'triangulation' (Mays & Pope 2000).

Objectives of triangulation

Triangulation aims to increase the understanding of a complex intervention by comparing the findings from two or more different methods of evaluating an intervention – most commonly a mixture of quantitative and qualitative studies (Mays & Pope 2000; Malterud 2001a). The researcher looks for patterns of convergence to develop or confirm an overall interpretation. The intention of triangulation is to counterbalance the limitation of one research design by the strengths of another, thereby increasing the ability to interpret the findings (Sim & Sharp 1998; Thurmond 2001). Triangulation has been used in nursing and sociological research where many of the interventions and issues are complex (Connelly et al 1997; Friedemann & Smith 1997; Murray 1999; Rees & Bath 2001).

Problems with triangulation

There are several major problems with using triangulation to assess the effects of an ICP (see **Table 2.5**). Firstly, triangulation assumes that any weaknesses in one method can be compensated by the strengths in other methods. Of course, this may not be possible in practice – it is difficult to imagine how the weaknesses of a non-randomised controlled trial can be fully compensated by the strengths of a questionnaire survey. Triangulation can therefore be better regarded as a way of maximising comprehensiveness and encouraging a more flexible analysis of the data, rather than as a method of obtaining accurate data (Mays & Pope 2000). Secondly,

the bringing together of quantitative and qualitative methods in triangulation tend to ignore the fundamental question as to whether data generated by different research methods can meaningfully be combined – it may simply compound the sources of bias and confounding (Begley 1996; Sim & Sharp 1998). One therefore needs to approach triangulation with extreme caution and in a critical fashion, with due regard to the rather dubious assumptions upon which it often rests (Sim & Sharp 1998).

Non-randomised research designs

Non-randomised studies are generally regarded as having lower levels of internal validity because the two comparison groups have not been created to be mathematically equivalent (as it should be the case in randomised trials) (Sacks et al 1982; Chalmers et al 1983; Egger & Smith 1998). Since each patient's treatment is deliberately chosen rather than randomly assigned, there is an unavoidable risk of selection bias and of systematic differences in outcomes that are not due to the treatment itself (Pocock & Elbourne 2000). Despite this, many believe that non-randomised and randomised studies can contribute complementary evidence about the effects of treatment, even on the major outcomes such as mortality (MacMahon & Collins 2001). Moreover, non-randomised studies may help to identify important but rare adverse effects of a treatment, and they may provide information about the risks of death and disability in particular circumstances that can help to generalise the results of a clinical trial (MacMahon & Collins 2001). Interestingly, two recent reports identified clinical questions where both randomised and non-randomised studies had been used to evaluate the same question, and performed a head to head comparison of them (Concato et al 2000; Benson & Hartz 2000). In contrast to the

belief that non-randomised studies more frequently report positive results and larger estimates of treatment effects, both reports appeared to find that non-randomised studies did not over-estimate the size of the treatment effect compared with the randomised counterpart (Ioannidis et al 2001a). However, the quality of these two reports is dubious (Ioannidis et al 2001b).

Major types of non-randomised research designs

The major types of non-randomised study designs have been summarised in **Table 2.6**. I have highlighted several examples here:

Open study design

In this study design, observations are only made after an intervention. Since observations are not made before the intervention, the researcher cannot be certain that the intervention has resulted in change. Furthermore, since there is no control group, allowance cannot be made for changes resulting from passage of time, season, or external factors other than the intervention. This design, which is commonly known as 'case series', has very limited application in informing clinical practice. Warlow commented that "*the plural of anecdote clearly is not data*" (Professor C Warlow, personal communication, 2001). However, post-test-only design is surprisingly common as a method of assessing the effects of ICPs (Wentworth & Atkinson 1996; Ramachandran et al 1996; Lagoe & Aspling 1997; van Straten et al 1997; Lagoe 1998; Summers & Soper 1998; Quigley et al 1998).

Before-and-after designs

There are two main types of before-and-after studies: controlled and uncontrolled (HTA 1999). *Uncontrolled* before-and-after studies are also known as single group pre-test/post-test studies. In this type of studies, since observations are made before and after an intervention in one group of patients only, it is impossible for the researcher to know what would have happened in the absence of the intervention (Cable 2001). Changes in the outcome from pre-test to post-test could in fact be due to many factors other than the intervention, for example, external events and cyclical variations in the outcome (Cable 2001). *Controlled* before-and-after studies are where observations are made before and after an intervention in two non-equivalent but similar groups of patients (e.g. two hospitals in the same Health Trusts). A variant of this type of study is when the intervention is implemented in one group, but the other group remains totally untreated throughout the study period. The major advantage of having a 'control' group is that external factors such as changes in outcome with time, may be estimated (HTA 1999).

Interrupted time series designs

Like before-and-after studies, interrupted time series can either be uncontrolled (i.e. investigating a single group of patients) or controlled (i.e. investigating two non-equivalent groups of patients). Interrupted time series are studies that make multiple observations (usually more than three) before and after an intervention (HTA 1999). The advantages of interrupted time series are similar to those of before-and-after studies, but the internal validity of interrupted time series are generally thought to be higher (Cable 2001). One drawback of interrupted time series is that data analysis

often involves complex mathematical modelling to determine the effects of the intervention on the entire series of observations, whilst taking into account the relative effects of other external factors. Another drawback of interrupted time series is that, for the data analysis to be accurate, each period of data collection has to have observed enough outcome events for the point estimate of effect to be precise (with a narrow confidence interval) – although there is no strict rule for this. This may require long periods of observations and hence considerable amount of resources. It may be for these reasons that interrupted time series have rarely been used to evaluate the effects of ICPs.

Qualitative research designs

The need for qualitative research rests on the fact that clinical decisions are rarely made on the basis of quantitative data or evidence alone – the clinician also relies on other factors such as experience, feelings, and understanding of the situation (i.e. the 'art of medicine') (Malterud 2001b). Qualitative research intends to explore the *what*, *how* and *why* of clinical decisions and phenomena (Giacomini & Cook 2000). In practice, qualitative research draws on text rather than numbers, applying procedures for interpretation of meaning instead of statistics to calculate probabilities, and aiming for wholeness rather than details – it seeks to "*reach the parts that other methods cannot reach*" (Pope & Mays 1995; Malterud 2001b). The Medical Research Council recommends that qualitative research can be useful in the evaluation of a complex intervention (Medical Research Council 2000). A range of qualitative methods are available, including group interviews (focus groups), individual in-depth interviews, observational (ethnographic) research, or

organisational case studies (Medical Research Council 2000). It is beyond the scope of this thesis to discuss these methods.

Approaches used to evaluate the effects of integrated care pathways for acute stroke in this thesis

The objectives of this thesis are listed in **Chapter 1**. I sought to evaluate the effects of ICPs for acute stroke using the following four approaches:

1. Assessing the evidence from previous studies of ICPs for non-stroke conditions;
2. Assessing the evidence from previous studies of ICPs for acute stroke;
3. Conducting two non-randomised studies of the ICP introduced for acute stroke at the Western General Hospital – a before-and-after study and a prospective comparative study;
4. Conducting two questionnaire surveys to assess the experience of the stroke unit staff regarding the use of the ICP for acute stroke at the Western General Hospital.

2.6 Summary of this chapter

- Integrated care pathways (ICPs) are being implemented across many hospitals without much debate about their definition, nature, and effects.
- There are many definitions of ICPs, they all differ slightly and none has been universally accepted as standard.
- ICPs are complex interventions with the following essential elements: a) they are plans of care; b) they are developed and used by a multidisciplinary team; and c) they are applicable to more than one aspect of care. A working definition of an ICP can include all of these three elements.
- The use of ICP can be associated with many potential advantages as well as disadvantages to the patient, healthcare professional, and healthcare system.
- All studies of ICPs may suffer from low levels of internal and external validity.
- There are many methodological problems associated with randomised controlled trials (including multicentre and cluster randomised trials) of ICPs.
- Evaluation of the effects of ICPs may have to involve multiple approaches such as the performance of non-randomised studies and qualitative studies.
- In thesis, I sought to evaluate the effects of ICPs for acute stroke by: a) assessing the evidence from previous studies of ICPs for non-stroke conditions; b) assessing the evidence from previous studies of ICPs for acute stroke; c) conducting two non-randomised studies of the ICP introduced for acute stroke at the Western General Hospital; and d) conducting two questionnaire surveys to assess the experience of the stroke unit staff regarding the use of the ICP for acute stroke at the Western General Hospital.

Table 2.1 Types of items that may be included in an ICP – using stroke ICP as an example.

Process of care items	Patient-specific items
▫ Investigations	▫ History & examination findings
▫ Pharmacological treatments	▫ Functional status (e.g. Barthel index)
▫ Rehabilitative therapy	▫ Physiological status (e.g. BP)
▫ Surgical procedures	▫ Neurological status (e.g. GCS)
▫ Education of patient & relative	▫ Symptoms (e.g. pain)
▫ Psychological support	▫ Cognitive status (e.g. mental test score)
▫ Spiritual support	▫ Emotional status
▫ Palliative support	▫ Quality of life (e.g. SF36)
▫ Discharge planning	▫ Patient satisfaction

Table 2.2 Four major aims of using ICPs.

- To assist healthcare professionals in making clinical decisions according to the best-available evidence, local policies, and national guidelines.
- To improve the quality of patient care by reducing variation in clinical practice and improving efficiency, which may in turn reduce length of stay and cost.
- To improve communication between disciplines, and between patient and healthcare professionals.
- To improve documentation and facilitate audit.

Table 2.3 Different methods of providing information to assist decision-making by healthcare professionals. **Numbers 1 to 8** indicate increasing complexity and detail of instruction. In the medical literature, ICPs have been used as a term to mean anything from **numbers 2 to 8**.

Method of providing information	Usual definition
1. Evidence	Findings from research
2. Guideline	Consensus panel reviews the evidence to produce recommendations on what best practice should encompass
3. Standard	Specific instruction for the best practice. Standards define the care that could be expected by patients and carers
4. Criteria	List of standards
5. Policy	Adjustment and application of national guidelines or standards to the local setting
6. Procedure or protocol	Detailed instructions on exactly how to perform a certain task according to guideline recommendations or standards
7. Flow chart or algorithm	Procedures or protocols with clearly charted sequence (and sometimes also timing) of tasks and/or outcomes
8. Integrated care pathway	Paper or electronic care plans that contain detailed checklists of recommended treatments for the different aspects of patient care from day to day

Table 2.4 United Kingdom Central Council (UKCC) guidelines for good record keeping. Adapted from UKCC (1998).

Patient records should be:

- Factual
- Up-to-date
- Clear
- Accurate
- Consistent
- In chronological order
- Legible
- Permanent
- Problem-based, describing care planned and delivered for each problem
- Without jargons and offensive statements
- Written with the involvement of the patient or relative
- Written in terms that patient or relative can understand

Table 2.5 Major problems of using triangulation to evaluate the effects of complex intervention such as ICPs. Many of these problems are not unique to triangulation. Adapted from Begley (1996).

- Internal and external validity of triangulation may be low
- Triangulation may compound sources of error and bias from different studies
- Research methods selected by the researcher may not be the appropriate ones
- Unit of analysis may not apply to all research methods
- Triangulation cannot compensate for researcher bias
- Triangulation can be very expensive
- Evaluation using triangulation is difficult to replicate

Table 2.6 Major types of non-randomised study designs according to the nature of the comparison groups and timing of observations. Adapted from HTA (1999).

Comparison groups	Timing of observations	Other names
Intervention group only	▪ After only	Open study
	▪ Before and after	Uncontrolled before-and-after study
	▪ Interrupted time series	Uncontrolled interrupted time series
Intervention group & non-equivalent control group	▪ After only	Comparative study
	▪ Before and after	Controlled before-and-after study
	▪ Interrupted time series	Controlled interrupted time series

References for Chapter 2

Anonymous (1995) Stroke path calls for care when evaluating variances. *Hosp Case Manag.* 3(11):176-177.

Abbot J, Young A, Haxton R et al. (1994) Collaborative care: a professional model that influences job satisfaction. *Nurs Econ.* 12(3):167-174.

Alberts MJ, Perry A, Dawson DV et al. (1992) Effects of public and professional education on reducing the delay in presentation and referral of stroke patients. *Stroke.* 23(3):352-356.

Ayestas ALS, Diaz E, Kirtland S. (1995) Clinical pathways: improving patient education and influencing readmission rates. *J Healthc Qual.* 17(6):17-25.

Bailey R, Weingarten S, Lewis M et al. (1998) Impact of clinical pathways and practice guidelines on the management of acute exacerbations of bronchial asthma. *Chest.* 113(1):28-33.

Barsan WG, Brott TG, Broderick JP et al. (1994) Urgent therapy for acute stroke. Effects of a stroke trial on untreated patients. *Stroke.* 25(11):2132-2137.

Barton S. (2000) Which clinical studies provide the best evidence? *The BMJ.* 321(7256):255-256.

Begley CM. (1996) Using triangulation in nursing research. *J Adv Nurs.* 24(1):122-128.

Benson K, Hartz AJ. (2000) A comparison of observational studies and randomized, controlled trials. *N Engl J Med.* 342(25):1878-1886.

Bertram DA, Thompson MC, Giordano D et al. (1996) Implementation of an inpatient case management program in rural hospitals. *J Rural Health.* 12(1):54-66.

Boult C, Kane R, Brown R. (2000) Managed care of chronically ill older people: the US experience. *The BMJ.* 321:1011-1014.

Braunholtz DA, Edwards SJ, Lilford RJ. (2001) Are randomized clinical trials good for us (in the short term)? Evidence for a "trial effect". *J Clin Epidemiol.* 54(3):217-224.

Bridge GE. (1997) *Care pathways in the quality management of healthcare.* MSc thesis: University of Southampton.

Bridge GE, Norris AC, Melhuish PM. (1997) *Care pathways In the quality management of UK healthcare. Proceedings of the second APAMI/Fifth HIC97 conference on health and medical informatics.* Sydney:

Brown SW, Nemeth LS. (1998) Developing a variance reporting system to facilitate quality improvement. *Outcomes Manag Nurs Pract.* 2:10-15.

Bryson A, Browning JD. (1999) *Clinical Audit and quality using integrated pathways of care.* Scottish Executive Health Department.

Cable G. (2001) Enhancing causal interpretations of quality improvement interventions. *Qual Health Care.* 10:179-186.

Campbell H, Hotchkiss R, Bradshaw N et al. (1998) Integrated care pathways. *The BMJ.* 316(7125):133-137.

Campbell M, Fitzpatrick R, Haines A et al. (2000) Framework for design and evaluation of complex interventions to improve health. *The BMJ.* 321(7262):694-696.

Campbell MK, Grimshaw JM. (1998) Cluster randomised trials: time for improvement. *The BMJ.* 317(7167):1171-1172.

Caplan LR. (1994) Of stroke treatment, algorithms, trials, and such. *Mayo Clin Proc.* 69(11):1120-1122.

Cardozo L, Aherns S. (1999) Assessing the efficacy of a clinical pathway in the management of older patients hospitalized with congestive heart failure. *J Healthc Qual.* 21(3):12-16.

Chalmers TC, Celano P, Sacks H et al. (1983) Bias in treatment assignment in controlled clinical trials. *N Engl J Med.* 309:1358-1361.

Collins R, MacMahon S. (2001) Reliable assessment of the effects of treatment on mortality and major morbidity, I: clinical trials. *Lancet.* 357(9253):373-380.

Compton J, Robinson M, O'Hara C. (1995) Benchmarking critical pathways - a method for achieving best practice. *Aust Health Rev.* 18(2):101-112.

Concato J, Shah N, Horwitz RI. (2000) Randomized, controlled trials, observational studies, and the hierarchy of research designs. *N Engl J Med.* 342(25):1887-1892.

Connelly LM, Bott M, Hoffart N et al. (1997) Methodological triangulation in a study of nurse retention. *Nurs Res.* 46(5):299-302.

Crombie IK, Davies HT. (1993) Missing link in the audit cycle. *Qual Health Care.* 2(1):47-48.

Crummer MB, Carter V. (1993) Critical pathways - the pivotal tool. *J Cardiovasc Nurs.* 7:30-37.

Currie L. (1998) *Directory of UK Trusts using care pathways*. Oxford: Royal College of Nursing Institute.

Davenport RJ, Dennis M, Warlow C. (1995) Improving the recording of the clinical assessment of stroke patients using a clerking pro forma. *Age Ageing.* 24:43-48.

Day SJ, Altman DG. (2000) Blinding in clinical trials and other studies. *The BMJ.* 321:504.

de Luc K. (2000) Are different models of care pathways being developed? *Int J Health Care Qual Assur.* 13(2):80-86.

Dignan MB, Howard G, Toole JF et al. (1986) Evaluation of the North Carolina stroke care program. *Stroke.* 17(3):382-386.

DoH – Department of Health. (1989) *Working for Patients*. London: HMSO.

DoH – Department of Health. (1992) *The Health of the Nation*. London: HMSO.

DoH – Department of Health. (1996) *Promoting clinical effectiveness: a framework for action in and through the NHS*. London: The Stationery Office.

DoH – Department of Health. (1997) *The new NHS: modern, dependable*. London: The Stationery Office.

DoH – Department of Health. (1998) *A first class service: quality in the new NHS*. London: The Stationery Office.

Duncan PW, Lai SM, van C, V et al. (1999) Development of a comprehensive assessment toolbox for stroke. *Clin Geriatr Med.* 15(4):885-915.

Edwards SJ, Braunholtz DA, Lilford RJ et al. (1999) Ethical issues in the design and conduct of cluster randomised controlled trials. *The BMJ.* 318(7195):1407-1409.

Effeney DJ, DeMartini J, Krupski WC et al. (1983) Algorithms in the management of cerebrovascular disease. *Aust N Z J Surg.* 53(6):509-520.

Egger M, Smith GD. (1998) Bias in location and selection of studies. *The BMJ.* 316(7124):61-66.

Ellis BW. (1997) Managed care: a hospital clinician's view. *J Managed Care.* 1:9-11.

Ellis BW, Johnson S. (1999) The care pathway: a tool to enhance clinical governance. *Br J Clin Governance.* 4(2):61-71.

Englander RN, Morich DH, Minniti MM. (1998) Accelerating the evaluation of acute stroke patients in a community hospital. *Neurology.* 50:A114 (Abstract P02.091).

Evans DM. (1998) Stroke education: the development of a documentation system and resource guide. *Axone.* 20(1):19-22.

Fairfield G, Hunter DJ, Mechanic D et al. (1997) Implications of managed care for health systems, clinicians, and patients. *The BMJ.* 314(7098):1895-1898.

Field MJ, Lohr KN. (1992) . *Guidelines for clinical practice: from development to use.* Washington DC: National Academy Press.

Freeland K, Falconer JA, Napolitan S. (1986) The critical path method: use of a management planning technique in arthritis inpatient rehabilitation. *Arch Phys Med Rehabil.* 67:648.

Friedemann ML, Smith AA. (1997) A triangulation approach to testing a family instrument. *West J Nurs Res.* 19(3):364-378.

Gabbay J, Layton AJ. (1992) Evaluation of audit of medical inpatient records in a district general hospital. *Qual Health Care.* 1(1):43-47.

Giacomini MK, Cook DJ. (2000) Users' guides to the medical literature: XXIII. Qualitative research in health care A. Are the results of the study valid? Evidence-Based Medicine Working Group. *JAMA.* 284(3):357-362.

GMC. (2001) . *Good medical practice.* London: General Medical Council.

Gomez CR, Malkoff MD, Sauer CM et al. (1994) Code stroke. An attempt to shorten inhospital therapeutic delays. *Stroke.* 25(10):1920-1923.

Goodyear HM, Lloyd BW. (1995) Can admission notes be improved by using preprinted assessment sheets? *Qual Health Care.* 4(3):190-193.

Grant PH, Campbell LL, Gautney LJ. (1995) Implementing case management and developing clinical pathways. *J Healthc Qual.* 17(6):10-16.

Hajewski C, Maupin JM, Rapp DA et al. (1998) Implementation and evaluation of nursing interventions classification and nursing outcomes classification in a patient education plan. *J Nurs Care Qual.* 12:30-40.

Hale C. (1995) Research issues in case management. *Nurs Stand.* 9(44):29-32.

Hale C. (2002) Issues in the evaluation of multidisciplinary pathways of care. In: Wilson J (ed.). *Integrated care management: the path to success?* Oxford: Butterworth/Heinemann.

Harding J. (1994) Practice guidelines. Cookbook medicine. *Physician Exec.* 20(8):3-6.

Hofmann PA. (1993) Critical path method: an important tool for coordinating clinical care. *J Qual Improvement.* 19(7):235-246.

HTA. (1999) Study design. *Health Technology Assessment.* 3(5):9-20.

Hunter DJ. (2000) Disease management: has it a future? *The BMJ.* 320(7234):530.

Hunter DJ, Fairfield G. (1997) Disease management. *The BMJ.* 315(7099):50-53.

Ioannidis JP, Haidich AB, Lau J. (2001b) Any casualties in the clash of randomised and observational evidence? *The BMJ.* 322(7291):879-880.

Ioannidis JPA, Haidich AB, Pappa M et al. (2001a) Comparison of evidence of treatment effects in randomized and nonrandomized studies. *JAMA.* 286(7):821-830.

Johnson S. (1997) Pathways of care: what and how? *J Integrated Care.* 1:15-17.

Juni P, Altman DG, Egger M. (2001) Systematic reviews in health care: assessing the quality of controlled clinical trials. *The BMJ.* 323(7303):42-46.

Karanjia PN, Nelson JJ, Lefkowitz DS et al. (1997) Validation of the ACAS TIA/stroke algorithm. *Neurology.* 48(2):346-351.

Kerry SM, Bland JM. (1998) Analysis of a trial randomised in clusters. *The BMJ.* 316(7124):54.

Kidd D, Stout RW. (1996) The assessment of acute stroke in general medical wards. *Disabil Rehabil.* 18(4):205-208.

Kidwell CS, Saver JL, Schubert GB et al. (1998) Design and retrospective analysis of the Los Angeles Prehospital Stroke Screen (LAPSS). *Prehosp Emerg Care.* 2(4):267-273.

Kitchiner D, Bundred P. (1999) Clinical pathways. A practical tool for specifying, evaluating and improving the quality of clinical practice. *Med J Aust.* 170:54-55.

Lagoe RJ. (1998) Basic statistics for clinical pathway evaluation. *Nurs Econ.* 16(3):125-131.

Lagoe RJ, Aspling DL. (1997) Benchmarking and clinical pathway implementation on a multihospital basis. *Nurs Econ.* 15(3):131-137.

Landry JA. (2001) *Project management: comparing PERT/CPM, Gantt charts, function points, metrics. Lecture notes for Agricultural and Biosystem Engineering.* McGill University, Canada.

Lee DT, Mackenzie AE, Dudley-Brown S et al. (1998) Case management: a review of the definitions and practices. *J Adv Nurs.* 27(5):933-939.

Luttman RJ, Laffel GL, Pearson SD. (1995) Using PERT/CPM (Program Evaluation and Review Technique/Critical Path Method) to design and improve clinical processes. *Qual Manag.Health Care.* 3(2):1-13.

MacMahon S, Collins R. (2001) Reliable assessment of the effects of treatment on mortality and major morbidity, II: observational studies. *Lancet.* 357(9254):455-462.

Malterud K. (2001a) Qualitative research: standards, challenges, and guidelines. *Lancet.* 358(9280):483-488.

Malterud K. (2001b) The art and science of clinical knowledge: evidence beyond measures and numbers. *Lancet.* 358(9279):397-400.

Mays N, Pope C. (2000) Qualitative research in health care: Assessing quality in qualitative research. *The BMJ.* 320(7226):50-52.

Medical Research Council. (2000) *Framework for design and evaluation of RCTs for complex interventions to improve health.*

Modell ME. (1996) *A professional's guide to system's analysis.* London: McGraw-Hill.

Morrison LG, Lam S, Sutherland M et al. (2001) A unitary patient record improves admission documentation in a medical assessment unit in a major teaching hospital. *Health Bull (Edinburgh).* 59(4):218-223.

Murray JS. (1999) Methodological triangulation in a study of social support for siblings of children with cancer. *J Pediatr.Oncol.Nurs.* 16(4):194-200.

Nelson S. (1995) Following pathways in pursuit of excellence. *Int J Health Care Qual Assur.* 8(7):19-22.

NHS Wales. (1999) *Value For Money (VFM) Unit. An introduction to clinical pathways*. NHS Wales.

Nolin CE. (1995) Malpractice claims, patient communication, and critical paths: a lawyer's perspective. *Qual Manag Health Care.* 3(2):65-70.

Norris AC. (1998) Care pathways and the new NHS. *J Integrated Care.* 2:78-83.

O'Malley S. (1997) Pathways: improving outcomes, not just 'cookbook medicine'. *Qual Lett Healthc Lead.* 9(4):12-14.

Odderson IR. (1996) Pathways to quality care at lower cost. *Clin Rehab Physiatric Prac.* 7(1):147-165.

Overill S. (1998) A practical guide to care pathways. *J Integrated Care.* 2:93-98.

Parsley K, Corrigan P. (1999) *Quality improvement in healthcare: putting evidence into practice.* Cheltenham: Stanley Thornes Ltd.

Pearson SD, Goulart-Fisher D, Lee TH. (1995) Critical pathways as a strategy for improving care: problems and potential. *Ann Intern Med.* 123(12):941-948.

Peto R, Baigent C. (1998) Trials: the next 50 years. Large scale randomised evidence of moderate benefits. *The BMJ.* 317(7167):1170-1171.

Pocock SJ, Elbourne DR. (2000) Randomised trials or observational tribulations? *N Engl J Med.* 342(25):1907-1909.

Pope C, Mays N. (1995) Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. *The BMJ.* 311(6996):42-45.

Quigley PA, Wallace Smith S, Strugar J. (1998) Successful experience with clinical pathways in rehabilitation. *J Rehabil.* 64(2):29-32.

Ramachandran TS, Culebras A, Hainworth D. (1996) Development and implementation of a clinical pathway for stroke in acute care. *Neurology.* 46(Suppl):A319 (P04.119).

Rees CE, Bath PA. (2001) The use of between-methods triangulation in cancer nursing research: a case study examining information sources for partners of women with breast cancer. *Cancer Nurs.* 24(2):104-111.

Riches T, Stead L, Espie C. (1994) Introducing anticipated recovery pathways: a teaching hospital experience. *Int J Health Care Qual Assur.* 7(5):21-24.

Riley K. (1998) Paving the way. Care pathways are a tool to standardise care. *Health Service J.* 26 March:30-31.

Rudd AG, Irwin P, Rutledge Z et al. (1999) The national sentinel audit for stroke: a tool for raising standards of care. *J R Coll Physicians Lond.* 33(5):460-464.

Sacks H, Chalmers TC, Smith JrH. (1982) Randomized versus historical controls for clinical trials. *Am J Med.* 72:233-240.

Sandercock P, Berge E, Dennis M et al. (2001) *A systematic review of the effectiveness, cost-effectiveness and barriers to implementation of thrombolytic and neuroprotective therapy for acute ischaemic stroke in the NHS.* NHS Health Technology Assessment (Report No 98/02/02).

Scally G, Donaldson LJ. (1998) The NHS's 50 anniversary. Clinical governance and the drive for quality improvement in the new NHS in England. *The BMJ.* 317(7150):61-65.

Schriefer J. (1995) Managing critical pathway variances. *Qual Manag Health Care.* 3(2):30-42.

Scofield A. (1997) Route to a seamless service? *J Managed Care.* 1:95-99.

Short MS. (1997) Charting by exception on a clinical pathway. *Nurs Manage.* 28:45-46.

SIGN. (1997) *Management of patients with stroke: I. Assessment, investigation, immediate management and secondary prevention.* Edinburgh: Scottish Intercollegiate Guidelines Network.

Sim J, Sharp K. (1998) A critical appraisal of the role of triangulation in nursing research. *Int J Nurs Stud.* 35(1-2):23-31.

Smith JE. (1998) Case management: a literature review. *Can J Nurs.* 11(2):93-109.

Smith WS, Corry M, Fazackerley J et al. (1999) Improved paramedic sensitivity in identifying stroke victims in the prehospital setting. *Prehosp Emerg Care.* 3:207-210.

Stone SP, Whincup P. (1994) Standards for the hospital management of stroke patients. *J R Coll Physicians Lond.* 28(1):52-58.

Summers D, Soper PA. (1998) Implementation and evaluation of stroke clinical pathways and the impact on cost of stroke care. *J Cardiovasc Nurs.* 13(1):69-87.

Sutton AJ, Duval SJ, Tweedie RL et al. (2000) Empirical assessment of effect of publication bias on meta-analyses. *The BMJ.* 320(7249):1574-1577.

Thomson R, Lavender M, Madhok R. (1995) How to ensure that guidelines are effective. *The BMJ.* 311(6999):237-242.

Thurmond VA. (2001) The point of triangulation. *J Nurs Scholarsh.* 33(3):253-258.

Torgerson DJ. (2001) Contamination in trials: is cluster randomisation the answer? *The BMJ.* 322(7282):355-357.

UKCC. (1998) *Guidelines for records and record keeping.* London: United Kingdom Central Council for Nursing, Midwifery and Health Visiting.

van Straten A, van der Meulen JH, van Crevel H et al. (1997) Quality of hospital care for stroke patients in The Netherlands. *Cerebrovasc Dis.* 7:251-257.

Walsh M. (1997) Will critical pathways replace the nursing process? *Nurs Stand.* 11(52):39-42.

Wee AS, Cooper WB, Chatham RK et al. (2000) The development of a stroke clinical pathway: an experience in a medium-sized community hospital. *J Miss State Med Assoc.* 41(7):648-653.

Wentworth DA, Atkinson RP. (1996) Implementation of an acute stroke program decreases hospitalization costs and length of stay. *Stroke.* 27(6):1040-1043.

Wigfield A, Boon E. (1996) Critical care pathway development: the way forward. *Br J Nurs.* 5(12):732-735.

Wigfield A, Gale G. (1998) Managed care: delivering the care of tomorrow today. *J Integrated Care.* 2:8-12.

Wilson J. (1999) Best practice guidelines. *Br J Nurs.* 8(5):293-294.

Woodyard LW, Sheetz JE. (1993) Critical pathway patient outcomes: the missing standard. *J Nurs Care Qual.* 8:51-57.

Woolf CR, Cass W, McElroy J. (1968) The use of "Program Evaluation and Review Technique" (PERT) in the design and control of a medical research project. *Comput Biomed Res.* 2(2):176-186.

Yandell B. (1995) Critical paths at Alliant Health System. *Qual Manag.Health Care.* 3(2):55-64.

Zander K. (1988) Nursing case management: strategic management of cost and quality outcomes. *J Nurs Adm.* 18(5):23-30.

CHAPTER THREE

EFFECTS OF INTEGRATED CARE PATHWAYS IN NON-STROKE CONDITIONS: A REVIEW OF THE RECENT LITERATURE

3.1 Background

Is there any evidence to support the use of ICPs in healthcare, and specifically, in the management of patients with acute stroke? To address this, I initially assessed the evidence from previous studies of ICPs for non-stroke conditions, and then the evidence from previous studies of ICPs for acute stroke. I anticipated that the process of examining the studies of ICPs for non-stroke conditions may facilitate the process of examining the studies of ICPs for acute stroke – for example: by further refining the search strategy; by informing about the possible outcome measures that should be assessed; and by highlighting the potential problems of data analysis.

In this chapter, I shall discuss the methods and findings of a literature review of ICPs for non-stroke conditions. Although the literature review was 'systematic' in nature, it was not intended to be exhaustive. In **Chapter 4**, I shall discuss the methods and findings of a Cochrane systematic review of ICPs for acute stroke.

3.2 Methods of the literature review

I sought all randomised controlled trials (RCTs) and non-randomised controlled trials that compared ICP care with conventional medical care for patients with non-stroke conditions. I searched MEDLINE from 1998 to June 2001 – I only searched for studies during the past three years because of the limited time and resources, and I wanted to concentrated on the latest studies. I used a detailed search strategy (see **Table 3.1**), which was designed with the help of the Cochrane Stroke Group.

Apart from controlled trials, I also considered studies of other weaker research designs, including before-and-after studies, interrupted time series, and comparative studies (see **Table 2.6** for definitions). However, I excluded publications that did not report original data (e.g. review articles, editorials) and studies that did not have a comparison group (e.g. open studies). Because of the limited time and resources, I only considered published reports written in English.

I screened all the titles and abstracts of reports identified by the search strategy and obtained full-text publications of those that were possibly relevant. I then screened the full-text reports and excluded the irrelevant ones.

Outcomes measures included: a) patient-specific outcomes (e.g. death, dependency, occurrence of complications); b) process of care (e.g. delay in care, patient education, use of appropriate tests); c) length of stay and hospital costs; and d) other outcomes (e.g. changes in physiological parameter, changes in life-style).

3.3 Results

Number of identified studies

I screened 476 titles, abstracts and keywords of publications, of which 39 were possible relevant. After examining the full-text version of these publications, 30 studies and two systematic reviews were included in the review. The characteristics of the included studies and systematic reviews are summarised in **Table 3.2**. Seven publications were excluded and the reasons for excluding them are presented in **Table 3.3**.

Characteristics of the included studies

Nine studies examined the effects of ICPs for medical conditions, 12 for surgical procedures, two for paediatric conditions, three for psychiatric conditions, and four for other conditions. There were also two systematic reviews of prospective studies of ICPs for psychiatric conditions. Of the 30 studies (a total of 28,378 patients), there were 12 RCTs (15,516 patients), one quasi-RCT (111 patients), one non-randomised controlled trials (349 patients), 14 before-and-after studies (11,558 patients), and two comparative studies (844 patients).

Methodological quality of the included studies

Amongst the RCTs, only one used blinded assessments of outcomes (Dougherty et al 2000), and another employed cluster randomisation of several hospitals (Marrie et al 2000). Two of the 14 before-and-after studies used a concurrent non-equivalent

control group (Bailey et al 1998; Chen et al 2000), but none of them has also included a historical non-equivalent control group.

To explore the influence of research design on the results of the studies, I divided the studies into prospective and retrospective ones. Prospective studies included the systematic reviews, RCTs and non-randomised controlled trials (total of 14 studies and 2 systematic reviews). Retrospective studies included the before-and-after studies and non-randomised comparative studies (total of 16 studies).

Results of the literature review

The results of the included studies and systematic reviews are summarised in **Table 3.2**. I shall therefore only provide a brief synopsis of the results for each of the four categories of outcome measures here. For the sake of simplicity, both the studies and systematic reviews will be known as 'reports' in this section.

Patient-specific outcomes

Ten reports found that ICPs improved patient-specific outcomes, 12 reports found that ICPs had no significant influence, and one report found that ICP worsened patient-specific outcomes. For example, Dougherty et al (2000) showed that ICP improved the control of anginal symptoms and quality of life; and Dowsey et al (1999) showed that ICP reduced the occurrence of complications after hip or knee arthroplasty. However, Spain et al (1998) – a before-and-after study – showed that the use of ICP was associated with a significantly higher mortality amongst patients with severe traumatic brain injury.

Process of care

Nine reports found that ICPs improved the process of care, five reports found that ICPs had no significant influence, and five reports found that ICPs worsened the process of care. For example, D'Amato et al (1998) showed that ICP reduced operational delay during hysterectomy. However, Marrie et al (2000) and Gagnon et al (1999) found that ICP increased the likelihood of being admitted to the hospital.

Length of stay and hospital cost

Seventeen reports found that ICPs reduced the length of stay or hospital cost, nine reports found that ICPs had no significant influence, and two reports found that ICPs actually increased the length of stay or hospital cost. For example, Hanna et al (1999) showed that ICP reduced the mean length of stay by 2.4 days and hospital cost by 14.4% amongst patients undergoing laryngectomy. However, Williams et al (1998a) and Issakidis et al (1999) showed that ICP increased the mean hospital cost.

Other outcomes

Four reports found that ICPs improved other outcomes, but no study reported neutral or negative effects of ICPs on other outcomes – this could possibly be a result of reporting or publication bias. For example, De Busk et al (1994) showed that ICP reduced the proportion of patients with coronary artery disease who continued to smoke; and Aubert et al (1998) showed that ICP reduced the fasting blood glucose level in patients with diabetes mellitus.

Prospective vs retrospective studies

This literature review has highlighted the wide variety of research designs that have been employed to evaluate the effects of ICPs for non-stroke conditions. Despite using a well-designed and specific search strategy to search for prospective controlled trials, many studies of weaker research designs, most notably before-and-after studies, were retrieved.

Table 3.4 summarises the nature of the results for each category of outcome for the prospective and retrospective studies. This is an exploratory exercise to see whether there are any significant differences in the reporting of positive, neutral and negative results between the prospective and retrospective studies. Overall, there did not seem to be any obvious difference. However, retrospective studies appeared to be more likely to report positive effects of ICP on the length of stay or hospital cost, compared with prospective studies.

3.4 Discussion

This literature review has found many randomised and non-randomised studies that have evaluated the effects of ICPs for non-stroke conditions. There was a surprisingly large number of prospective studies, and especially, RCTs. However, the majority of included studies were non-randomised and retrospective studies. Studies conducted using these weaker research designs are invariably susceptible to many biases and their results would therefore be less reliable and valid. This literature review was not intended to find every published and unpublished study that has ever been conducted, but rather it was meant to give an indication about the number and types of studies that have recently been published on this topic, and the nature of their reported findings.

I found that, even though there were 39 reports of positive findings, there were also 35 reports of neutral or negative effects of ICPs on the different outcomes. In particular, a significant number of reports have not provided evidence of beneficial effect, or have even found some evidence of harm, on patient-specific outcomes and process of care. In contrast, many reports appeared to have found that ICPs may be effective in reducing the length of stay and hospital cost. This finding could be because positive results on this particular outcome may be more likely to be reported (i.e. reporting bias), and positive reports of this outcome may in turn be more likely to be published (i.e. publication bias). If these biases exist, then the harmful effects of using ICPs could be under-reported in the medical literature, and any review of literature may therefore under-estimate the true harmful effects of using ICPs.

I found that the interventions and settings were very heterogeneous between the studies in this literature review, so an overall estimate of the effects of ICPs would be relatively meaningless. Nevertheless, the evidence may be accumulating that ICPs could be of benefit, but in order to reliably assess the balance of benefit and harms, one would need more focussed reviews with quantitative synthesis of the evidence (see **Chapter 4**).

Previous review articles on the topic of ICP have presumed that there would be very few prospective studies of ICPs, and it has been suggested that conclusions about the effects of ICP "*would have to be drawn from studies of weaker research designs*" (Hale 1995; Ellis & Johnson 1999). However, the present review of the recent literature has found many prospective trials of ICPs for non-stroke conditions; there were 12 RCTs published in the last three years alone. One should therefore interpret the conclusions of review articles with extreme caution, and if in doubt, one should refer to the original publications.

Implications for practice and research

From this non-quantitative review of the recent literature, one cannot draw overall conclusions about the effects of ICPs for non-stroke conditions or the balance of benefits and harms. However, an ongoing Cochrane systematic review, which is assessing the effects of case management on professional practice and other health-related outcomes, is seeking to address these issues in greater detail (Zwarenstein et al 2002).

3.5 Summary of this chapter

- In the last three years, there have been many published randomised and non-randomised studies that have evaluated the effects of ICPs for non-stroke conditions.
- Positive, neutral and negative findings have all been reported.
- There was no obvious difference in the nature of the reported findings between prospective and retrospective studies.
- An ongoing Cochrane systematic review on this topic should provide more information.

Table 3.1 Search strategy for the literature review of studies of ICPs for non-stroke conditions. Note: **lines 1-6** refer to the intervention, **lines 7-25** to the type of studies, and **lines 26-30** to our method of refining the search.

1. critical pathway/
2. case management/
3. exp Delivery of health care, integrated/
4. Managed care programs/
5. stroke program$.tw.
6. ((care or clinical or critical) adj5 (path$ or map$)).tw.

---

7. randomized controlled trial.pt.
8. randomized controlled trials/
9. controlled clinical trial.pt.
10. controlled clinical trials/
11. random allocation/
12. double-blind method/
13. single-blind method/
14. clinical trial.pt.
15. exp clinical trials/
16. (clin$ adj25 trial$).tw.
17. ((singl$ or doubl$ or tripl$ or trebl$) adj25 (blind$ or mask$)).tw.
18. random$.tw.
19. research design/
20. intervention studies/
21. meta-analysis.pt.
22. meta-analysis/
23. (meta?analysis or systematic review or overview).tw.
24. controls.tw.
25. (controlled adj (stud$ or trial$)).tw.

---

26. or/1-6
27. or/7-25
28. 26 and 27
29. limit 28 to human
30. limit 29 to english language

Table 3.2 Literature review of studies of ICPs for non-stroke conditions: characteristics and results of the included studies and systematic reviews, which are ranked according to speciality, then study design, then year (most recent first).

Speciality	Study design	Reference	Intervention	No of pts	Effects of ICP
Medicine	RCT	Nordmann et al 2001	ICP for ischaemic heart disease	201	▪ ICP increased proportion of patients with 'normal' cholesterol level. ▪ No change in BP control, absolute lipid values, fasting glucose level, body mass index or proportion of patients smoking.
Medicine	RCT, single-blind	Dougherty et al 2000	Outpatient ICP for angina	107	▪ ICP improved anginal control, patient satisfaction and quality of life at 3 and 6 months.
Medicine	RCT, cluster randomisation of 19 hospitals	Marrie et al 2000	ICP for community-acquired pneumonia	1743	▪ ICP increased admission of lower-risk patients and administration of single-class antibiotics. ▪ ICP reduced LOS. ▪ No change in mortality, complication rate, readmission, or quality of life.
Medicine	RCT	Gagnon et al 1999	ICP for 'frail old people'	427	▪ ICP increased admission to emergency room. ▪ No change in functional status, quality of life, patient satisfaction, admission to hospital, or LOS.
Medicine	RCT	Harris et al 1998	Intensive ICP for chronic renal failure	437	▪ ICP increased outpatient visits. ▪ No change in mortality, renal function, health service use in first 5 years.

Speciality	Study design	Reference	Intervention	No of pts	Effects of ICP
Medicine	RCT	Aubert et al 1998	ICP for diabetes mellitus	138	▪ ICP improved "health status". ▪ ICP reduced HbA1c and fasting glucose levels. ▪ No change in medications or dose, body weight, BP, lipids or adverse events.
Medicine	Before-and-after study	Cheah 2000	ICP for acute myocardial infarction	269	▪ ICP reduced LOS. ▪ No change in mortality, complication rate, or readmission.
Medicine	Before-and-after study with concurrent control	Bailey et al 1998	ICP for acute asthma	80	▪ ICP increased conversion from hand-held nebuliser to metered-dose inhaler. ▪ No change in LOS or patients discharged with peak flow meter or steroid.
Medicine	Non-randomised comparative study (selected controls)	Lob & Kohatsu 2000	ICP for diabetes mellitus	752	▪ ICP reduced LOS and admissions. ▪ No change in use of preventive services or visits to emergency room.
Surgery	RCT	Dowsey et al 1999	ICP for hip and knee arthroplasty	163	▪ ICP reduced mean LOS, delay from surgery to walking, complication rate, and readmission. ▪ ICP increased proportion of patients discharged home.
Surgery	Quasi-RCT	Choong et al 2000	ICP for fractured neck of femur	111	▪ ICP reduced LOS. ▪ No change in complication rate or readmission.
Surgery	Non-randomised controlled trial	D'Amato, Jr. et al 1998	ICP for hysterectomy	349	▪ ICP increased use of appropriate prophylactic antibiotics. ▪ ICP reduced delay in operating theatre. ▪ No change in LOS or readmission.

Speciality	Study design	Reference	Intervention	No of pts	Effects of ICP
Surgery	Before-and-after study	Pearson et al 2001	ICP for coronary bypass surgery, knee replacement, colectomy, thoracic surgery and hysterectomy	6796	▪ No change in LOS (similar trends of reducing LOS before and after ICP).
Surgery	Before-and-after study with concurrent control	Chen et al 2000	ICP for head and neck cancer surgery procedures	190	▪ No change in complication rate or readmission. ▪ ICP group had the lowest LOS and cost but result not statistically significant.
Surgery	Before-and-after study	Hwang et al 2000	ICP for breast reconstruction	69	▪ ICP reduced LOS and cost. ▪ No change in complication rate.
Surgery	Before-and-after study	Jano & Harlin 2000	ICP for carotid endarterectomy	81	▪ ICP reduced LOS and cost.
Surgery	Before-and-after study	Chan & Wong 1999	ICP for urology (18 different procedures)	2661	▪ ICP reduced complication rate, pain, and use of intravenous antibiotics. ▪ ICP reduced mean LOS and cost.
Surgery	Before-and-after study	Hanna et al 1999	ICP for total laryngectomy	45	▪ ICP reduced LOS, cost, and readmission.
Surgery	Before-and-after study	Spain et al 1998	ICP for traumatic brain injury (neurosurgery)	133	▪ ICP increased mortality. ▪ ICP reduced LOS in intensive care and period of ventilation amongst survivors. ▪ No change in other functional outcomes or complication rate.
Surgery	Before-and-after study	Williams et al 1998a	ICP for surgery and anaesthetics (conditions not specified)	505	▪ ICP increased cost but reduced cost variability. ▪ ICP reduced post-operative admission.

Speciality	Study design	Reference	Intervention	No of pts	Effects of ICP
Surgery	Non-randomised comparative study	Kelly, Jr. et al 2000	ICP for paediatric inguinal hernia repair	92	▪ ICP reduced cost. ▪ No change in wound infection rate, readmission, or duration of operation.
Paediatrics	RCT	Johnson et al 2000	ICP for acute asthma	110	▪ ICP reduced use of nebulised beta-agonist and LOS.
Paediatrics	Before-and-after study	Kelly et al 2000	ICP for acute asthma	68	▪ ICP increased patient education and % discharged with peak flow meter and spacer device. ▪ ICP reduced LOS and cost.
Psychiatry	Systematic review (Cochrane)	Marshall et al 2002	ICP/case management for severely mental illness (conditions not specified)	11 RCTs with 700 patients	▪ ICP increased proportion of patients in contact with services and admission to hospital. ▪ No change in functional or social status, or cost.
Psychiatry	Systematic review (non-Cochrane)	Ziguras & Stuart 2000	ICP/case management for mental illness (conditions not specified)	44 studies	▪ ICP increased admission to hospital and family satisfaction. ▪ ICP reduced LOS and cost.
Psychiatry	RCT	Burns et al 1999	Intensive vs standard case management for severe psychotic illness	708	▪ No change in admission to hospital, psychiatric or social functioning.
Psychiatry	RCT	Issakidis et al 1999	Intensive vs standard case management for schizophrenia and bipolar disorder	73	▪ Intensive case management improved social functioning and compliance to therapy. ▪ Intensive case management increased cost. ▪ No change in admission to hospital or LOS.
Psychiatry	Before-and-after study	Preston & Fazio 2000	Intensive case management for chronic mental illness	160	▪ Case management reduced use of inpatient service and cost.

Speciality	Study design	Reference	Intervention	No of pts	Effects of ICP
Others	RCT	Hodgkinson et al 2001	Nurse-led ICP for geriatric patients in general practice	5000	▪ ICP increased health status, patient information provided, and 'some measures' of patient satisfaction and quality of life.
Others	RCT	Boult et al 2000	Social-work-oriented ICP for 'older people'	6409	▪ No change in cost of healthcare.
Others	Before-and-after study	Wong et al 2000	ICP for oxygen therapy	130	▪ ICP increased 'discontinuation orders' and cost. ▪ No change in prescription of oxygen (dose and duration), frequency of oxygen saturation or blood gas monitoring, or clinical outcome.
Others	Before-and-after study	de Luc 2000	ICPs for breast and maternity care	371	▪ Maternity care ICP reduced LOS. ▪ Maternity care ICP increased patient satisfaction. ▪ No change in LOS or patient satisfaction for breast care ICP.

Note:

LOS Length of stay

RCT Randomised controlled trial

Table 3.3 Reasons for excluding seven publications from the literature review.

Speciality	Reference	Intervention	Reason for exclusion
Medicine	Oliver et al 2000	ICP for acute myocardial infarction	Inadequate information on methodology.
Surgery	Patterson et al 1999	ICP for traumatic brain injury (neurosurgery)	Systematic review with one useful study, Greenwood 1994, the data of which are presented in Table 3.2.
Surgery	Worwag & Chodak 1998	ICP for radical prostatectomy	Open study with no comparison group (only post-ICP data collected).
Surgery	Williams et al 1998b	ICP for surgery and anaesthetics (conditions not specified)	Dual publication (same trial as Williams 1998a).
Surgery	Edwards, Sr. et al 1996	ICP for vascular surgery	Open study.
Psychiatry	Johnston et al 1998	Intensive vs standard ICP for schizophrenia and bipolar disorder	Dual publication (same trial as Issakidis 1999).
Nursing	Moloney & Maggs 1999	Conditions not specified	Literature review with no trial data presented.

Table 3.4 Prospective vs retrospective studies. This table presents the nature of the reported results according to the study design. Numbers (n) represent numbers of studies that have reported positive, neutral and negative results for each category of outcome.

Category of clinical outcome	Reported result			
	Positive n (%)	**Neutral** n (%)	**Negative** n (%)	**Total** n
Patient-specific				
Prospective	7 (50)	7 (50)	0	**14**
Retrospective	3 (30)	6 (60)	1 (10)	**10**
Process of care				
Prospective	5 (45)	2 (18)	4 (36)	**11**
Retrospective	4 (50)	3 (38)	1 (13)	**8**
Length of stay and cost				
Prospective	4 (36)	6 (55)	1 (9)	**11**
Retrospective	12 (75)	3 (19)	1 (6)	**16**
Others				
Prospective	3 (100)	0	0	**3**
Retrospective	1 (100)	0	0	**1**
Total				
Prospective	**19**	**15**	**5**	-
Retrospective	**20**	**12**	**3**	-

References for Chapter 3

Aubert RE, Herman WH, Waters J et al. (1998) Nurse case management to improve glycemic control in diabetic patients in a health maintenance organization. A randomized, controlled trial. *Ann Intern Med.* 129(8):605-612.

Bailey R, Weingarten S, Lewis M et al. (1998) Impact of clinical pathways and practice guidelines on the management of acute exacerbations of bronchial asthma. *Chest.* 113(1):28-33.

Boult C, Rassen J, Rassen A et al. (2000) The effect of case management on the costs of health care for enrollees in Medicare Plus Choice plans: a randomized trial. *J Am Geriatr Soc.* 48(8):996-1001.

Burns T, Creed F, Fahy T et al. (1999) Intensive versus standard case management for severe psychotic illness: a randomised trial. UK 700 Group. *Lancet.* 353(9171):2185-2189.

Chan SW, Wong KF. (1999) The use of critical pathways in caring for schizophrenic patients in a mental hospital. *Arch Psychiatr Nurs.* 13:145-153.

Cheah J. (2000) Clinical pathways - an evaluation of its impact on the quality of care in an acute care general hospital in Singapore. *Singapore Med J.* 41(7):335-346.

Chen AY, Callender D, Mansyur C et al. (2000) The impact of clinical pathways on the practice of head and neck oncologic surgery: the University of Texas M. D. Anderson Cancer Center Experience. *Arch Otolaryngol Head Neck Surg.* 126(3):322-326.

Choong PF, Langford AK, Dowsey MM et al. (2000) Clinical pathway for fractured neck of femur: a prospective, controlled study. *Med J Aust.* 172(9):423-426.

D'Amato LO, Jr., Talmage LA, Hyde K et al. (1998) Outcomes in abdominal hysterectomy patients with benign disease. Use of physician-developed clinical protocols. *J Reprod Med.* 43(11):975-985.

de Luc K. (2000) Care pathways: an evaluation of their effectiveness. *J Adv Nurs.* 32(2):485-496.

Dougherty CM, Spertus JA, Dewhurst TA et al. (2000) Outpatient nursing case management for cardiovascular disease. [Review] [36 refs]. *Nurs Clin N Am.* 35(4):993-1003.

Dowsey MM, Kilgour ML, Santamaria NM et al. (1999) Clinical pathways in hip and knee arthroplasty: a prospective randomised controlled study. *Med J Aust.* 170(2):59-62.

Edwards WH, Sr., Edwards WH, Jr., Martin RS, III et al. (1996) Resource utilization and pathways: meeting the challenge of cost containment. *Am Surg.* 62(10):830-834.

Ellis BW, Johnson S. (1999) The care pathway: a tool to enhance clinical governance. *Br J Clin Governance.* 4(2):61-71.

Gagnon AJ, Schein C, McVey L et al. (1999) Randomized controlled trial of nurse case management of frail older people. *J Am Geriatr Soc.* 47(9):1118-1124.

Hale C. (1995) Research issues in case management. *Nurs Stand.* 9(44):29-32.

Hanna E, Schultz S, Doctor D et al. (1999) Development and implementation of a clinical pathway for patients undergoing total laryngectomy: impact on cost and quality of care. *Arch Otolaryngol Head Neck Surg.* 125(11):1247-1251.

Harris LE, Luft FC, Rudy DW et al. (1998) Effects of multidisciplinary case management in patients with chronic renal insufficiency. [see comments]. *Am J Med.* 105(6):464-471.

Hodgkinson J, Townsend J, McKinnon M et al. (2001) Evaluation of nurse-led case management of older patients [abstract]. *Age Ageing.* 30(Suppl 1):41.

Hwang TG, Wilkins EG, Lowery JC et al. (2000) Implementation and evaluation of a clinical pathway for TRAM breast reconstruction. *Plastic & Reconstructive Surg.* 105(2):541-548.

Issakidis C, Sanderson K, Teesson M et al. (1999) Intensive case management in Australia: a randomized controlled trial. *Acta Psychiatrica Scandinavica.* 99(5):360-367.

Jano S, Harlin SA. (2000) Designing a carotid endarterectomy critical pathway for your organization. *Military Medicine.* 165(5):385-389.

Johnson KB, Blaisdell CJ, Walker A et al. (2000) Effectiveness of a clinical pathway for inpatient asthma management. *Pediatrics.* 106(5):1006-1012.

Johnston S, Salkeld G, Sanderson K et al. (1998) Intensive case management: a cost-effectiveness analysis. *Aust N Z J Psychiatr.* 32(4):551-559.

Kelly CS, Andersen CL, Pestian JP et al. (2000) Improved outcomes for hospitalized asthmatic children using a clinical pathway. *Annals of Allergy, Asthma, & Immunology.* 84(5):509-516.

Kelly RE, Jr., Wenger A, Horton C, Jr. et al. (2000) The effects of a pediatric unilateral inguinal hernia clinical pathway on quality and cost. *J Pediatr Surg.* 35(7):1045-1048.

Lob SH, Kohatsu ND. (2000) Case management: a controlled evaluation of persons with diabetes. *Clinical Performance & Quality Health Care.* 8(2):105-111.

Marrie TJ, Lau CY, Wheeler SL et al. (2000) A controlled trial of a critical pathway for treatment of community-acquired pneumonia. CAPITAL Study Investigators. Community-Acquired Pneumonia Intervention Trial Assessing Levofloxacin. *JAMA.* 283(6):749-755.

Marshall M, Gray A, Lockwood A et al.Case management for people with severe mental disorders (Cochrane systematic review). In: *Cochrane Library, Issue 2, 2002.* Oxford: Update Software.

Moloney R, Maggs C. (1999) A systematic review of the relationships between written manual nursing care planning, record keeping and patient outcomes. *J Adv Nurs.* 30(1):51-57.

Nordmann A, Heilmbauer I, Walker T et al. (2001) A case-management program of medium intensity does not improve cardiovascular risk factor control in coronary artery disease patients: the Heartcare I trial. *Am J Med.* 110(7):543-550.

Oliver CM, Why H, Dutoy K et al. (2000) Introduction of an evidence-based care pathway for acute coronary syndromes has led to changes in practice and improved patient care. *J Integrated Care.* 4(1):42.

Patterson PK, Maynard H, Chesnut RM et al. (1999) Evidence of case management effect on traumatic-brain-injured adults in rehabilitation. *Care Manag J.* 1(2):87-97.

Pearson SD, Kleefield SF, Soukop JR et al. (2001) Critical pathways intervention to reduce length of hospital stay. *Am J Med.* 110(3):175-180.

Preston NJ, Fazio S. (2000) Establishing the efficacy and cost effectiveness of community intensive case management of long-term mentally ill: a matched control group study. *Aust N Z J Psychiatr.* 34(1):114-121.

Spain DA, McIlvoy LH, Fix SE et al. (1998) Effect of a clinical pathway for severe traumatic brain injury on resource utilization. *J Trauma-Injury Infection & Critical Care.* 45(1):101-104.

Williams BA, DeRiso BM, Engel LB et al. (1998b) Benchmarking the perioperative process: II. Introducing anesthesia clinical pathways to improve processes and outcomes and to reduce nursing labor intensity in ambulatory orthopedic surgery. *J Clin Anesthesia.* 10(7):561-569.

Williams BA, DeRiso BM, Figallo CM et al. (1998a) Benchmarking the perioperative process: III. Effects of regional anesthesia clinical pathway techniques on process efficiency and recovery profiles in ambulatory orthopedic surgery. *J Clin Anesthesia.* 10(7):570-578.

Wong C, Visram F, Cook D et al. (2000) Development, dissemination, implementation and evaluation of a clinical pathway for oxygen therapy. *CMAJ.* 162(1):29-33.

Worwag E, Chodak GW. (1998) Overnight hospitalization after radical prostatectomy: the impact of two clinical pathways on patient satisfaction, length of hospitalization, and morbidity. *Anesthesia & Analgesia.* 87(1):62-67.

Ziguras SJ, Stuart GW. (2000) A meta-analysis of the effectiveness of mental health case management over 20 years. *Psychiatric Services.* 51(11):1410-1421.

Zwarenstein M, Stephenson B, Johnston L. (2002) Case management: effects on professional practice and health care outcomes (Protocol for a Cochrane Review). In: *The Cochrane Library, Issue 2, 2002.* Oxford: Update Software.

CHAPTER FOUR

EFFECTS OF INTEGRATED CARE PATHWAYS IN ACUTE STROKE: A SYSTEMATIC REVIEW OF THE LITERATURE

4.1 Background

Guidance on how stroke care should be organised or coordinated is lacking

Professional bodies have been calling for stroke services to be more organised and better co-ordinated, but there is currently little guidance on how this can be achieved (RCP 2001). Even though strategies such as holding weekly multidisciplinary team meetings are recommended to promote organised stroke care, there are no other practical guidelines on how to improve the organisation and co-ordination of *routine* patient care. This lack of guidance may in part explain why, over five years after the first published guidelines recommended the widespread adoption of organised stroke care, there are still substantial variations in the process of stroke care in the UK (Aboderin & Venables 1996; Rudd et al 2001).

Different forms of stroke integrated care pathways

ICPs for in-hospital management of stroke were originally developed in the USA with the primary objective of cost-containment (Zander 1988). Since then, many forms of stroke ICPs have been developed, such as those used to aid the diagnosis of acute stroke and guide the physician in deciding whether the patient is suitable for thrombolytic therapy (Hickman 1998; Broderick 1998). Others have been developed to guide patient care in the community after hospital discharge (Dignan et al 1986; Schmidt et al 1999). In general, stroke ICPs can be broadly divided into three categories: a) those used for acute stroke management only; b) those used for stroke rehabilitation only; and c) those used for both acute stroke management and stroke rehabilitation.

Integrated care pathways for acute stroke management

Management of acute stroke is complex, consisting of many components including thorough clinical assessment, urgent investigations, assessment of the patient for thrombolysis, correction of deranged physiological parameters, prevention and treatment of early complications, and commencement of secondary preventive measures. Effective acute stroke management therefore requires an organised and highly trained team of healthcare professionals, working efficiently within a well-equipped and dedicated stroke service structure (Adams, Jr. et al 1996; Broderick 1998). However, recent surveys have demonstrated that many hospitals were not providing a high quality acute stroke service (Ebrahim & Redfern 1999; Roberts 2001). It is conceivable that ICPs, with their many potential advantages as outlined in **Chapter 2**, could help to improve acute stroke care and standardise practice (Langhorne & Dennis 1998). For instance, ICPs could help to ensure that physiological disturbances are appropriately managed soon after stroke onset, and that aspirin is started in those patients whose CT scans have excluded haemorrhage, in accordance with the National Service Framework for Older People (DoH 2001).

During the acute phase of stroke, individually-tailored treatment strategy is important because stroke patients often have multiple medical problems and their course of illness can be unpredictable (Warlow et al 2000). These factors should in theory make ICPs for acute stroke management more difficult to design and implement (Anon. 1995). Despite this, there are many examples of ICPs for acute stroke management across the world (Zander 1988; Pasquarello 1990; Bowen & Yaste 1994; Odderson et al 1995; Abissi et al 1995; Wentworth & Atkinson 1996; Duryee

et al 1996; Ramachandran et al 1996; Barch et al 1997; Ross et al 1997; Lagoe & Aspling 1997; Hainsworth et al 1997; Baker et al 1998; Summers & Soper 1998; Jungkind & Corish 1999; Wilkinson et al 2000). When Zander et al were designing their stroke ICP, they found that the physicians often had individual preferences regarding treatment strategies for certain groups of patients. Interestingly, the authors recommended designing "*a different critical path for each physician*" (Zander 1988)! Not only would this be unworkable in most hospitals, this practice would more importantly be in direct conflict with one of the major objectives of using ICPs, which is to use forms of healthcare interventions that are based on good evidence (and not just on the physician's opinion), in a consistent and standardised manner.

Integrated care pathways for stroke rehabilitation

One to two weeks after stroke onset, patients with significant residual neurological deficits are usually transferred to a stroke rehabilitation unit (Dennis & Langhorne 1994). During rehabilitation, the stroke patient is usually medically more stable. However, neurological problems (e.g. communication problems, dysphagia, incontinence), and complications (e.g. chest infections, depression, painful shoulder), though not immediately life-threatening, can add significantly to the patient's impairment, disability and handicap. Meticulous attention to the prevention and early treatment of complications is important, which may in turn lead to improved outcome. The more efficiently and equitably such interventions are applied, the more patients are likely to benefit. Moreover, prior to discharge, secondary preventive treatments (Anderson et al 1994) should be given according the latest evidence and clinical guidelines (SIGN 1997; SIGN 1998; RCP 2001).

ICPs for stroke rehabilitation are potentially useful in enhancing the process of stroke rehabilitation, for example, by improving organisation, increasing multidisciplinary communication, and facilitating the application of evidence and guideline recommendations (Langhorne & Dennis 1998). There are several reports of the use of ICPs for stroke rehabilitation in the literature, some of which have been associated with positive results (Romito 1990; Falconer et al 1993; Goldberg et al 1997; Quigley et al 1998; Schmidt et al 1999; Sulch et al 2000).

Integrated care pathways for acute stroke management and stroke rehabilitation

Some ICPs have been designed for both acute stroke management and stroke rehabilitation (Dignan et al 1986; Hamrin & Lindmark 1990; Schull et al 1992; Crawley 1996; Moloney et al 1999; Rosenberger & Wiemers 1999; Wee et al 2000; Jones et al 2001). This type of ICP may be particularly useful in hospitals which have a combined acute and rehabilitation stroke unit.

Effectiveness of integrated care pathways may depend on the basic structure of the stroke service

Many experienced physicians believe that ICPs can only be effective in improving stroke care if the basic structure of the stroke service is already in place, such as the routine admission of patients to a stroke unit where patient care is provided by a team of motivated and skilled healthcare professionals (Gainer 1996; Lanska 1998). If the basic structure is not in place (e.g. if stroke patients are managed by different medical teams in several general medical wards), then ICPs are less likely to significantly influence the process of care since there would be many barriers in

terms of the development, implementation and operation of the ICP (Luttman 1993). It is therefore common to find that ICPs are introduced as part of an overall quality improvement scheme, rather than as a stand-alone organisational intervention (Ringel & Hughes 1996).

How frequently are integrated care pathways being introduced for stroke management in the UK?

Two postal questionnaire surveys were conducted to determine how frequently stroke ICPs were implemented in Scotland and the UK (unpublished data). The first one, which was conducted in 2000, was a postal questionnaire survey of all the Scottish hospitals that provided stroke care. Twenty-eight hospitals were surveyed and all of them responded. It showed that: 5/28 (18%) hospitals were using stroke ICPs; 11 (39%) were planning to introduce stroke ICPs in the near future; 2 (7%) have used stroke ICPs in the past but the ICPs concerned have been abandoned; and 10 (36%) were not using stroke ICPs and had no plan to introduce them. Of the latter 10 hospitals which had no plan to introduce stroke ICPs, the reasons given were: a) there was no convincing evidence of benefit (5 hospitals, 50%); b) discussion with colleagues had dissuaded them from implementing stroke ICPs (3 hospitals, 30%); and c) other reasons.

The same questions were posed in a second postal questionnaire survey in 2000, conducted by the British Association of Stroke Physicians (BASP) as part of the Benchmarking Survey of Stroke Services 2000. All the members of the BASP (from 40 acute stroke units) were surveyed and stroke consultants from 30 acute stroke

units responded (75% response rate). Of the 30 acute stroke units: 14 (47%) hospitals were using stroke ICPs; 12 (40%) were planning to introduce stroke ICPs in the near future; 2 (7%) have used stroke ICPs in the past but the ICPs concerned have been abandoned; and 2 (7%) were not using stroke ICPs and had no plan to introduce them. Of the 2 latter hospitals which had no plan to introduce stroke ICPs, the reasons were: a) there was no convincing evidence of benefit (1 hospital); and b) the process of design and implementation would take too much time (1 hospital).

In summary, these two recent surveys showed that many of the hospitals in the survey – 57% of the hospitals in Scotland and 87% of the hospitals in the UK – were either already using stroke ICPs or had plans to implement them in the near future.

Is the implementation of stroke integrated care pathways supported by good evidence?

Despite the widespread implementation of stroke ICPs, there are still many uncertainties about their effects and how they should be developed, implemented and evaluated (Pearson et al 1995). Underlying these concerns is that, like many other promising technologies and organisational tools, the implementation of stroke ICPs is recommended *before* well-conducted trials have provided evidence of net benefit (Pearson et al 1995; Sulch & Kalra 2000).

There have been few attempts to review the literature for previous studies of stroke ICPs (Lanska 1998; Sulch & Kalra 2000). Some general review articles simply stated that there have been no controlled studies of stroke ICPs (Pearson et al 1995). A

more recent literature review on stroke ICPs was performed by Sulch et al (2000). The authors identified and described the results of seven studies (Odderson & McKenna 1993; Bowen & Yaste 1994; Wentworth & Atkinson 1996; Ross et al 1997; Anon. 1998; Summers & Soper 1998). Six of these were non-randomised studies of acute stroke ICPs, and one was a RCT of a stroke rehabilitation ICP. Three of the non-randomised studies were before-and-after studies (Odderson & McKenna 1993; Bowen & Yaste 1994; Ross et al 1997), two were open studies (Wentworth & Atkinson 1996; Summers & Soper 1998), and one study did not describe its study methodology at all (Anon. 1998). Although most studies appeared to demonstrate a reduction in length of stay, the authors of the review concluded that the effects of stroke ICPs were unclear (Sulch & Kalra 2000).

There are three major problems with the methodology of the literature review by Sulch et al (2000). Firstly, the search strategy described was very limited and did not take into account of the complex nature of the intervention, and important studies could have been missed as a result. Secondly, there was no mention of the date on which the electronic databases were searched, making it impossible to determine how up-to-date the review was. Finally, it was unclear whether any effort was made to (hand-)search for unpublished or non-English articles (Kwan 2000).

With this in mind, I undertook a Cochrane systematic review to assess the effects of ICPs, as compared to standard medical care, among patients with acute stroke who had been admitted to hospital. This review was aimed to: a) be more up to date; b) employ a more comprehensive search strategy; c) search for studies from a wider

variety of bibliographic sources; and d) use the standardised methods of the Cochrane Collaboration.

4.2 Methods of the systematic review

Criteria for considering studies for this review

Types of studies

I sought unconfounded RCTs that compared ICP care versus standard medical care. However, since I anticipated that there would only be a few of these studies, I also sought studies with weaker research designs, i.e. quasi-randomised trials, controlled and uncontrolled before-and-after studies, and interrupted time series. I sought studies with at least two study groups for comparison, with due allowance for the large number of biases that are likely to be associated with non-randomised designs. I included only studies with an adequate description of its methodology such that studies claiming certain effects of ICPs but without adequate information were to be excluded.

Types of participants

I used the World Health Organisation definition of stroke for this review (WHO 1989). I included all studies that recruited patients who had been admitted to hospital with a new neurological deficit consistent with a clinical diagnosis of stroke. However, I excluded studies that recruited only patients with subarachnoid haemorrhage since the management of these patients would have been very different to the generality of stroke patients. Studies that recruited all types of ischaemic and haemorrhagic strokes (including subarachnoid haemorrhage) were included. I also included studies that recruited patients with a mixture of conditions including stroke, but only where the results for stroke patients could be clearly extracted.

Types of interventions

For this systematic review, I used the definition of an ICP as described in **Chapter 2**, i.e. a plan of care that: a) involved two or more disciplines; and b) involved two or more of the following aspects of care: assessment, investigation, diagnosis, and treatment. Furthermore, I anticipated that there would be three main clinical settings for which ICPs were designed: a) for acute stroke only; b) for stroke rehabilitation only; and c) for acute stroke and rehabilitation.

I also included studies that examined "case management", "disease management", "stroke protocols", or "stroke programmes" only if the description of the intervention satisfied the above definition. I excluded studies of ICPs that had been designed for a single aspect of care (e.g. diagnosis, administration of thrombolytic therapy), as well as those designed for patients undergoing carotid endarterectomy. I sought advice from the Cochrane Effective Practice and Organisation of Care (EPOC) group regarding the definition of an ICP for this review.

Types of outcome measures

The primary outcome measure was the proportion of patients who were dead or dependent at the end of the scheduled follow-up period. For studies that did not systematically report dependency, I sought data on the proportion of patients who required long-term institutional care. "Independent" individuals were defined as those who did not require regular physical assistance from another person for activities of daily living, such as mobility, dressing, transfers, and feeding. "Dependent" individuals were those who failed to meet one or more of these criteria.

The criteria for independence were approximately equivalent to a modified Rankin score of 0 to 2, or a Barthel Index of greater than 18/20 (Wade 1992). Institutional care was defined as care within a residential home, nursing home, or hospital at the end of scheduled follow up or at discharge.

Secondary outcome measures included:

1. Occurrence of complications during the hospital stay (e.g. pneumonia, urinary tract infection, deep vein thrombosis, skin breakdown);
2. Readmission or emergency department attendance;
3. Use of investigations (e.g. proportion of patients having a computed tomography brain scan or carotid duplex study);
4. Patient and carer satisfaction;
5. Duration of hospital stay;
6. Cost of hospitalisation;
7. Quality of life (using recognised scoring system such as SF36 and Euroqol).

Search strategy for identification of studies

This review drew on the search strategy developed for the Cochrane Stroke Group as a whole. The Cochrane Stroke Group Specialised Trials Register was searched on 8th May 2001. In addition, I undertook specialised searches of the following electronic databases:

- Cochrane Controlled Trials Register (CCTR/Central, Issue 4, 2001) - 159 reports identified
- MEDLINE (1975 to 2000) - 4503 reports identified

- EMBASE (1980 to 2000) - 3673 reports identified
- CINAHL (1982 to 2000) - 470 reports identified
- The Index to Scientific and Technical Proceedings (ISTP, May 2001) - a database of conference proceedings on ISI Web of Science Services (Web of Science Proceedings, WOSP) - no report identified
- HealthSTAR (May 2001) - an online bibliographic database that provides access to published literature of Health Services Technology, administration, and research - 54 reports identified

As I mentioned in **Chapter 2**, ICPs for health care have only existed since the beginning of 1980s. I therefore only searched MEDLINE from 1975 onwards. I handsearched the entire collection of the Journal of Managed Care (1997 to 1998), which was later renamed the Journal of Integrated Care (1998 to 2001). I also checked the reference lists of the papers retrieved from the above searches and attempted to contact authors of relevant papers where clarification of information was needed. Personal contact with colleagues and researchers identified ongoing and unpublished studies. The search strategy for MEDLINE can be found in **Table 4.1**.

Methods of the review

Selection of trials

I screened all the titles, abstracts and keywords of publications identified by the searches to assess their eligibility. I was blinded to the names of the authors, institution where the work had been carried out, and the journal (by printing out the titles, abstracts and keywords without the author names etc). Publications that clearly

did not meet the inclusion criteria were excluded at this stage. Another reviewer (PS) then independently checked the decisions. We then obtained a paper copy of the full publication of every study that was possibly relevant. Both reviewers then assessed them according to pre-specified selection criteria. We excluded articles that did not contain results of any study (e.g. a report simply describing a new ICP). We resolved any disagreement by discussion.

Assessment of methodological quality

PS and I independently assessed the methodological quality of all the included studies and recorded the findings. We noted the important aspects of methodology: study design, type of control, method of allocation concealment, completeness of follow-up, and the presence of blinding for assessments of non-fatal outcomes. We did not use pre-printed selection forms or an overall scoring system to evaluate methodological quality.

Data extraction

I extracted the data onto a data extraction form, and PS independently checked the extracted data. I attempted to contact the chief investigator of the studies where clarification or additional data were needed. Pilot testing of the data collection forms was done on a sample of studies to improve reliability. Disagreement was resolved by discussion and a consensus decision was made.

Data analysis

Data analysis abided by the guidelines set out by the Cochrane Collaboration

regarding statistical methods and I also consulted a statistician throughout the review (Mulrow & Oxman 2002). For dichotomous data, I expressed relative treatment effects as odds ratios with 95% confidence intervals. For continuous data, I used weighted mean difference with 95% confidence intervals. A P value of less than 0.05 was taken as significant. The denominators used in the analyses were the total numbers of patients included in the studies; dead patients have not been removed from any comparison groups.

Heterogeneity between studies was tested using the standard chi-squared test. I found significant heterogeneity in 2 of the 24 main outcome measures (i.e. performance of first or second CT scan, and duration of hospital stay). I used a 'random effects' method for all outcome measures. However, it should be noted that the 'random effects' method gives more weight to the smaller studies than the 'fixed effects' method, and smaller studies are often of poorer quality and may be more susceptible to bias (Mulrow & Oxman 2001). Because of the presence of between-study variations for certain outcome measures, one should be cautious when interpreting these results.

Description of studies

I screened a total of 8859 titles, abstracts and keywords of publications. I excluded 8616 of these immediately and retrieved 243 full-text publications. From these 243 publications, only 51 were descriptions of studies. I included three randomised controlled trials (total of 340 patients) and seven non-randomised studies (total of 1673 patients) that compared ICP care with standard care. All included studies were

published in the English language. Thirty-eight studies were excluded for the following reasons (some studies were excluded for more than one reason) (see **Table 4.2**):

Excluded randomised studies:

- Community-based intervention (1 study, Goldberg et al 1997)
- The intervention tested did not fulfil the criteria for a ICP (1 study, Pearson et al 1988)

Excluded non-randomised studies:

- The intervention tested in this study did not fulfil the definition criteria for a ICP (17 studies)
- The participants recruited in this study did not suffer a condition that fulfilled the definition for a stroke (2 studies)
- Claims of some beneficial effects of a new ICP but there was inadequate information on the intervention and the methodology of the study (6 studies)
- All data were collected after the introduction of the intervention (6 studies)
- Community-based (or mixed hospital- and community-based) intervention (2 studies)
- Other reasons (5 studies)

Included randomised studies

I included three randomised controlled trials. Two studies (Falconer et al 1993; Sulch et al 2000) included patients with all types of stroke, whereas one study (Schull et al 1992) only included patients with ischaemic stroke. The intervention tested was

generally well described and were known by different names: "critical path method" (Falconer et al 1993), "case managed care with anticipatory comprehensive planning" (Schull et al 1992) and "integrated (managed) ICP" (Sulch et al 2000). The common elements of care shared by all these interventions included the involvement of multiple disciplines, setting of pre-defined patient goals and therapeutic activities, and regular multidisciplinary team meetings. In one study, the ICP was computer-generated (Falconer et al 1993); in another study, it was a paper document that became part of the patient's case notes (Sulch et al 2000); in the third study, it was called an "anticipatory comprehensive planning" but it was unclear whether it involved a paper document (Schull et al 1992). The ICPs were implemented for stroke rehabilitation in two studies (Falconer et al 1993; Sulch et al 2000), and for acute stroke and rehabilitation in one study (Schull et al 1992). The patient care given to the control groups was poorly defined in every study, but in two studies, it was simply described as multidisciplinary care with regular team meetings to discuss patients' progress (Falconer et al 1993; Sulch et al 2000).

Included non-randomised studies

I included one retrospective comparative study (Baker et al 1998) and six before-and-after studies (Pasquarello 1990; Hamrin & Lindmark 1990; Odderson & McKenna 1993; Bowen & Yaste 1994; Crawley 1996; Ross et al 1997), two of which had a concurrent control group (Bowen & Yaste 1994; Ross et al 1997). None were truly controlled before-and-after studies (i.e. those with a non-equivalent control group). Two studies (Hamrin & Lindmark 1990; Bowen & Yaste 1994) included strokes of all types and transient ischaemic attacks, whereas five studies

(Pasquarello 1990; Odderson & McKenna 1993; Crawley 1996; Ross et al 1997; Baker et al 1998) included only ischaemic strokes. The interventions tested were known by different names: "case managed care" (Crawley 1996; Baker et al 1998), "clinical or critical pathway" (Odderson & McKenna 1993; Ross et al 1997), "multidisciplinary stroke protocol or programme" (Pasquarello 1990; Bowen & Yaste 1994), and "systematic care planning with care plans" (Hamrin & Lindmark 1990). The interventions were less well described than in randomised studies and the common elements of care included the involvement of multiple disciplines and care planning with specific care protocol. The ICPs involved paper documents in five studies (Hamrin & Lindmark 1990; Odderson & McKenna 1993; Bowen & Yaste 1994; Ross et al 1997; Baker et al 1998), whereas it was unclear in two studies (Pasquarello 1990; Crawley 1996). The ICPs were implemented for acute stroke in five studies (Pasquarello 1990; Odderson & McKenna 1993; Bowen & Yaste 1994; Ross et al 1997; Baker et al 1998) and for acute stroke and rehabilitation in two studies (Hamrin & Lindmark 1990; Crawley 1996). Three of the acute stroke ICPs began with treatment at the emergency department (e.g. thrombolytic therapy) (Bowen & Yaste 1994; Ross et al 1997; Baker et al 1998). The patient care provided by the control groups was very poorly described.

In both the randomised and non-randomised studies, the outcome measures and length of follow-up were very variable between studies. It was therefore difficult to perform quantitative analyses for some outcome measures. For example, one study reported the median Barthel index as a measure of disability (Sulch et al 2000), but another study reported the mean functional independence measure (Falconer et al

1993). For continuous variables, some studies reported the means without standard deviations, whereas some reported the medians. Since means are influenced by extremes of values, our data analyses could only use means if the standard deviations were also reported. Where cost was reported, some studies have used the actual mean hospitalisation cost in US dollars (e.g. Schull et al 1992; Crawley 1996), whereas some have calculated the relative reduction in percentage (e.g. Odderson & McKenna 1993). Many studies simply reported "*no difference*" for some outcome measures but no data were presented.

Methodological quality of included studies

Randomised studies

The reporting of methodology was adequate only in one study (Sulch et al 2000). In this study, randomisation was performed by computer in blocks of ten but the method of concealing treatment allocation was not stated. No randomised patient was reported to have crossed over to the other group. The medical care that the patients received before randomisation was not defined, nor was the location of acute care (e.g. acute stroke unit or general medical ward). The study stated that the treatment and control groups were managed by two "*separate teams of nurses*", but it did not state whether the doctors, therapists, or social worker(s) were shared between the two groups (which could be a source of contamination). Follow-up assessments were undertaken by two observers who were "not directly involved in patient care", but it was unclear whether they were blinded to the treatment allocation, and what level of training and expertise each person had. It also did not report whether the patients or the statistician(s) were blinded to the treatment allocation. This was the only study

that reported a power calculation (based on reducing the mean length of stay from 53 to 46 days). Follow-up to six months was carried out in 136/136 (100%) patients. Reliability for the primary outcome measures was moderate to high; the kappa value for inter-observer agreement on whether the patient was independent was 0.78 for the Barthel index and 0.86 for the Rankin scores (high).

The reporting of methodology in the other two randomised studies was poor. In one study (Falconer et al 1993), there was no information on the method of randomisation, concealment of allocation or blinding. Of the 128 randomised patients, seven did not complete the rehabilitation programme because of "*sickness*"; those patients were excluded from analysis. Patients were randomised within 120 days of stroke onset and some patients might already have had some rehabilitation prior to randomisation. The group sizes were unequal because of "*random irregularities in the admission process*". It did not state whether the doctors, nurses, therapists, or social workers were shared between the two groups. Again, the medical care that the patients received before randomisation was not defined, nor was the location of acute care. The proportion of patients who were followed up to one year was not reported. There was also no indication of the reliability of the primary outcome measures.

In the other randomised study (Schull et al 1992), sixty patients were "*selected randomly*" from among ischaemic stroke patients admitted to a neurology service over a six-month period. They were then "*divided randomly*" into treatment and control groups with 30 patients in each. However, there was no information on the

method of randomisation, allocation or blinding. Some initial selection bias could have been present. It did not state whether the doctors, nurses, therapists, or social workers were shared between the two groups. The ICP was for both acute stroke and rehabilitation but there was no description of the location in which patient care was provided during each phase of the admission. There were no follow-up assessments after discharge.

In all of these studies, the unit of analysis was the number of patients and not stroke events (assuming any readmission for recurrent stroke would be counted as a separate unit of analysis). None of the trials reported major differences in observed baseline characteristics between the two groups of patients. In some studies only limited data were reported (e.g. no data on subtype of stroke, pre-stroke disability or handicap).

Non-randomised studies

In the non-randomised studies, the reporting of methodology was generally poor. In the only comparative study (Baker et al 1998), 273 patients were retrospectively identified to have non-haemorrhagic stroke ("*diagnosis-related group 14*") and their records were retrieved. Of these records, 30 were randomly selected for review; 15 of these patients were by chance managed by ICP and eight by standard medical care. Baseline characteristics only included age and gender but no other variables such as stroke severity or subtypes. The other six non-randomised studies were before-and-after studies, two of which included a concurrent control group (but no historical control group). I found no quasi-randomised studies or interrupted time series. For

the six before-and-after studies, data collection was purely prospective in one study (Hamrin & Lindmark 1990), mixed prospective and retrospective in one study (Crawley 1996), and purely retrospective in four studies (Pasquarello 1990; Odderson & McKenna 1993; Bowen & Yaste 1994; Ross et al 1997). Data for all non-randomised studies were analysed as a single group.

No study stated that the patients recruited were consecutive and none described the location of care. Although the patient care given to each treatment group in these non-randomised studies was described in similar detail to the randomised studies, the care given to the control groups was poorly defined. Characteristics of the patients in the treatment and control groups were not reported in one study (Odderson & McKenna 1993), and in four of the remaining studies, the groups were different in certain aspects such as race, gender, and proportions of haemorrhagic strokes (Pasquarello 1990; Hamrin & Lindmark 1990; Bowen & Yaste 1994; Baker et al 1998). The groups were similar in only two groups (Crawley 1996; Ross et al 1997). Due to lack of information, it was unclear in all of the non-randomised studies whether the introduction of the ICP was independent of other organisational changes over time.

In this review, I have compared patients managed using a ICP with a similar historical group (a before-and-after design). For three non-randomised studies (Odderson & McKenna 1993; Bowen & Yaste 1994; Ross et al 1997), concurrent controls were also recruited. However, the treatment of these patients, and the reasons for not managing them using a ICP, were not described in any of the studies.

For instance, it was not clear whether they were managed in the same ward or by the same team, or whether their characteristics were similar to the other groups. Due to the huge numbers of potential biases and confounding factors that could influence outcome in these concurrent controls, I have decided to exclude them in the data analyses of this review.

4.3 Results

I report 24 outcome measures in total. For each outcome measure, I have presented the results for randomised and non-randomised studies separately and also as an aggregate result (all using a 'random effects' method). Due to the small number of studies in each outcome, it was not possible to break the results down according to the clinical setting of the ICP (acute stroke, stroke rehabilitation, or both). The detailed findings of each study are presented in **Table 4.3**. The results of the dichotomous outcomes are summarised in **Table 4.4**.

Death by the end of follow-up

Two studies (one randomised and one non-randomised, total of 432 patients) reported this outcome. The randomised study showed a trend toward more deaths by the end of follow-up in the ICP group (OR 1.77, CI 0.61 to 5.14). The non-randomised study showed a trend toward fewer deaths by the end of follow-up in the ICP group (OR 0.62, CI 0.37 to 1.03). The aggregate result showed no significant difference (OR 0.94, CI 0.34 to 2.57, P=0.9). Two studies (Falconer et al 1993; Bowen & Yaste 1994) reported "no difference" in mortality but no data were given.

Death in hospital

Two non-randomised studies with 491 patients showed no significant difference (OR 0.98, CI 0.59 to 1.64, P=0.9). Two studies (Falconer et al 1993; Bowen & Yaste 1994) reported "no difference" in mortality but no data were given.

Death or dependency at the end of follow-up

One randomised study with 152 patients showed no significant difference (OR 1.36, CI 0.68 to 2.72, P=0.4). Two studies (Falconer et al 1993; Bowen & Yaste 1994) reported "no difference" in mortality but no data were given.

Discharge to institutional care

Five studies (one randomised and four non-randomised, total of 716 patients) reported this outcome. The randomised study showed a trend toward fewer patients discharged to institutional care in the ICP group (OR 0.57, CI 0.24 to 1.35). The non-randomised studies showed a trend toward fewer patients discharged to institutional care in the ICP group (OR 0.66, CI 0.36 to 1.21). Overall, there was a non-significant trend toward fewer patients discharged to institutional care in the ICP group (OR 0.64, CI 0.4 to 1.01, P=0.06). Two studies (Falconer et al 1993; Bowen & Yaste 1994) reported "no difference" in discharge destinations but no data were given.

Death in hospital or discharge to institutional care

Two non-randomised studies with 491 patients showed a non-significant trend toward fewer deaths in hospital or discharges to institutional care in the ICP group (OR 0.71, CI 0.49 to 1.02, P=0.07). Two studies (Falconer et al 1993; Bowen & Yaste 1994) reported "no difference" in death or discharge destinations but no data were given.

Discharge to home

Five studies (one randomised and four non-randomised, total of 716 patients)

reported this outcome. The randomised study showed no significant difference (OR 1.14, CI 0.56 to 2.32). The non-randomised studies also showed no significant difference (OR 1.38, CI 0.72 to 2.65). Overall, there was no significant difference (OR 1.33, CI 0.82 to 2.15, P=0.3). Two studies (Falconer et al 1993; Bowen & Yaste 1994) reported "no difference" in discharge destinations but no data were given.

Occurrence of complications

Pneumonia

Two non-randomised studies with 189 patients showed no significant difference (OR 0.4, CI 0.03 to 5.11, P=0.5). One study (Bowen & Yaste 1994) reported "no difference" in pneumonia but no data were given.

Urinary tract infection

Four non-randomised studies with 675 patients showed that significantly fewer patients suffered urinary tract infections in the ICP group (OR 0.38, CI 0.18 to 0.79, P=0.01).

Deep vein thrombosis

One non-randomised study with 139 patients showed no significant difference (OR 0.93, CI 0.04 to 19.91, P>0.9). One study (Bowen & Yaste 1994) reported "no difference" in complications but no data were given.

Dehydration

One non-randomised study with 50 patients showed a non-significant trend toward

fewer patients suffering from dehydration in ICP group (OR 0.06, CI <0.1 to 1.11, P=0.06).

Fluid and electrolyte imbalance

One non-randomised study with 50 patients showed no significant difference (OR 0.48, CI 0.04 to 5.65, P=0.6).

Seizures

One non-randomised study with 50 patients showed no significant difference (OR 0.31, CI 0.03 to 3.16, P=0.3).

Skin breakdown or pressure sore

One non-randomised study with 50 patients showed no significant difference (OR 0.13, CI 0.01 to 2.58, P=0.18).

Falls or fractures

One non-randomised study with 50 patients showed no significant difference (OR 0.18, CI 0.01 to 4.04, P=0.3).

Myocardial infarction

One non-randomised study with 139 patients showed no significant difference (OR 1.56, CI 0.06 to 39.39, P=0.8).

Readmission or emergency department attendance

Two studies (one randomised and one non-randomised, total of 110 patients) reported this outcome. The randomised study showed significantly fewer readmissions or emergency department attendance in the ICP group (OR 0.15, CI 0.04 to 0.59). The non-randomised study showed that significantly fewer readmissions or emergency department attendance in the ICP group (OR 0.03, CI <0.1 to 0.63). The overall result showed significantly fewer readmissions or emergency department attendance in the ICP group (OR 0.11, CI 0.03 to 0.39, P=0.0006).

Use of investigations

First or second computed tomography brain scan

Two non-randomised studies with 824 patients showed that significantly more patients received a first or second CT brain scan in the ICP group (OR 3.66, CI 1.45 to 9.27, P=0.006).

Carotid duplex study

One non-randomised study with 275 patients showed that significantly more patients received a carotid duplex study in ICP group (OR 2.45, CI 1.3 to 4.61, P=0.005).

Electrocardiography

One non-randomised study with 544 patients showed no significant difference (OR 1.02, CI 0.38 to 2.71, P>0.9). One study (Bowen & Yaste 1994) reported "no difference" in echocardiography but no data were given.

Therapy input by the multidisciplinary team

Two studies (one randomised and one non-randomised, total of 427 patients) reported this outcome. The randomised study showed no significant difference in the cumulative duration of physiotherapy or occupational therapy at various follow-up time points. The non-randomised study found "no difference" in therapy input but no data were given.

Patient and carer satisfaction

One randomised study with 121 patients reported this outcome. Patient satisfaction was measured using a scale ranging from one (least satisfied) to ten (most satisfied). Patients answered the questions wherever possible unless the patient experienced significant communication problems (then relatives or carers would answer). Patients were significantly less satisfied with their hospital care in the ICP group (WMD -1.1, CI -1.91 to -0.29, P=0.008).

Quality of life

One randomised study with 152 patients reported this outcome, using Euroqol score as a measure of quality of life. This study found no significant difference in the Euroqol score at one or three months. However, at six months, the Euroqol score was found to be significantly lower in the ICP group (median scores 63 vs 72, P<0.005), which suggests a lower quality of life in the ICP group.

Length of stay

Four studies (two randomised and two non-randomised, total of 1028 patients)

reported this outcome. The randomised studies showed a trend toward longer hospital stay in ICP group (WMD 3.99, CI -0.29 to +8.27). The non-randomised studies showed that hospital stay was significantly shorter in ICP group (WMD -1.91, CI -3.19 to -0.63). Overall, there was a non-significant trend toward shorter hospital stay in ICP group (WMD -1.19, CI -2.76 to +0.39, P=0.14). One study (Bowen & Yaste 1994) reported "no difference" in duration of rehabilitation but no data were given.

Hospital cost

Five studies reported this outcome. One randomised study found no significant difference in hospital cost between ICP and control groups (Falconer et al 1993) and another randomised study found a fall in the mean hospital cost (Schull et al 1992). Two non-randomised studies found a fall in the mean hospital cost (Bowen & Yaste 1994; Crawley 1996), and one non-randomised study reported a 14.6% fall (no actual cost data given) in the mean hospital cost (Odderson & McKenna 1993). No study reported standard deviation or other measures of variance.

4.4 Discussion

The results of this review are difficult to interpret

This systematic review was difficult to conduct since I included both randomised and non-randomised studies. One has to interpret the results with caution because non-randomised studies are highly susceptible to bias and there is significant statistical heterogeneity between the studies (Sacks et al 1982; Chalmers et al 1983; Egger & Smith 1998).

The most obvious bias is selection bias, i.e. stroke patients may have been selected to be managed using a ICP and may have differed from those who were managed using standard medical care. In one study, it was stated that patients were selected for ICP care using strict screening criteria (Baker et al 1998) and I suspect that this might also have been a common practice in other studies. Consequently, the clinicians may have selected the stroke patients with better (or worse) prognosis and biased their findings.

There are other potentially important biases in non-randomised studies. Five of the seven studies were retrospective and all of them included non-consecutive cases. It is possible that some cases were missed or excluded; this may have influenced outcome. The investigators who assessed the outcomes were not reported to be blinded to the treatment option and this may have biased their assessment of non-fatal outcomes. Moreover, publication bias may have influenced the results of the non-randomised studies, such that those showing no benefit or worse outcome with

ICP care may have been less likely to be published (Sutton et al 2000). Finally, authors may have chosen to write "no difference" rather than report the actual data, or to omit the negative results all together from their publication. This reporting bias may have influenced the outcome.

Factors which add to the difficulty in interpreting the results of this review include variations in the definition and components of the intervention, and the small number of studies included in the data analysis. Since the reporting of methodology in many studies was poor, there may be other confounding factors and sources of contamination that have not been identified. Another factor that limited the reliability of the quantitative meta-analyses was the presence of statistical heterogeneity in a number of the analyses (i.e. CT scanning, duration of hospital stay). I have presented the numerical analyses in order to make the data available, but the overall estimates of effect in the presence of such heterogeneity are difficult to interpret.

Nature of the intervention varied between studies

This review has highlighted the variable definition of a ICP. No two included studies seemed to have used the term 'ICP' to describe the same type of intervention. Their ICPs appeared to have differed in terms of their components, target patient groups, location of use, and methods of design and implementation. For two studies which were published as abstracts, I attempted to contact the authors to clarify the details of their interventions, study methodology and results (Abissi et al 1995; Moloney et al 1999). However, neither of them agreed to provide any extra information and both studies were excluded in this review.

Like stroke unit care, it may be extremely difficult to know with any degree of certainty which components may account for which effect. By examining the ICPs described in the included studies, I was at least able to extract their shared components, which were basically those outlined in the definition of an ICP used for this review. However, the relation between the components of the ICP and the effects observed was not clarified by this review.

There was weak evidence of benefit

I did not find evidence that ICP care provided additional benefit over standard medical care in terms of major clinical outcomes: death (in hospital or by the end of follow-up), dependency (at discharge or end of follow-up), or discharge to home. There was, however, weak evidence to suggest that ICP care may be associated with fewer patients being discharged to institutional care.

Data, chiefly from non-randomised studies, provided weak evidence that ICPs improved the process of care, hence leading to fewer complications (urinary tract infections, readmissions or emergency department attendance) and more thorough investigations (more CT brain scans and carotid duplex studies). No study reported the proportion of therapeutic activities that achieved pre-defined standards based on the best evidence or guidelines. In the US, ICPs have primarily been implemented to reduce duration of hospital stay and hospital costs. In the UK, their primary purpose is to improve process of care and promote evidence- and guideline-based care (which may lead to improved patient outcomes). However, there is no evidence that the

latter has ever been evaluated.

There was weak evidence of harm

I found evidence from two randomised trials that patient satisfaction and quality of life may be lower in patients managed using a ICP (Falconer et al 1993; Sulch et al 2000). The reasons for these effects are unclear, but if the aim of the ICPs in these studies was to shorten the duration of hospital stay, then there may be pressure for the staff to discharge the patients as quickly as possible, but the patients or carers might not have been ready for discharge. These outcomes should be assessed in future studies.

Evidence on hospital cost was difficult to interpret

The chief determinant of hospital cost is the length of stay. The analyses of this variable are difficult to interpret because of substantial heterogeneity; evidence from the randomised studies suggests that ICP care may increase the length of stay, whereas the non-randomised studies showed a reduction. These data therefore provide a plausible range for the potential effects of ICP care on the length of stay, but do not provide a reliable summary estimate.

In this review, four studies (Bowen & Yaste 1994; Crawley 1996; Schull et al 1992; Odderson & McKenna 1993) reported a reduction in mean hospital cost and one study found no difference in cost (Falconer et al 1993). Only one study reported the items of costs (i.e. what items were included in the final sum) and their individual values (Falconer et al 1993). Without knowing the cost of individual items, comparison between studies is meaningless. Furthermore, using ICPs can be

associated with many indirect and opportunity costs such as the time and effort invested in designing the pathway, time and resources in promoting its use and educating staff from different disciplines, printing costs of the paper documents and wall posters, as well as time and effort in maintaining staff enthusiasm and continuous quality improvement (e.g. variance analysis). All these costs are very difficult to estimate and could account for a large proportion of the total cost of using ICPs. More detailed assessment of the economic impact of using ICPs in future research would be extremely helpful.

Implications for practice

This systematic review has provided the best-available evidence so far on the effects of ICPs for the hospital management of acute stroke or stroke rehabilitation. There is insufficient evidence currently available to support the routine implementation of stroke ICPs.

Implications for research

Further research is necessary before widespread implementation of stroke ICPs is recommended. In particular, well-conducted randomised and non-randomised studies should be undertaken. The present review has included non-randomised studies which may only represent weak evidence, but they at least suggest which variables might be tested in future randomised trials.

This systematic review has been published in the Cochrane Library, Issue 2, 2002.

4.5 Summary of this chapter

- I conducted a Cochrane systematic review to assess the effects of ICPs, as compared to standard medical care, among patients with acute stroke who had been admitted to hospital.
- There were three randomised controlled trials (total of 340 patients) and seven non-randomised studies (total of 1673 patients) that compared ICP care with standard medical care. There was significant heterogeneity between the studies.
- There was no significant difference between ICP and control groups in terms of death, dependency, or discharge destination.
- Evidence from mainly non-randomised studies suggests that patients managed using an ICP may be: a) less likely to suffer a urinary tract infection; b) less likely to be readmitted; and c) more likely to have a CT scan or carotid duplex study.
- Evidence from randomised trials suggests that patient satisfaction and quality of life may be significantly lower in the ICP group.
- I conclude that the use of ICPs to manage stroke patients in hospital may be associated with both positive and negative effects on the process of care and clinical outcomes. Since most of the results have been derived from non-randomised studies, they are likely to be influenced by potential biases and confounding factors.
- Previous studies do not provide sufficient evidence to support the routine implementation of ICPs for acute stroke management or stroke rehabilitation.

Table 4.1 Search strategy for MEDLINE. This was also adapted to other electronic databases. Note that: **lines 1-17** = diagnosis of stroke or transient ischaemic attack; **lines 18-31** = the intervention; **lines 32-61** = randomised or controlled trials; **lines 62-71** = other types of non-randomised studies; and **lines 72-78** = our method of refining the search.

1. exp cerebrovascular disorders/
2. (stroke$ or poststroke$ or cva$).tw.
3. (cerebrovascular$ or cerebral vascular).tw.
4. (cerebral or cerebellar or brainstem or vertebrobasilar).tw.
5. (infarct$ or isch?emi$ or thrombo$ or apoplexy or emboli$).tw.
6. 4 and 5
7. (cerebral or intracerebral or intracranial or parenchymal).tw.
8. (brain or intraventricular or brainstem or cerebellar).tw.
9. (infratentorial or supratentorial or subarachnoid).tw.
10. 7 or 8 or 9
11. (haemorrhage or hemorrhage or haematoma or hematoma).tw.
12. (bleeding or aneurysm).tw.
13. 11 or 12
14. 10 and 13
15. trans$ isch?emic attack$.tw.
16. brain attack.tw.
17. 1 or 2 or 3 or 6 or 14 or 15 or 16

---

18. critical pathway/
19. patient care planning/
20. case management/ or disease management/
21. patient care team/ or exp patient care management/
22. clinical protocols/
23. program development/
24. exp Delivery of health care, integrated/
25. Managed care programs/
26. ((care or clinical) adj10 map).tw.
27. stroke program$.tw.
28. ((clinical or treatment or care) adj10 (protocol or planning)).tw.
29. managed care.tw.
30. ((multidisciplinary or inter?disciplinary or integrated) adj10 care).tw.
31. (path or paths or pathway$ or map or maps or caremap$).tw.

---

32. randomized controlled trial.pt.
33. randomized controlled trials/
34. controlled clinical trial.pt.
35. controlled clinical trials/
36. random allocation/
37. double-blind method/

38. single-blind method/
39. clinical trial.pt.
40. exp clinical trials/
41. (clin$ adj25 trial$).tw.
42. ((singl$ or doubl$ or tripl$ or trebl$) adj25 (blind$ or mask$)).tw.
43. random$.tw.
44. research design/
45. clinical trial phase ii.pt.
46. clinical trial phase iii.pt.
47. clinical trial phase iv.pt.
48. multicenter study.pt.
49. intervention studies/
50. control$.tw.
51. "comparative study"/
52. exp evaluation studies/
53. Follow-up studies/
54. Prospective studies/
55. prospective.tw.
56. (quasi?experimental or quasi?random$).tw.
57. matched pair analysis/
58. meta-analysis.pt.
59. meta-analysis/
60. (meta?analysis or systematic review or overview).tw.
61. 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60

---

62. exp epidemiologic studies/
63. program evaluation/
64. efficiency, organizational/
65. time series.tw.
66. ((case-control or observational) adj10 (stud$ or evaluat$)).tw.
67. exp Quality of Health Care/
68. exp patient care/
69. exp Health Care Evaluation Mechanisms/
70. quality-adjusted life years/
71. benchmarking/

---

72. or/62-71
73. or/18-31
74. 17 and 73
75. 74 and 61
76. 74 and 72
77. 76 not 75
78. 74 not (75 or 76)

Table 4.2 Reasons for excluding the 38 studies in the systematic review (studies arranged in alphabetical order).

Study	Reference	Reason for exclusion
Alberts 1996	*Alberts MJ, Bennett CA, Rutledge VR. Hospital charges for stroke patients. Stroke 1996;27:1825-1828.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Bokemark 1995	*Bokemark L, Blomstrand C, Fagerberg B. How are guidelines for the management of acute stroke optimally implemented in clinical practice. In: Pan-European Consensus Meeting On Stroke Management. Helsingborg, Sweden, 8-10 November 1995:No 19.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Chui 1997	*Chui L, Goh MH, Hung CT, Shyu WC, Chang TP. The effectiveness of systematic stroke care. Kaohsiung Journal of Medical Sciences 1997;13:496-502.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Dignan 1986	*Dignan MB, Howard G, Toole JF, Becker C, McLeroy KR. Evaluation of the North Carolina stroke care program. Stroke 1986;17(3):382-386.*	The intervention studied was a mixed hospital- and community-based "stroke programme". Data were collected from 3 separate groups of hospitals (19 hospitals in total), which had introduced different programmes at different times
Duryee 1996	*Duryee R, Calanchini P, Miller R. The impact of a stroke clinical pathway: measuring effectiveness. Neurology 1996;46(Suppl):A428 (Abstract S63.007).*	The treatment group included a period before the intervention had been introduced
Edwards 1996	*Edwards WH, Sr, Edwards WH, Jr, Martin RS, Mulherin JL, Bullock D. Resource utilization and pathways: meeting the challenge of cost containment. American Surgeon 1996;62(10):830-834.*	The participants who had been recruited by this study did not suffer a condition that fulfilled the definition for a stroke
Englander 1998	*Englander RN, Morich DH, Minniti MM. Accelerating the evaluation of acute stroke patients in a community hospital. Neurology 1998;50:A114 (Abstract P02.091).*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Evans 1995	*Evans R, Connis R, Hendricks R, Haselkorn J. Meta-analysis of stroke outcome: survival, function, and residence. Stroke 1995;26(1):156.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway

Study	Reference	Reason for exclusion
Friedman 1990	*Friedman PJ. Stroke rehabilitation in the elderly: a new patient management system. New Zealand Medical Journal 1990;103:234-236.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Goldberg 1997	*Goldberg G, Segal ME, Berk SN, Schall RR, Gershkoff AM. Stroke transition after inpatient rehabilitation. Topics in Stroke Rehabilitation 1997;4(1):64-79.*	This was a randomised controlled trial but the intervention was community-based case management of stroke patients after discharge from hospital
Goldstein 1998	*Goldstein LB, Hey LA, Laney R. North Carolina stroke prevention and treatment facilities survey. rtPA therapy for acute stroke. Stroke 1998;29:2069-2072.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Hainsworth 1997	*Hainsworth DS, Lockwood-Cook E, Pond M, Lagoe RJ. Development and implementation of clinical pathways for stroke on a multihospital basis. Journal of Neuroscience Nursing 1992;29:156-162.*	Data were collected from 3 separate hospitals that had introduced different care pathways at different times. It was unclear which data belonged to the intervention groups and which belonged to the control groups
Horgan 1996	*Horgan F, Crowe M, Keating D, McNamara A, Leahy P. The development of a comprehensive stroke programme in the acute hospital. Irish Medical Journal 1996;89(6):222.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Ivey 1995	*Ivey MF, Armitstead JA, Sangha KS. Critical pathways at University of Cincinnati hospital. American Journal of Health-System Pharmacy 1995;52:1053-1058.*	This article described some beneficial effects of a new care pathway but there was inadequate information on the intervention and the methodology of the study
Jungkind 1999	*Jungkind K, Corish C. Pilot acute ischemic stroke program saves $9,756 per case. Hospital Case Management 1999;7:87-90.*	This article described some beneficial effects of a new care pathway but there was inadequate information on the intervention and the methodology of the study
Karanjia 1997	*Karanjia PN, Nelson JJ, Lefkowitz DS, Dick AR, Toole JF, Chambless LE, Hayes R, Howard VJ. Validation of the ACAS TIA/stroke algorithm. Neurology 1997;48:346-351.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Lagoe 1997	*Lagoe RJ, Aspling DL. Benchmarking and clinical pathway implementation on a multihospital basis. Nursing Economics 1997;15(3):131-137.*	The control group was inappropriate because it consisted of different hospitals in other states. All data were collected after the introduction of the intervention

Study	Reference	Reason for exclusion
Lagoe 1998	*Lagoe RJ. Basic statistics for clinical pathway evaluation. Nursing Economics 1998;16(3):125-131.*	This article described some beneficial effects of a new care pathway but there was inadequate information on the intervention and the methodology of the study. All data were collected after the introduction of the intervention.
MacKenzie 1998	*MacKenzie AE, Chang AM. The effectiveness of nursing care: use of a protocol to promote stroke rehabilitation. In: Improving Health Services through Research in Hong Kong: A Compendium of Abstracts for Projects Funded by the Health Services Research Committee 1994-1998. Hong Kong: Health Services Research Committee, 1998:12.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Monane 1996	*Monane M, Kanter DS, Glynn RJ, Avorn J. Variability in length of hospitization for stroke. The role of managed care in an elderly population. Archives of Neurology 1996;53:875-880.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Odderson 1995	*Odderson IR, Keaton JC, McKenna BS. Swallow management in patients on an acute stroke pathway: quality is cost effective. Archives of Physical Medicine and Rehabilitation 1995;76:1130-1133.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway: the care pathway only managed swallowing difficulties after stroke (i.e. not truly multidisciplinary)
Pearson 1988	*Pearson A, Durand I, Punton S. Effects of admission to a nursing unit. Australian Journal of Advanced Nursing 1988;6(1):38-42.*	This was a randomised controlled trial but the intervention was stroke care within a nursing unit and the intervention did not fulfil the definition criteria for a care pathway
Quigley 1998	*Quigley PA, Wallace Smith S, Strugar J. Successful experiences with clinical pathways in rehabilitation. Journal of Rehabilitation 1998;64(2):29-32.*	This was an open study of care pathways for both stroke and traumatic brain injury. There was no pre-care pathway group for comparison. All data were collected after the introduction of the intervention
Ramachandran 1996	*Ramachandran TS, Culebras A, Hainsworth D. Development and implementation of a clinical pathway for stroke in acute care. Neurology 1996;46(Suppl):A319 (Abstract P04.119).*	All data were collected after the introduction of the intervention
Retchin 1997	*Retchin SM, Brown RS, Yeh SCJ, Chu D, Moreno L. Outcomes of stroke patients in medicare fee for service and managed care. JAMA 1997;278(2):119-124.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway

Study	Reference	Reason for exclusion
Reuben 1995	*Reuben DB, Borok GM, Wolde-Tsadik G, Ershokk DH, FIshman LK, Ambrosini VL, Lui Y, Rubenstein LZ, Beck JC. A randomized trial of comprehensive geriatric assessment in the care of hospitalized patients. New England Journal of Medicine 1995;332:1345-1350.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Romito 1990	*Romito D. A critical path for CVA patients. Rehabilitation Nursing 1990;15(3):153-156.*	This article described some beneficial effects of a new care pathway but there was inadequate information on the intervention and the methodology of the study
Rosenberger 1999	*Rosenberger JM, Wiemers NE. CareMaps in medical rehabilitation. Journal of Care Management 1999;5(2):23-37.*	This article described some beneficial effects of a new care pathway but there was inadequate information on the intervention and the methodology of the study
Rossiter 1995	*Rossiter D, Thompson AJ. Introduction of integrated care pathways for patients with multiple sclerosis in an inpatient neurorehabilitation setting. Disability and Rehabilitation 1995;17(8):443-448.*	The participants who had been recruited by this study did not suffer a condition that fulfilled the definition for a stroke
Schmidt 1999	*Schmidt SM, Guo L, Scheer S, Boydston J, Pelino C, Berger SK. Epidemiological determination of community-based nursing case management for stroke. Journal of Nursing Administration 1999;29(6):40-47.*	This was an open study of community-based nursing case management for stroke, which was delivered through a care pathway
Sulch 2000	*Sulch D, Kalra L. Integrated care pathways in stroke management. Age and Ageing 2000;29:349-352.*	This was a systematic review containing one randomised controlled trial - Falconer 1993
Summers 1998	*Summers D, Soper PA. Implementation and evaluation of stroke clinical pathways and the impact on cost of stroke care. Journal of Cardiovascular Nursing 1998;13(1):69-87.* *Rymer MM, Summers D, Soper P. Development of clinical pathways for stroke management. An example from Saint Luke's Hospital, Kansas City. Clinics in Geriatric Medicine 1999;15(4):741-764.*	All data were collected after the introduction of the intervention
Underwood 1999	*Underwood F, Parker J. Developing and evaluating an acute stroke care pathway through action research. Nurse Reseacher 1999;6(2):27-38.*	There was inadequate definition of the intervention and the methodology of the study

Study	Reference	Reason for exclusion
van Straten 1997	*van Straten A, van der Meulen JHP, van Crevel H, Habbema JDF, Limburg M. Quality of hospital care for stroke patients in The Netherlands. Cerebrovascular Disease 1997;7:251-257.*	All data were collected after the introduction of the intervention
von Reutern 1998	*von Reutern GM, Allendorfer J. Schlaganfallbehandlung mit Stroke Unit and Rehabilitation durch ein Team [Stroke treatment with stroke unit and rehabilitation by a team. A model for a staged management]. Nervenarzt 1999;70:149-154.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Wentworth 1996	*Wentworth DA, Atkinson RP. Implementation of an acute stroke program decreases hospitalization costs and length of stay. Stroke 1996;27:1040-1043.*	All data were collected after the introduction of the intervention
Wood-Dauphinee 1984	*Wood-Dauphinee S, Shapiro S, Bass E, Fletcher C, Georges P, Hensby V, Mendelsohn B. A randomized trial of team care following stroke. Stroke 1984;15(5):864-872.*	The intervention that had been tested in this study did not fulfil the definition criteria for a care pathway
Zander 1988	*Zander K. Nursing case management: strategic management of cost and quality outcomes. Journal of Nursing Administration 1988;18:23-30.*	This article described some beneficial effects of a new care pathway but there was inadequate information on the intervention and the methodology of the study

Table 4.3 Detailed results of the ten included studies in the systematic review (studies arranged in chronological order of publication).

Study	Methods	Notes	No of Cases	Outcome data
Hamrin 1990	Uncontrolled before-and-after study	Acute stroke and rehabilitation	280	Median LOS (days): ICP=11 (range 2-251) vs Before=13 (range 3-177). Mortality at 1 week: ICP=11/173 vs Before=5/107. Mortality at discharge: ICP=35/173 vs Before=24/107. Mortality at 3 months: ICP=42/173 vs Before=29/107. Mortality at 1 year: ICP=48/173 vs Before=41/107. Discharge home: ICP=97/173 vs Before=51/107. Institutionalisation: ICP=40/173 vs Before=32/107. CT scan: ICP=126/173 vs Before=58/107.
Pasquarello 1990	Uncontrolled before-and-after study	Acute stroke	50	Mean LOS (days): ICP=17 vs Before=8. Patients with complications: ICP=5/25 vs Before=16/25. Discharged home: ICP=21/25 vs Before=13/25. Institutionalisation: ICP=4/25 vs Before=12/25. Readmission: ICP=0/25 vs Before=9/25. Therapy ordered: ICP=18/25 vs Before=20/25. Time to therapy (days): ICP=0.75 vs Before=1.5. Non-compliance with follow-up appointment: ICP=6/25 vs Before=15/25.
Schull 1992	RCT	Acute stroke and rehabilitation	60	Mean LOS (days): ICP=11.4 vs Control=14.3. Readmission <30 days: ICP=1/30 vs Control=1/30. Emergency room visits <90 days: ICP=1/30 vs Control=12/30. Mean follow-up compliance (%): IICP=79 vs Control=56. Mean hospital cost ($): IICP=195143 vs Control=248605. Compliance to ICP generally good.

Study	Methods	Notes	No of Cases	Outcome data
Falconer 1993	RCT	Stroke rehabilitation	128	Mean LOS (days): ICP=35.6+/-15.5 vs Control=32.3+/-15.4. FIM at discharge: ICP=80+/-27.6 vs Control=84.9+/-26.1. Mean patient satisfaction score: ICP=7.7+/-2.6 vs Control=8.8+/-1.7. No difference in costs, institutionalisation on discharge, 12-month survival, 12-month hospitalisation or institutionalisation
Odderson 1993	Uncontrolled before-and-after study	Acute stroke	291	Mean LOS (days): ICP=7.3+/-0.5 vs 1989=10.9+/-1.2 vs 1990=9.8+/-0.9. Mortality on discharge: ICP=11/121 vs 1989=4/80 vs 1990=6/90. Discharged home: ICP=56/121 vs 1989=34/80 vs 1990=36/90. Institutionalisation: ICP=50/121 vs 1989=32/80 vs 1990=47/90. UTI: ICP=8/121 vs 1990=16/90 (S). Mean hospital costs ($): ICP vs 1990= reduced by 14.6%. PEG insertion: ICP=10/121 vs 1990=8/90.
Bowen 1994	Uncontrolled before-and after study, with one concurrent control (CC) group	Acute stroke	346	Mean LOS (days): ICP=5.5 vs Before=8.8 vs CC=6.7 (no CI). Carotid Doppler performed: ICP=37/54 vs Before=104/221 vs CC=36/71. DVT prophylaxis: ICP=14/54 vs 9/71 vs CC=30/221. UTI: ICP=1/54 vs Before=32/221 vs CC=4/71. No difference in discharge destination, mortality, complications (DVT, pneumonia, infections), length or cost of rehabilitation, neuroimaging, EEG, LP, catheter angiography, 24-hour ECG, Echocardiography, therapy input, or heparin use. Median hospital cost ($): ICP=4756 vs HC=7072 vs CC=7044.

Study	Methods	Notes	No of Cases	Outcome data
Crawley 1996	Uncontrolled before- and after study	Acute stroke and rehabilitation	139	Mean LOS (days): ICP=7.87 vs Before=12.17. UTI: ICP=3/24 vs Before=16/115. Pneumonia: ICP=0/24 vs Before=1/115. DVT: ICP=0/24 vs Before=2/115. MI: ICP=0/24 vs Before=1/115. Mean hospital cost ($): ICP=5759 vs Before=8894.
Ross 1997	Uncontrolled before- and after study, with one concurrent control group	Acute stroke	544	Mean LOS (days): ICP=6.33+/-4.45 vs Before=7.52 +/-5.26. Median LOS (days): ICP=5.0 vs Before=6.17. Mean LOS (Aug to Dec 1994): ICP=5.83+/-4.2 vs CC=5.85+/-5.36. Mean LOS (Jan to July 1995): ICP=5.42+/-3.56 vs CC=8.22+/-5.05. Documentation of focal neurological deficit: ICP=287/322 vs Before=169/222. ECG: ICP=312/322 vs Before=215/222. Coagulation screen: ICP=280/322 vs Before=167/222. Second CT scan: ICP=290/322 vs Before=135/222. Compliance to ICP was generally good.
Baker 1998	Retrospective comparative study	Acute stroke	23	Mean LOS (days): ICP=4.5 vs Control=2.8. Discharged home: ICP=4/15 vs Control=5/8. Institutionalisation: ICP=10/15 vs Control=3/8. PT: ICP=11/15 vs Control=5/8. OT: ICP=11/15 vs Control=5/8. Social worker: ICP=3/15 vs Control=0/8. SALT: ICP=5/15 vs Control=3/8. Education on stroke risk factors: ICP=6/15 vs Control=0/8. Education on medications: ICP=14/15 vs Control=0/8. Team communication documented: ICP=15/15 vs Control=0/8.

Study	Methods	Notes	No of Cases	Outcome data
Sulch 2000	RCT	Stroke rehabilitation.	152	Mean LOS (days): ICP=50+/-19 vs Control=45+/-23. Mortality at 6 months: ICP=10/76 vs Control=6/76. Discharged home: ICP=56/76 vs 54/76. Institutionalisation: ICP=10/76 vs Control=16/76. Median Euroqol at 6 months: ICP=63 vs Control=72. No difference in Barthel index, Rankin score, anxiety score, or depression score at 1, 3 or 6 months. No difference in duration of PT or OT input. Compliance to care pathway generally good.

Notes:

CC	Concurrent control
ICP	Integrated care pathway
CT	Computed tomography
DVT	Deep vein thrombosis
ECG	Electrocardiogram
EEG	Electroencephalogram
FIM	Functional independence measure
LOS	Length of stay (in hospital)
LP	Lumbar puncture
MI	Myocardial infarction
OT	Occupational therapy
PEG	Percutaneous endoscopic gastrostomy
PT	Physiotherapy
RCT	Randomised controlled trial
SAH	Subarachnoid haemorrhage
SALT	Speech and language therapy
UTI	Urinary tract infection

Table 4.4 Summary of the results for all the dichotomous outcomes. Results are presented as odds ratios (OR) and their 95% confidence intervals (CI). Note: *Number of studies: R = RCTs and NR = non-randomised studies. ** Significant results with $p<0.05$.

Outcome measure	Number of studies (R, NR)*	Randomised studies OR (95% CI)	Non-randomised studies OR (95% CI)	Overall effect OR (95% CI)
Death by end of follow-up	2 (R=1, NR=1)	1.77 (0.61-5.14)	0.62 (0.37-1.03)	0.94 (0.34-2.57)
Death in hospital	2 (R=0, NR=2)	-	0.98 (0.59-1.64)	0.98 (0.59-1.64)
Dead or dependent at the end of follow-up	1 (R=1)	1.36 (0.68-2.72)	-	1.36 (0.68-2.72)
Discharge to institution	5 (R=1, NR=4)	0.57 (0.24-1.35)	0.66 (0.36-1.21)	0.64 (0.40-1.01)
Dead in hospital or discharge to institution	2 (R=0, NR=2)	-	0.71 (0.49-1.02)	0.71 (0.49-1.02)
Discharge to home	5 (R=1, NR=4)	1.14 (0.56-2.32)	1.38 (0.72-2.65)	1.33 (0.82-2.15)
Pneumonia	2 (R=0, NR=2)	-	0.41 (0.03-5.11)	0.41 (0.03-5.11)
Urinary tract infection**	4 (R=0, NR=4)	-	0.38 (0.18-0.79)	**0.38 (0.18-0.79)**
Deep vein thrombosis	1 (NR=1)	-	0.93 (0.04-19.91)	0.93 (0.04-19.9)
Dehydration	1 (NR=1)	-	0.06 (<0.1-1.11)	0.06 (<0.1-1.11)
Fluid and electrolyte imbalance	1 (NR=1)	-	0.48 (0.04-5.65)	0.48 (0.04-5.65)
Seizures	1 (NR=1)	-	0.31 (0.03-3.16)	0.31 (0.03-3.16)
Skin breakdown or pressure sore	1 (NR=1)	-	0.13 (0.01-2.58)	0.13 (0.01-2.58)
Falls or fractures	1 (NR=1)	-	0.18 (0.01-4.04)	0.18 (0.01-4.04)
Myocardial infarction	1 (NR=1)	-	1.56 (0.06-39.39)	1.56 (0.06-39.4)
Readmission or ER attendance**	2 (R=1, NR=1)	0.15 (0.04-0.59)	0.03 (<0.1-0.63)	**0.11 (0.03-0.39)**
First or second CT brain scan**	2 (R=0, NR=2)	-	3.66 (1.45-9.27)	**3.66 (1.45-9.27)**
Carotid Doppler**	1 (R=0, NR=1)	-	2.45 (1.3-4.61)	**2.45 (1.30-4.61)**
Electrocardiography	1 (NR=1)	-	1.02 (0.38-2.71)	1.02 (0.38-2.71)

References for Chapter 4

Anonymous (1995) Hospital's stroke path proves myth wrong. *Hosp Case Manag.* 34(11):168-175.

Anonymous (1998) CVA (cerebrovascular accident) pathway cuts across seven hospital units. *Hosp Case Manag.* 6(2):33-34.

Abissi CJ, Sepe E, Patlak C et al. (1995) Cerebral infarction : comparison of a care plan with case-management to traditional care [abstract]. *Neurology.* 45 (Suppl 4):A240 (280P).

Aboderin I, Venables G. (1996) Stroke management in Europe. Pan European consensus meeting on stroke management (Helsingborg Declaration). *J Intern Med.* 240(43):173-180.

Adams HP, Jr., Brott TG, Furlan AJ et al. (1996) Guidelines for thrombolytic therapy for acute stroke: a supplement to the guidelines for the management of patients with acute ischemic stroke. A statement for healthcare professionals from a special writing group of the Stroke Council, American Heart Association. *Stroke.* 27(9):1711-1718.

Anderson CS, Jamrozik KD, Broadhurst RJ et al. (1994) Predicting survival for 1 year among different subtypes of stroke. Results from the Perth Community Stroke Study [see comments]. *Stroke.* 25(10):1935-1944.

Baker CM, Miller I, Sitterding M et al. (1998) Acute stroke patients comparing outcomes with and without case management. *Nurs Case Manag.* 3(5):196-203.

Barch C, Spilker J, Bratina P et al. (1997) Nursing management of acute complications following rt-PA in acute ischemic stroke. The NINDS rt-PA Stroke Study Group. *J Neurosci Nurs.* 29(6):367-372.

Bowen J, Yaste C. (1994) Effect of a stroke protocol on hospital costs of stroke patients. *Neurology.* 44(10):1961-1964.

Broderick JP. (1998) Practical considerations in the early treatment of ischemic stroke. *Am Fam Physician.* 57(1):73-80.

CAST (Chinese Acute Stroke Trial Collaborative Group). (1997) CAST: randomised placebo-controlled trial of early aspirin use in 20,000 patients with acute ischaemic stroke. *Lancet.* 349(9066):1641-1649.

Chalmers TC, Celano P, Sacks H et al. (1983) Bias in treatment assignment in controlled clinical trials. *N Engl J Med.* 309:1358-1361.

Crawley WD. (1996) Case management: improving outcomes of care for ischaemic stroke patients. *Medsurg Nurs.* 5:239-244.

Dennis M, Langhorne P. (1994) So stroke units save lives: where do we go from here? *The BMJ.* 309(6964):1273-1277.

Dignan MB, Howard G, Toole JF et al. (1986) Evaluation of the North Carolina stroke care program. *Stroke.* 17(3):382-386.

DoH – Department of Health. (2001) . *National Service Framework for Older People.* London: The Stationery Offce.

Duryee R, Calancjini P, Miller R. (1996) The impact of a stroke pathway: measuring effectiveness. *Neurology.* 46 (Suppl):A428 (S63.007).

Ebrahim S, Redfern J. (1999) *Stroke care - a matter of chance: a national survey of stroke services.* London: The Stroke Association.

Egger M, Smith GD. (1998) Bias in location and selection of studies. *The BMJ.* 316(7124):61-66.

Falconer JA, Roth EJ, Sutin JA et al. (1993) The critical path method in stroke rehabilitation: lessons from an experiment in cost containment and outcome improvement [see comments]. *QRB Qual Rev Bull.* 19(1):8-16.

Gainer FE. (1996) Developing a clinical pathway for stroke. *OT Practice.* 1(6):30-33.

Goldberg G, Segal ME, Berk SN et al. (1997) Stroke transition after inpatient rehabilitation. *Top Stroke Rehabil.* 4(1):64-79.

Hainsworth DS, Lockwood-Cook E, Pond M et al. (1997) Development and implementation of clinical pathways for stroke on a multihospital basis. *J Neurosci Nurs.* 29(3):156-162.

Hamrin EKF, Lindmark B. (1990) The effect of systematic care planning after acute stroke in general hospital medical wards. *J Advanced Nurs.* 15:1146-1153.

Hickman JL. (1998) Outcomes management for stroke patients using thrombolytics. *Crit Care Nurs Clin N Am.* 10(1):101-115.

Jones S, Sulch D, Starke I. (2001) Effect of the introduction of a care pathway and educational programme on quality of care and outcome in stroke [Abstract]. *Age Ageing.* 30(Suppl 2):54.

Jungkind K, Corish C. (1999) Critical path network. Pilot acute ischaemic stroke program saves $9756 per case. *Hosp Case Manag.* 7:87-90.

Kwan J. (2000) Systematic Review: Integrated care pathways in the management of stroke. Comments on Sulch et al (*Age Ageing* 2000;29:329-352). *S Files.* 6:3-4.

Lagoe RJ, Aspling DL. (1997) Benchmarking and clinical pathway implementation on a multihospital basis. *Nurs Econ.* 15(3):131-137.

Langhorne P, Dennis M. (1998) *Stroke units: an evidence based approach.* London: BMJ Books.

Lanska DJ. (1998) The role of clinical pathways in reducing the economic burden of stroke. *Pharmacoeconomics.* 14(2):151-158.

Luttman RJ. (1993) The critical path method alone does nothing to improve performance. *QRB Qual Rev Bull.* 19(5):142-143.

Moloney A, Critchlow B, Jones K. (1999) A multi-disciplinary care pathway in stroke - does it improve care? [abstract]. *Age Ageing.* 28 (Suppl 1):42-43.

Mulrow CD, Oxman AD. (2002) Cochrane Collaboration Handbook. In: *The Cochrane Library, Issue 2, 2002.* Oxford: Update Software.

Odderson IR, Keaton JC, McKenna BS. (1995) Swallow management in patients on an acute stroke pathway: quality is cost effective. *Arch Phys Med Rehabil.* 76(12):1130-1133.

Odderson IR, McKenna BS. (1993) A model for management of patients with stroke during the acute phase. Outcome and economic implications. *Stroke.* 24(12):1823-1827.

Pasquarello MA. (1990) Measuring the impact of an acute stroke program on patient outcomes. *J Neurosci Nurs.* 22(2):76-82.

Pearson A, Durand I, Punton S. (1988) Effects of admission to a nursing unit. *Aust J Adv Nurs.* 6(1):38-42.

Pearson SD, Goulart-Fisher D, Lee TH. (1995) Critical pathways as a strategy for improving care: problems and potential. *Ann Intern Med.* 123(12):941-948.

Quigley PA, Wallace Smith S, Strugar J. (1998) Successful experience with clinical pathways in rehabilitation. *J Rehabil.* 64(2):29-32.

Ramachandran TS, Culebras A, Hainworth D. (1996) Development and implementation of a clinical pathway for stroke in acute care. *Neurology.* 46(Suppl):A319 (P04.119).

RCP. (2001) *National Clinical Guidelines for Stroke.* Royal College of Physicians.

Ringel SP, Hughes RL. (1996) Evidence-based medicine, critical pathways, practice guidelines, and managed care. Reflections on the prevention and care of stroke. *Arch Neurol.* 53(9):867-871.

Roberts MA. (2001) *Scottish Stroke Service Audit. Report of an audit on the organisation of services for stroke patients, 1997-1998.*

Romito D. (1990) A critical path for CVA patients. *Rehabil Nurs.* 15(3):153-156.

Rosenberger JM, Wiemers NE. (1999) CareMaps in medical rehabilitation. *J Care Manag.* 5(2):23-37.

Ross G, Johnson D, Kobernick M. (1997) Evaluation of a critical pathway for stroke. *J Am Osteopath Assoc.* 97(5):269-6.

Rudd A, Lowe D, Irwin P et al. (2001) National stroke audit: a tool for change? *Quality in Health Care.* 10:141-151.

Sacks H, Chalmers TC, Smith JrH. (1982) Randomized versus historical controls for clinical trials. *Am J Med.* 72:233-240.

Schmidt SM, Guo L, Scheer S et al. (1999) Epidemiologic determination of community-based nursing case management for stroke. *J Nurs Adm.* 29(6):40-47.

Schull DE, Tosch P, Wood M. (1992) Clinical nurse specialists as collaborative care managers. *Nurs Manage.* 23:30-33.

SIGN. (1997) *Management of patients with stroke: III. Identification and management of dysphagia.* Edinburgh: Scottish Intercollegiate Guidelines Network.

SIGN. (1998) *Management of patients with stroke: IV. Rehabilitation, prevention and management of complications, and discharge planning.* Edinburgh: Scottish Intercollegiate Guidelines Network.

Sulch D, Kalra L. (2000) Integrated care pathways in stroke management. *Age Ageing.* 29:349-352.

Sulch D, Perez I, Melbourn A et al. (2000) Randomized controlled trial of integrated (managed) care pathway for stroke rehabilitation. *Stroke.* 31(8):1929-1934.

Summers D, Soper PA. (1998) Implementation and evaluation of stroke clinical pathways and the impact on cost of stroke care. *J Cardiovasc Nurs.* 13(1):69-87.

Sutton AJ, Duval SJ, Tweedie RL et al. (2000) Empirical assessment of effect of publication bias on meta-analyses. *The BMJ.* 320(7249):1574-1577.

Wade D. (1992) *Measurements in neurological rehabilitation.* Oxford: Oxford University Press.

Warlow C, Dennis M, van Gijn J et al. (2000) *Stroke. A practical guide to management.* Malden: Blackwell Science.

Wee AS, Cooper WB, Chatham RK et al. (2000) The development of a stroke clinical pathway: an experience in a medium-sized community hospital. *J Miss State Med Assoc.* 41(7):648-653.

Wentworth DA, Atkinson RP. (1996) Implementation of an acute stroke program decreases hospitalization costs and length of stay. *Stroke.* 27(6):1040-1043.

WHO. (1989) Recommendations on stroke prevention, diagnosis, and therapy: Report of the World Health Organisation Task Force on stroke and other cerebrovascular disorders. *Stroke.* 20:1407-1431.

Wilkinson G, Parcell M, MacDonald A. (2000) Cerebrovascular accident clinical pathway. *J Qual Clin Practice.* 20:109-112.

Zander K. (1988) Nursing case management: strategic management of cost and quality outcomes. *J Nurs Adm.* 18(5):23-30.

CHAPTER FIVE

EFFECTS OF INTRODUCING AN INTEGRATED CARE PATHWAY IN THE STROKE UNIT AT THE WESTERN GENERAL HOSPITAL: A BEFORE AND AFTER STUDY

5.1 The integrated care pathway for acute stroke at the Western General Hospital

In the Lothian region of Scotland, healthcare is provided by three Health Trusts: the Lothian University Hospitals NHS Trust, Lothian Primary Care NHS Trust, and the West Lothian Healthcare NHS Trust. The Western General Hospital (WGH) is one of two teaching hospitals providing acute hospital stroke services within the Lothian University Hospitals NHS Trust. The WGH serves a population of about a quarter of a million people. It has 550 beds and treats more than 150,000 patients every year. In this section, I shall describe how patients with acute stroke were managed at the WGH and the ICP that was introduced in the acute stroke unit. After that, I shall describe my evaluation of the ICP.

Patient's pathway for acute stroke at the WGH

The acute stroke service provided by the WGH has been evolving for the past few years. During 1999 and 2000, stroke patients from North Edinburgh were brought by ambulance to the Acute Receiving Unit (ARU) where resuscitation and acute assessment took place. Patients referred by the general practitioner (GP) with suspected stroke were also brought to the ARU for emergency treatment. Those with minor strokes or transient ischaemic attacks who the GP or the ARU physician would judge not to require hospital admission were referred to the twice weekly neurovascular outpatient clinic at the WGH. Patients with more severe strokes were assessed in the ARU by on-call medical staff. Those who required admission were transferred to the acute stroke unit (if beds were available), where the patient care

was provided by the specialist stroke team. If the stroke unit was full, the patients were transferred instead to a general medical ward (before October 2000), or the Acute Medical Assessment Unit (AMAU, opened in October 2000), where one of the medical teams was responsible for their care for the initial one to two days. Such patients might later be referred to and reviewed by one of the two stroke specialist consultants (MSD or RIL). Depending on the clinical needs, these patients were then transferred to the stroke unit or a rehabilitation unit. Those who were not transferred to the stroke unit were admitted instead to a general medical ward where they usually remained under the care of a general physician until discharge. A summary of a typical stroke patient's pathway of care is presented in **Figure 5.1**.

Patient care in the stroke unit before the integrated care pathway was introduced

At the time of the study (July 2000 to April 2001), the stroke unit was a 10-bedded unit consisting of two 5-bedded bays, situated within a larger 25-bedded general medical and geriatric ward; the usage of the beds was flexible depending on clinical needs. In the stroke unit, the patients underwent a period of assessment, early rehabilitation and medical treatment. Those who required further rehabilitation were transferred to the 26-bedded stroke rehabilitation unit at the adjacent Royal Victoria Hospital, where the patients remained under the care of MSD or RIL. Occasionally patients were transferred to one of the other three rehabilitation units in Edinburgh depending on their age and place of residence.

In the stroke unit and the rest of the 25-bedded ward, medical cover was provided by two consultants (MSD and RIL), one junior house officer and one senior house officer. Nurses rotated between the stroke unit and the rest of the ward, and the nurse-to-bed ratio was usually between 0.15 (night shift) to 0.27 (early shift). Therapy was provided by 1.5 working time equivalent (WTE) physiotherapist, 1.5 WTE occupational therapist, and 0.5 WTE speech therapist. A dietician and social worker also provided input into patient care. There was informal stroke training for the junior doctors, nurses, and other healthcare professionals. Acute stroke care was multidisciplinary and the patients' progress and treatment aims were discussed at the weekly multidisciplinary team meetings. All newly admitted stroke patients were reviewed by a consultant within 12 hours of admission on weekdays and within 24 hours at weekends. The stroke service had access to neuroimaging 24 hours a day; non-urgent CT brain scans and carotid duplex scans were usually performed within one to two working days of admission.

Patient care in the general medical wards throughout the study

In contrast to the stroke unit, stroke care in the general medical wards was provided by general medical consultants and nursing staff who had no special interest or training in stroke. Acute stroke care did not have to follow a specific hospital protocol or use specific documentation, although a handbook on emergency medical conditions was available for reference on every ward *including* the stroke unit. This A4 sized handbook contained 1½ pages of information on stroke, which was basically a brief summary of what would normally be contained in a medical textbook, with some guidance on the acute management of a stroke patient (e.g.

resuscitation, swallowing assessment), investigations to order, and the use of aspirin in patients with ischaemic stroke. This handbook was also available as a pocket size version and was given to every junior doctor in the WGH.

The doctors and nurses were different from those in the stroke unit, but the therapists were shared with the stroke unit. The amount of time that each therapist spent on each ward was not strictly divided and the decision on the intensity of therapy was left to the individual therapist (e.g. a therapist might choose to spend more time treating patients in the stroke unit). Stroke patients who required further rehabilitation were transferred to the same rehabilitation units as those from the stroke unit. Access to neuroimaging was similar to the patients in the stroke unit.

Introduction of the integrated care pathway in the stroke unit at the WGH

At the end of 1999, the multidisciplinary team on the stroke unit decided to introduce an ICP to try and further improve patient care. The ICP was launched in March 2000. It was a 50-page multidisciplinary patient record which was designed to guide the management of a stroke patient over the first five days after admission (see **Appendix 1**). It consisted mainly of questions and tick-box answers, which aimed to summarise the key aspects of the relevant national and local guidelines. There were three main sections to the ICP: the doctor's section, the nurses' section, and the therapists' section (including physiotherapy, occupational therapy, and speech therapy). There was also a section to document communications with the patient's family. The doctor's section also included a clerking proforma that was based on the Royal College of Physicians stroke audit package (1993-1994) (Rudd et al 1999).

It was intended for all the healthcare staff to record their patient notes in the ICP so that each discipline would be aware of the others' opinions. The pages of each section were colour-coded for ease of identification. The whole document was bound in one plastic folder (not the usual hospital case notes) and placed at the end of each patient's bed. Patients and relatives were free to read the document if they wished. The ICP was designed to be used on the stroke unit by the staff there, but copies of the doctor's section of the ICP were also kept in the ARU so that on-call medical staff could use them as a clerking proforma if they wished. Since its launch and during the course of the study, there had been no major changes to the ICP. The full details regarding the process of design and implementation of the ICP can be found in **Appendix 2**.

Other significant changes to the service structure during the study

Apart from the introduction of the ICP, there were three other important changes to the structure of services for stroke patients during the course of the study. All of these changes could potentially have influenced patient care and outcome. Firstly, as I have already mentioned, the Acute Medical Assessment Unit (AMAU) opened in October 2000, three months after the start of the prospective data collection phase of the study. AMAU received all the acute medical admissions except patients with stroke, who normally should have been admitted directly to the stroke unit. However, because the number of beds in the stroke unit was limited, many patients were initially admitted to the AMAU for the first one or two days. The medical and nursing care of stroke patients in the AMAU was similar to that in a general medical ward. The AMAU had its own team of therapists who mainly carried out assessments

and commenced therapy wherever appropriate, but they did not continue to treat the patient after his or her transfer out of the ward.

Secondly, unified patient records were introduced at the same time as the opening of the AMAU. This was an attempt to amalgamate the written records of the medical, nursing and therapy staff. The unified patient record was different from the ICP because it did not contain any reference to specific stroke-related treatment strategies. This document was based on the one used in a neighbouring teaching hospital within the same Health Trust (the Royal Infirmary of Edinburgh), where it has been found to improve documentation (Morrison et al 2001). Its introduction in the AMAU initially caused some confusion for the stroke unit staff because it was unclear whether a patient transferred to the stroke unit with the unified patient record should also be started on the ICP. This issue was decided in a subsequent team meeting that any patient who was transferred to the stroke unit within five days of admission should be started on the ICP.

Thirdly, in June 2000, a senior 2 physiotherapist was appointed, increasing the physiotherapy input from 1.5 whole time equivalent (WTE) to 2.0 WTE.

For a detailed account of the major changes in the WGH's stroke services in the past decade, please refer to **Appendix 3**.

5.2 Aims of the non-randomised studies

I sought to evaluate the effects of introducing an ICP in the stroke unit at the WGH by conducting two non-randomised studies: a) a before-and-after study to assess the difference in patient care and outcome before and after the introduction of the ICP; and b) a prospective comparative study to compare the patient care and outcome between the stroke unit after the introduction of the ICP and the general medical wards where there was no ICP. I shall report the before-and-after study in this chapter and the prospective comparative study in the next chapter.

When these two studies were planned, I fully acknowledged that the evidence derived from them would not be robust, easy to interpret, or necessarily generalisable to other settings (see **Chapter 2**). However, I felt that these studies would at least: a) enhance the understanding of the nature and operation of the ICP; b) explore the aspects of care that an ICP might influence; c) provide estimates of the effects of the ICP on the various aspects of patient care and outcome; and d) provide some useful information for future research studies.

5.3 Methods of the before-and-after study

Study design

I compared the outcome and process of care between two groups of stroke patients. For the intervention group, I prospectively collected data from consecutive stroke patients admitted to the stroke unit (SU) during the nine months *after* the ICP was introduced – I shall call this the 'SU-after-ICP' group. For the control group, I retrospectively collected data from consecutive stroke patients admitted to the same stroke unit during the nine months *before* the introduction of the ICP – I shall call this the 'SU-before-ICP' group. In this study, I did not recruit a non-equivalent group of controls – for example, patients admitted to a similar stroke unit in a nearby teaching hospital.

Selection criteria

I used the World Health Organisation's definition for stroke in this study (WHO 1978). I included consecutive patients admitted to the WGH with a diagnosis of stroke or TIA. All patients who were found to have non-stroke conditions such as brain tumour, hypoglycaemia, and epilepsy were excluded. In general, patients with subarachnoid haemorrhage were excluded. However, there was one patient who was admitted to the stroke unit with a clinical diagnosis of stroke but a non-urgent CT scan showed subarachnoid haemorrhage; she was not transferred to the neurosurgical unit and was managed on the stroke unit in the same manner as a stroke patient – I included this patient.

Prospective data collection

I prospectively identified every stroke patient admitted to the WGH with a stroke or TIA between 23rd July 2000 and 22nd April 2001 (i.e. a nine month period). There was a lag time of almost five months between the introduction of the ICP (1st March 2000) and the start of data collection. This served two purposes: a) to give the stroke unit staff a period of time to adjust to the new way of managing patients using the ICP; and b) to pilot the methods of case ascertainment and data collection.

I used several overlapping methods of case ascertainment: the Acute Receiving Unit (ARU) admission record; paging by the nurses and doctors from the ARU; the consultants in charge of the acute stroke unit; and the x-ray meeting in the Department of Clinical Neurosciences each morning. After the opening of the Acute Medical Admission Unit (AMAU) in October 2000, I also inspected their admission record. Although I did not routinely inspected the admission records in the neurology or neurosurgery wards, I recruited some patients from these wards when I knew of their admissions from x-ray meetings or I have been alerted by the neurology or neurosurgical teams.

Throughout the period of prospective data collection, two research fellows (PJH and myself) went to the ARU and AMAU each morning (Monday to Friday) to examine their admission records. The admission records stated the personal details and suspected diagnosis of every patient who had been assessed by the medical staff. I retrieved and examined the case notes for all the patients who had a suspected diagnosis of "stroke", "cerebrovascular accident" or "TIA". To maximise the

sensitivity of our identification process, I also examined the case notes of patients admitted with "weakness", "speech problem", "blind", "visual problem", "collapse", "fit", "fall", "headache", and "unwell". This was an over-inclusive strategy but I found many stroke patients who would otherwise have been missed.

I then assessed the identified patients on the ward by taking a thorough history and performing a comprehensive physical examination. The aim was to assess the patients as soon after admission as possible; this was usually done on the day of admission (day 0) or the next working day (or on Monday if the patient was admitted in the weekend). I then used the information from the history to assess the degree of dependency prior to admission (modified Rankin score, mRS) (Bamford et al 1989). I also used the clinical signs found on examination to assess and graded the severity of stroke; I recorded the Glasgow coma score (GCS), National Institute of Health stroke score (NIHSS), and the Oxfordshire Community Stroke Project (OCSP) subtype of stroke (Jennett & Bond 1975; Goldstein et al 1989; Bamford et al 1991). In an inter-rater study of 42 stroke patients, the research fellows (including PJH and myself) were found to have high levels of consistency in history-taking, examination, and diagnosis (see **Appendix 4**).

If the patient was still in hospital on the fifth day after admission (day 5), I would carry out another clinical assessment. I have chosen day 5 because: a) the ICP was designed for the patient care during the first five days, and b) many patients were transferred to other wards or hospitals at around one week, making it practically more difficult to perform clinical assessments after the first five days. On day 5, I

performed the same clinical examination as the first assessment, with the addition of the Barthel index (Mahoney & Barthel 1965). I also examined the case notes or the ICP to extract data related to the outcome measures of interest (see below). A summary of the scales and stroke classification system used in this study can be found in **Table 5.1**.

Occasionally, the acute stroke team was alerted by the nurses or doctors in the ARU that a stroke patient had arrived at the ARU. PJH or myself would then assess the patient in the ARU and arrange for admission where necessary. For those who had been admitted within the first six hours of stroke onset and satisfied the treatment criteria for intravenous thrombolysis, we would arrange for an immediate CT scan to exclude intracranial haemorrhage.

After any clinical assessment, the research fellows (PJH and myself) would document a short summary of the history and examination findings in the case notes (but not in the ICP). However, we would not initiate any investigations (except for immediate CT scans if the patient was eligible for thrombolysis) or alter the medications.

Retrospective data collection

I retrospectively identified consecutive stroke patients admitted to the stroke unit during a nine-month period before the introduction of the ICP in March 2000 (between 1st June 1999 and 29th February 2000). Patients were identified from the stroke unit admission record and I attempted to retrieve their case notes. Since this

was a retrospective process, it was not possible to obtain the NIHSS or Barthel index. The GCS on admission was usually recorded by the medical or nursing staff at the ARU. The pre-stroke mRS was estimated from the documented social history, but the mRS on day 5 was unobtainable. The OCSP subtype of stroke was also estimated from the documented clinical symptoms and signs.

Outcome measures of the study

In this study, I sought to assess the effects of introducing an ICP for acute stroke on four major categories of outcome measures (see below). Data for all of the outcome measures were extracted from the case notes or ICP, and I recorded an outcome measure as having occurred only if it was clearly documented. The quality of the collected data, and hence the frequency of each outcome measure, depended on the quality of the documentation; poor documentation may have led to under-ascertainment of certain non-fatal outcome measures in this study.

1. Documentation within the first 24 hours (see Table 5.2)

I assessed the quality of documentation using the questions from the Royal College of Physicians' national sentinel audit package (Rudd et al 1999). I was particularly interested in the documentation of the neurological examination and diagnostic description within the first 24 hours after admission.

2. Process of care during the first five days (see Table 5.3)

These included:

- Immediate management (e.g. measurement of blood glucose, chest x-ray);

- Use of investigations (e.g. CT scanning, carotid duplex); use of medications (e.g. antiplatelet agent, warfarin, antibiotics);
- Use of therapy and nursing interventions (e.g. physiotherapy, speech therapy, urinary catheterisation);
- Length of stay at the end of hospitalisation. This was defined as the difference in the number of days between the date of admission to the WGH and the date of discharge from the WGH. Any period of treatment or rehabilitation in other hospitals (e.g. Royal Victoria Hospital) was not counted.

3. Occurrence of complications during the first five days (see Table 5.4)

I assessed the occurrence of 13 different medical complications (e.g. chest infections, urinary tract infections, falls, constipation). All of these complications were defined prior to data extraction.

4. Outcome: death and discharge destination

I assessed death, discharge to institution and discharge to home by day 5 and at the end of hospitalisation. In this study, 'institutions' included rest homes, nursing homes, long-stay hospitals, or other hospitals (e.g. rehabilitation units); and 'end of hospitalisation' was defined as when the patient was discharged from the WGH.

Data extraction and management

On day 0, or as soon after admission as possible, I recorded data related to the patients' baseline characteristics (including those used to adjust for case mix) and certain details related to the hospital admission (e.g. date and ward of admission).

Data on the outcome measures were extracted from the patients' case notes on day 5 using pre-printed data extraction forms (see **Appendix 5**). Before the start of the study, I circulated the forms amongst my supervisors (PAGS and MSD) for comments. They were then piloted on a few stroke patients and modified where necessary. Any information written in the case notes by PJH or myself after our assessments was *not* extracted as data for the study (see Discussion).

The extracted data were then entered into a database by myself and a trained data entry clerk (SG). For the highest level of security, the entered data were anonymised and stored on the departmental network, which was backed up daily. The paper copies of the data extraction forms were stored in a locked cabinet inside a locked office.

Before data analysis, I checked all the entered data on two separate occasions to minimise typing errors. Any missing items were sought from case notes and/or the hospital patient data system (e.g. date of discharge). Certain variables were also cross-checked with the database of my colleague (PJH), who conducted his own study on the same patients. I was confident that the final data set was as accurate and free of missing values as was practicable.

Ethical aspects

The present study was an observational study using routinely collected data and did not involve any specific intervention. The data were stored in an anonymised format and the patient's confidentiality was respected. Moreover, the Data Protection

legislation was unclear the time of planning this study, and has remained unclear in Scotland (www.show.scot.nhs.uk/csags) (Al Shahi & Warlow 2000). After discussing with my supervisors, it was decided this was an audit which did not need specific approval from the ethical committee. However, the ethical committee had previously approved the routine collection of data on hospital referral cases to evaluate the services being developed. The committee has subsequently approved the prospective collection of data for similar purposes.

Statistical methods

Estimation of the sample size required

I used two different approaches to estimate the required sample size. Firstly, I assumed that 85% of stroke patients would suffer at least one complication in hospital (Langhorne et al 2000), and I proposed that the ICP might reduce this proportion to 75% (odds ratio, OR 0.53, relative risk, RR 0.88). To detect this 10% difference at 5% significance level with 80% power would require a sample size of 250 patients per arm. Secondly, I assumed that 80% of stroke patients would receive a CT brain scan within 48 hours, and I proposed that the ICP might increase this proportion to 90% (Wee et al 2000). To detect this 10% difference at 5% significance level with 80% power would require a sample size of 200 patients per arm. I therefore sought to collect data on at least 500 patients. In the present study, I included a total of 520 admissions (in 501 patients). There were 202 admissions in the retrospective group and 318 in the prospective group.

The above sample size estimations might be conservative since the Cochrane review (see **Chapter 4**) found that certain beneficial effects might in fact be more substantial. For instance, I found that ICPs could significantly reduce the risk of urinary tract infections in hospital (OR 0.38, RR 0.43) and significantly increase the use of CT brain scans (OR 3.66, RR 1.45). These odds ratios are both larger than those used in the above sample size estimations.

Statistical methods and reporting of results

All the data were exported from the original database to an Excel spreadsheet (Microsoft® Excel, Microsoft Corporation, 1997) and statistical tests were carried out using SPSS for Windows (version 10.1, SPSS Inc, 2000). In the results sections, I reported the absolute numbers and percentages (absolute risks). For continuous variables (e.g. age), I also reported the means and standard deviations. For scales and variables that had a skewed distribution (e.g. NIHSS, length of stay), I also reported the medians and interquartile ranges.

For comparisons of dichotomous outcomes, I calculated the risk difference and odds ratios (OR) with their 95% confidence intervals (CI). I also presented the ORs as summary charts for easier visual comparison (using Review Manager 4.1, Wintertree Software, 1997). Where the OR indicated that the result was significant at the 5% level, I performed a Yates-corrected Chi-square test or Fisher's exact test (the latter was used when any of the expected frequencies were less than five), and calculated the exact p values.

I checked the continuous data for normality of distribution using standard statistical tests of significance: the Kolmogorov-Smirnov test if the number of cases was greater than 50, and the Shapiro-Wilk test if the number of cases was less than 50 (with $p>0.05$ indicating a normal distribution). For normally distributed data, comparisons between two groups were performed using an independent t-test. For non-normally distributed data, the non-parametric Mann-Whitney U test was used. For reports of these results, I have specified which test has been used in each case.

Approach to data analysis

I used intention-to-treat (ITT) analysis to compare the results between groups of patients. I have chosen to use this approach rather than treatment-received analysis because it was more appropriate for my research question, i.e. what were the effects of *introducing* the ICP on the stroke unit? In other words, I hypothesised that the introduction of the ICP in the stroke unit might influence the outcome of *all* the patients admitted to the stroke unit, including those in whom the ICP had *not* been used at all. Nevertheless, I have also analysed the data using treatment-received analysis to explore the influence of compliance; the results the latter analyses will be reported in the Discussion section of this chapter.

Adjustment for case mix

For outcome measures that could be affected by case mix, I adjusted the data using a prognostic model that had been developed in this department by Counsell et al between 1992 and 1999 (Counsell 1999). The model contained six variables which were independent indicators of prognosis (i.e. the probability of being alive and

independent at 6 months). These were: 1) age in years; 2) whether the patient was living alone before stroke; 3) whether the patient was independent before stroke; 4) whether the GCS verbal score was 5; 5) whether the patient was able to walk independently; and 6) whether the patient was able to lift both arms against gravity. This model was developed using data from the 530 patients recruited in the Oxfordshire Community Stroke Project (Bamford et al 1988), and it has been externally validated using data from two other community-based stroke studies – the SEPIVAC Study with 310 patients and the Perth Community Stroke Study with 228 patients (Ricci et al 1991; Anderson et al 1993).

Using logistic regression (SPSS version 10.1), I inserted the outcome as the dependent variable and forced all the aforementioned six variables into the analysis as covariates. I then added the 'comparison' variable (e.g. SU-after-ICP or SU-before-ICP) as the last covariate. The adjusted ORs with 95% confidence intervals were calculated and I have presented them as summary charts.

5.4 Baseline characteristics

In this section, I shall describe the patients in both the before-and-after study *and* the prospective comparative study because they shared a common group of patients (i.e. the SU-after-ICP group). The patients in the two studies can be divided into the following three groups:

Name of Group	Description	Which study?
SU-before-ICP group	Patients admitted to the stroke unit *before* the introduction of the ICP (retrospective)	**Before-and-after study**
SU-after-ICP group	Patients admitted to the stroke unit *after* the introduction of the ICP (prospective)	**Before-and-after study**
GMW group	Patients admitted to the general medical wards with no ICP (prospective)	**Prospective comparative study**

Total number of recruited patients

I identified a total of 501 patients who accounted for 520 admissions. Seventeen patients were admitted twice and one patient was admitted three times (but one of these was for a non-stroke condition). Of these 18 patients, five were admitted for non-stroke conditions for one of those admissions, which means that there were 13 patients readmitted with a stroke or TIA in this study. However, three patients appeared in both the retrospective and the prospective groups, whereas 15 patients

appeared in only one group. This complex situation meant that there were great difficulties with using individual patients as the basic units for calculations. Hence, in this study, I chose to use the *episode of admission* as the basic unit for calculations, and not the individual patients. In the remainder of this chapter, I shall use the term 'patients' to refer to the episodes of admission and not the individual persons.

I retrospectively identified 202 patients in the SU-before-ICP group. Of these 202 patients, four patients (2%) had been transferred to the stroke unit more than five days after admission, and the case notes of a further 12 patients (6%) were unobtainable despite comprehensive searching. I excluded these 16 patients, leaving 186 potentially eligible patients. Of these 186 patients, 32 (17%) had non-stroke conditions and were also excluded. The final number of patients included in the SU-before-ICP group was 154. In this group, 136 patients had a stroke and 18 had a TIA.

I prospectively identified 318 patients who had been admitted to the WGH with a possible stroke. Of these, 33 (10%) had non-stroke conditions and were excluded. Of the remaining 285 patients, 197 (69%) were admitted to the stroke unit within five days (the SU-after-ICP group), and 88 (31%) were admitted to the general medical wards (the GMW group). In the SU-after-ICP group, 184 patients had a stroke and 13 had a TIA. In the GMW group, 78 patients had a stroke and 10 had a TIA.

The recruitment and inclusion process is summarised in **Figure 5.2**. The diagnoses of the 65 non-stroke conditions found in this study are listed in **Table 5.5**.

Patients' baseline characteristics (see Table 5.6 and Figure 5.3A & B)

The three groups were similar in the distribution of age and gender. The mean age (standard deviation, SD) was 74.5 (11.7) years in the SU-before-ICP group, 74.5 (12.2) years in the SU-after-ICP group, and 72.0 (13.8) years in the GMW group. The proportions of males were 50%, 49%, and 48% respectively. The three groups were also similar in terms of the pre-stroke level of independence (indicated by mRS of <3 and whether living alone), presence of major risk factors for stroke, pathological subtype of stroke (CT scan result), and medications taken before admission.

There were differences in the distribution of OCSP classifications of stroke between the groups. Compared with the SU-before-ICP group, the SU-after-ICP group had more total anterior circulation strokes (29% vs 18%, p=0.005) and fewer partial anterior circulation strokes (30% vs 42%, p=0.04). Compared with the GMW group, the SU-after-ICP group had fewer posterior circulation strokes (9% vs 22%, p=0.004), but more lacunar strokes (28% vs 17% p=0.05).

The left side of the body was affected in 42% of patients in the SU-before-ICP group, 43% in the SU-after-ICP group, and 44% in the GMW group (not statistically significant). The right side of the body was affected in 40%, 52%, and 47% respectively (not statistically significant). The remaining few percentages of patients in each group had either both sides of their bodies affected, or the side of the body affected could not be determined, e.g. patients presenting with dysphasia only.

Compared to the GMW group, the patients in the SU-after-ICP appeared to have suffered more severe strokes (median NIHSS 9.5 vs 7, p=0.0005). I have not presented the data on the GCS because its assessment was found to be inconsistent in patients who presented with dysphasia. Using the language section of the NIHSS as a screening tool, 41% of patients in the SU-after-ICP group and 28% in the GMW group presented with dysphasia (overall = 37%).

Furthermore, as additional surrogate makers of stroke severity, I assessed the early 'consequences' of stroke in each group, which were classified as: a) neurological sequelae including dysphagia, reduced consciousness and incontinence; and b) physiological disturbances including hyperglycaemia, hypoxia and fever on admission. I adjusted these results for case mix and compared between the three groups (see **Table 5.7**). In summary, there was no significant difference between the SU-before-ICP and SU-after-ICP groups. However, despite have a higher median NIHSS, patients in the SU-after-ICP group were less likely to have had a fever on admission as compared to the GMW group (p=0.01).

I recorded the place of residence before stroke, whether the patient was living alone, and whether formal help was needed at home. Formal help was defined as the any regular social help (e.g. home help, meals-on-wheels) or district nurse visits. The findings are summarised in **Table 5.8**. There was no significant difference between the three groups.

I excluded 12 patients in whom their case notes could not be retrieved. These 12 patients did not differ significantly from the other groups in terms of age or gender distribution. The mean age (SD) was 77.2 (9.7) years and 5 (42%) were males. Furthermore, by the end of hospitalisation, 2/12 (17%) had died, 5 (42%) had been discharged to an institution, and 5 (42%) had been discharged home. These outcomes again did not appear to differ significantly from the other two groups.

Finally, amongst the prospectively recruited patients, there were 12 patients who suffered a stroke whilst in hospital; stroke occurred in the medical wards in seven patients, surgical wards in three patients, neurosurgical ward in one patient, and the coronary care unit in one patient. Of these 12 patients, the mean age (SD) was 81.7 (4.9) years and 5 (42%) were males. All but four of the patients were transferred to the stroke unit by day 5. By the end of hospitalisation, 3/12 (25%) had died, 7 (58%) had been discharged to an institution, and 2 (17%) had been discharged home. It appeared that this group of patients were older and might have a poorer prognosis.

Delay in admission to the stroke unit

Delay in admission to hospital

Although the *dates* of stroke and admission were known and recorded in all the patients, the *times* of stroke onset and admission could not be determined accurately in many cases. The patient may not be able to accurately recall or express clearly the exact time of stroke onset, for instance, if the patient woke with the symptoms, if the patient was dysphasic (with no witness available), or if the patient did not look at the clock at the time of stroke. If an ambulance was called, I could have taken the time of

the emergency (999) call as an estimate of the time of stroke onset, but the delay in making that first call could have been significant; I therefore did not do this. **Table 5.9** shows the numbers of patients for whom the dates and times of stroke onset and admission could be determined, and the numbers of patients who woke with their symptoms. I found that the time of stroke onset was not determinable in 61% of patients in the SU-before-ICP group, as compared to only 40% in the SU-after-ICP group ($p<0.0001$). This was most likely to have been a result of less detailed history taking or documentation.

Since the dates of stroke and admission were recorded in all the patients, I have calculated the delay from stroke onset to admission in terms of days and not hours. There was no significant difference in the delay in admission to hospital between the three groups (see **Figure 5.4**). In all three groups, about 70% of patients were admitted to the hospital on the same day as the stroke onset.

Delay in transfer to the stroke unit

For the patients who were admitted to the stroke unit, not all of them were admitted there on the day of admission. In the SU-before-ICP group, 136/154 (88%) patients were admitted directly to the stroke unit, but 18 (12%) were transferred there from another ward. Of these 18 patients, 11 (61%) were transferred to the stroke unit between days 0 and 2.

In the SU-after-ICP group, 111 (56%) patients were admitted directly to the stroke unit, but 86 (44%) patients were transferred there from another ward. Of these 86

patients, 76 (88%) were transferred to the stroke unit between days 0 and 2, and 79 (92%) were initially admitted to the AMAU before being transferred to the stroke unit.

5.5 Compliance with the integrated care pathway document

Even with a well-designed ICP, if it is infrequently used or poorly completed, it is less likely to have a significant impact on patient care or outcome. Any evaluation of an ICP should therefore also include an assessment of compliance, which can be loosely defined as the extent to which medical and nursing staff comply with the instructions of the ICP and how well they document those actions. It is important to assess compliance because compliance may reflect how acceptable an ICP is to the staff, and how feasible it might be to introduce the ICP more widely. Hence, items that are not associated with good compliance may be impractical. Previous studies of ICP for stroke have commented on the level of compliance, but none of them have clearly described the method of assessment (Schull et al 1992; Ross et al 1997; Sulch et al 2000). In Sulch et al (2000), for example, the ICP recordings were divided into "complete" and "incomplete", but it was unclear what these terms meant or who assessed the completeness.

In the present study, I assessed compliance in two ways. Firstly, I assessed whether the doctor's and nurses' sections of the ICP were used at all. Secondly, if the sections were used, I assessed the completeness of the recording. I did not assessed the compliance with the therapists' section because the therapists recorded the patients' progress in detail in their own departmental patient records, and only a short summary was written in the ICP. Hence, full assessment of the compliance with the therapists' section of the ICP would not have been meaningful.

Use of the different sections of the ICP

The use of the different sections of the ICP is summarised in **Table 5.10**. Of the 197 patients in the SU-after-ICP group, 163 (83%) had a doctor's and/or nurses' sections used, 129 (65%) had both sections used, but 34 (17%) patients had neither sections used. I examined the possible reasons why the ICPs were not used in these 34 patients (see **Table 5.11**). In 23/34 (68%) patients, the reason was that the patients were transferred to the stroke unit from another ward during the first five days, and the staff did not initiate the ICP, probably because they thought it would have duplicated information.

Within the SU-after-ICP group, I compared the baseline characteristics of the 163 patients who were managed using an ICP with the 34 patients who were not (see **Table 5.12**). I found that patients who were not managed using the ICP were less likely to have a history of hypertension or to be on antihypertensive medications (p=0.001 for both), but more likely to have a *higher* median NIHSS (13 vs 9, p=0.03). The reasons for these findings are unclear, but the staff might have believed that the ICP was less useful for patients with very severe stroke, but more useful for patients with milder stroke.

Interestingly, the doctor's section was used in a small proportion (14/88, 16%) of patients in the GMW group. This could have occurred because the on-call medical staff had used them as a clerking proforma in the ARU. This highlights the potential for cross-contamination of the intervention in clinical studies such as this one.

Completeness of recording

I assessed the completeness of recording using a simple ordinal scale: 'complete', 'partially complete', and 'not used'. A 'complete' recording was defined as one with every question filled in, or all but one question filled in. A 'partially complete' record was one with more than one question missed out. A section of the ICP was defined as 'not used' if it was left totally blank. This simple classification system was applied to the doctor's and nurses' sections of the ICP. The completeness of recording for the two sections is summarised in **Table 5.13**. I found that 97/147 (66%) of the doctor's sections, and 82/145 (57%) of the nurses' sections, were completely recorded. I also assessed whether completeness of recording influenced certain outcome measures, the results of which will be presented later in the Discussion section of this chapter.

5.6 Results of the before-and-after study

I shall now report the main results for each category of outcome measures in this study. **Table 5.14** presents the frequencies of the six variables that were used to adjust the results for case mix.

1. Documentation in the first 24 hours

See **Table 5.15** and **Figure 5.5**. Documentation of neurological examination was significantly more thorough in the SU-after-ICP group. This was evident in the documentation of sensation ($p=0.01$), truncal control or gait ($p<0.0001$), formal testing of the mental ability ($p=0.0001$), and swallowing ($p=0.03$). Similarly, documentation of the diagnostic description was significantly more thorough, in terms of the anatomical site of the lesion ($p<0.0001$) and the pathological type of stroke ($p=0.0002$).

2. Process of care during the first five days

i) Immediate management

See **Table 5.16** and **Figure 5.6**. Patients in the SU-after-ICP group were significantly more likely to: a) have their blood glucose measured ($p=0.003$); b) have their oxygen saturation measured ($p=0.02$); and c) be informed of their diagnosis and plan of management ($p=0.0004$). However, they were significantly less likely to have a chest x-ray ($p=0.0004$). There were also non-significant trends to suggest that patients in the SU-after-ICP group were more likely to have their antihypertensive medications continued, and less likely to have been prescribed antibiotics. Overall, there was no

significant difference in: a) measurement of blood pressure or temperature; b) use of supplemental oxygen, insulin or thrombolytic therapy; or c) performance of electrocardiograms, blood tests or immediate CT scans.

ii) Use of investigations during the first five days

See **Table 5.17** and **Figure 5.7**. I have adjusted the use of investigations for case mix. Both the adjusted and unadjusted results showed that patients in the SU-after-ICP group were significantly more likely to have a CT brain scan between days 0 and 1 (p=0.02), and between days 0 and 2 (p=0.02). There was also a non-significant trend to suggest that patients in the SU-after-ICP group might be more likely to have an echocardiogram (transthoracic or transoesophageal). There was no significant difference in the performance of carotid duplex, angiography, or other procedures; there was also no significant difference in the proportion of patients being referred for a neurosurgical opinion.

iii) Use of medications during the first five days

See **Table 5.18** and **Figure 5.8**. There was no significant difference in the proportion of patients being *newly* started on antiplatelet agents (aspirin, dipyridamole or clopidogrel), anticoagulation (heparin or warfarin), antihypertensive agents, or statins. There was also no significant difference in the proportion of patients with ischaemic stroke who received any antiplatelet agent within the first one or two days. Furthermore, for the use of antipyretic therapy, oral antibiotics, intravenous antibiotics and intravenous fluids, the results were adjusted for case mix and there was no significant difference between the two groups.

iv) Use of therapy and nursing interventions during the first five days

See **Table 5.19** and **Figure 5.9**. I have adjusted the use of therapy and nursing interventions for case mix. Both adjusted and unadjusted results showed that patients in the SU-after-ICP group were significantly more likely to receive physiotherapy during the first five days of admission (p=0.0005). However, there was no significant difference in the provision of other forms of therapy. In terms of nursing interventions, there was no significant difference in the use of urinary catheters, nasogastric feeding, thromboembolic deterrent (TED) stockings, or any feeding (oral or parenteral).

v) Length of stay at the end of hospitalisation

See **Table 5.20**. There was no significant difference in the median length of stay between the two groups (SU-before-ICP = 8 days, SU-after-ICP = 10 days, p=0.65, Mann-Whitney U test). The distribution of the data for length of stay was positively skewed for both groups; the maximum length of stay was 164 days for the SU-before-ICP group and 96 days for the SU-after-ICP group.

3. Occurrence of complications during the first five days

See **Table 5.21** and **Figure 5.10**. I have adjusted the occurrence of complications for case mix. Although unadjusted results did not suggest any significant difference between the two groups, there was a general tendency for all the complications to occur less often in the SU-after-ICP group (except DVT which only occurred in two patients). After adjusting for case mix, I found that patients in the SU-after-ICP group were significantly less likely to have suffered urinary tract infections (p=0.03).

Furthermore, there were non-significant trends to suggest that patients in the SU-after-ICP group might be less likely to have suffered fever, constipation, other complications, or any complication. 'Other complications' suffered by both groups included asthmatic attack, cardiac failure, cellulitis, cholecystitis, upper and lower gastrointestinal haemorrhage, renal failure, and paraphimosis.

4. Outcome: death and discharge destination

See **Table 5.22** and **Figure 5.11**. I have adjusted death and discharge destination for case mix. Both the adjusted and unadjusted results showed no significant difference between the two groups in terms of death, likelihood of being discharged to institution or to home (by day 5 or at the end of hospitalisation). However, after adjustment, the point estimates appeared more favourable for the SU-after-ICP group in terms of mortality.

5.7 Discussion

Limitations of this study

The results of this study are likely to have been influenced by a large number of potential biases and confounding factors. I shall discuss these in turn.

Potential sources of bias

Ascertainment bias

In this study, patient identification was unselected and consecutive. Although I used overlapping methods of case ascertainment, I may have missed a small number of patients, especially those who had been admitted to the neurology and neurosurgery wards. The clinical presentation of these patients was frequently unusual (e.g. younger patients with gradual onset or atypical neurological symptoms) or they had suffered a catastrophic intracerebral haemorrhage that required immediate neurosurgery and intensive care. Similarly, a small number of patients might not have been included in the SU-before-ICP group. Although it was normal practice to record the admission of every patient to the stroke unit, some patients may not have been noted if they had died or were discharged within a few hours of arrival. If this type of mistake did occur, it is likely to have been rare.

Post-entry exclusion

In this study, I have excluded 65 patients with non-stroke conditions, 4 patients who had been transferred beyond five days after admission, and 12 patients whose case notes had been lost (all of them were in the SU-before-ICP group). The 12 patients

whose case notes were missing did not differ significantly from the other two groups in terms of age, gender, or outcome by the end of hospitalisation. However, I could not exclude the possibility that the care of these patients was significantly different. If that was the case, and since all the missing notes were in the SU-before-ICP group, this might have influenced the results.

Assessment and reporting bias

Another major area for potential bias in this study is that involved with the method of data extraction from the case notes. The occurrence of a particular outcome measure (e.g. chest infection) was only recorded into our database if it had been documented. If it had not been documented, it did not necessarily mean that it never occurred. Therefore, the quality and completeness of the documentation could have influenced the accuracy of the data extraction. I found in this study that documentation of the initial assessment was significantly more thorough after the introduction of the ICP, and it is likely that the documentation of other aspects of care was also better. However, it is difficult to assess the impact of this bias because better documentation of good outcomes would have led to bias *in favour* of ICP care, whereas better documentation of bad outcomes would have led to bias *against* ICP care. It is also worth noting that the documentation of certain aspects of care (e.g. occurrence of complications) might in theory be *less thorough* because the ICP was in a tick-box format and the staff rarely recorded the events in free-text. Finally, reporting bias could have occurred for some of the outcome measures. For example, positive events (e.g. haemoptysis, seizure) might have been more likely to be documented than negative ones (e.g. low mood, not eating, not interacting with staff).

No blinding of the assessor to the intervention

During data extraction, I (the assessor) could not be blinded to the intervention. It was immediately obvious which group the patient belonged to by looking at the date and ward of admission, and whether there was an ICP in the case notes. This lack of blinding may have resulted in observer bias, hence influencing the quality of data extraction and possibly outcome (Rothwell & Warlow 1995). Though the use of pre-printed data extraction forms might have helped, observer bias could not be eliminated. It is worth noting that I had no direct interest in obtaining a positive result from this study.

Using admissions rather than individual patients as units of calculation

I chose to analyse the data using episodes of admission rather than individual patients as the unit for calculation. There are both advantages and disadvantages in doing so. The main advantage is that the data from each admission were treated independently, which would be sensible because the management of a patient during one admission should not in any way affect their management during subsequent admissions. Another advantage is that the age of the patient, place of residence, medications taken on admission, pre-stroke level of dependence, and past medical history might have changed between the first and second admissions (e.g. patient might have been discharged to a rest home after the first stroke). The main disadvantage of using episodes of admission as the unit for calculation is the possibility of introducing bias because each admission might not be truly independent of each other. For example, poor patient care during the first admission might have increased the risks of

recurrent stroke, readmission, or poorer outcome after the second stroke (e.g. if warfarin was not commenced for atrial fibrillation, or hypertension not treated).

Potential confounding factors

In this study, I compared data from a retrospectively identified group of patients with data from a group that was prospectively identified. Any changes observed in this study may have been due to factors other than the introduction of the ICP, and the real effects of the intervention could have been obscured by these factors. Thus, to reliably assess the effects of introducing the ICP, all other factors would have to be comparable or held constant. These factors would include case mix, bed availability in the stroke unit, level of staffing (medical, nursing and therapists), training and education activity for the staff, rate of patient admission, hospital admission policy (especially in the AMAU), and so on. Therefore, one must interpret any differences observed in patient care and outcome against a background of many changes in the stroke service over the course of the study. Although the presence of confounding factors may reduce the external validity of the study, they do not necessarily invalidate the assessment of their effects in the local setting. I shall discuss several important confounding factors in greater detail.

Differences in case mix – were they real?

The baseline characteristics of the patients could have significantly influenced the patient care and outcome. In the before-and-after study, the two comparison groups were different in terms of the OCSP classification of stroke. Total anterior circulation strokes (TACS) were more common, and partial anterior circulation strokes (PACS)

were less common, amongst patients in the SU-after-ICP group. Previous observation studies have found that the prognosis of TACS is much poorer than that of PACS; the 30-day case fatality is almost 40% for TACS as compared to only 4% for PACS (Bamford et al 1990).

However, the observed differences in clinical subtype were likely to be spurious for three main reasons. Firstly, I found that the documentation of neurological examination was less thorough in the SU-before-ICP group; this could have reduced the accuracy of estimating the OCSP clinical subtype in that group. In particular, a failure to detect subtle cortical signs (e.g. dyspraxia, dyscalculia) could have led to a systematic under-diagnosis of TACS and PACS, and many patients with TACS might have been wrongly labelled as PACS or LACS.

Secondly, if the observed differences in clinical subtype were real, then I would have expected the outcome to have been significantly different between the two groups. However, I found no significant difference in the unadjusted results for death or discharge destination (on day 5 or by the end of hospitalisation) between the two groups.

Thirdly, adjustment of the results for case mix has made no significant difference for the majority of outcomes, suggesting that case mix probably did not contribute greatly towards the observed differences in the process of care and outcome. In adjusting for case mix, I did not use the OCSP subtype as a co-variate; in retrospect, this was the correct thing to do because it would probably have been biased.

Effects of changes in service structure, research evidence and hospital policy

The major changes in the service structure during the study have been described earlier in this chapter. For example, the apparent difference in the provision of physiotherapy was most likely to be due to the appointment of extra physiotherapy staff after the ICP was introduced. Other changes also deserved comment. Firstly, the third International Stroke Trial (IST-3) started recruiting patients in April 2000 (three months before the prospective data collection of this study). This multicentre trial aimed to assess the efficacy of intravenous thrombolysis within six hours of stroke onset. The start of patient recruitment for this trial has meant that some patients presenting within the first few hours of onset would have been quickly assessed by the research fellows and 'fast-tracked' to the CT scanner. In this study, I found that immediate CT scans were performed in 19% of the patients in the SU-before-ICP group, as compared to 22% in the SU-after-ICP group. Similarly, thrombolysis was used in 1% and 3% of the patients, respectively. It is possible that the (non-significant) observed differences were due to the 'fast-tracking' of patients by the research fellows. Interestingly, I also found that patients in the SU-after-ICP group were more likely to have a CT scan between days 0-1 and 0-2, but this difference is unlikely to be due to the IST-3 since the performance of *immediate* CT scans was not significantly different.

Secondly, patient care in the stroke unit might have evolved as new medical knowledge and research evidence emerged, and as new hospital policies were developed. For example, the Royal College of Physicians of Edinburgh Consensus Conference on Stroke Treatment and Service Delivery took place in November 2000.

The proceedings of this conference contained updated research evidence and guidelines (RCP 2001a). The distribution of publications like this might have influenced patient care in both the stroke unit as well as the general medical wards.

Thirdly, the staff on the stroke unit knew that I was collecting data on process of care and outcome. This knowledge might have influenced patient care and outcome; for example, the staff might have been more active in looking for, treating, and documenting complications after the introduction of the ICP. On the other hand, some staff might have wanted the ICP (and the stroke unit) to 'look good' by choosing not to document complications. This is also known as the 'Hawthorn effect', which is named after the experiments performed at the Hawthorn Plant of the General Electric Company in the 1920s and 1930s (Piantadosi 1997).

Clinical assessments by the research fellows

I tried to reduce the research fellows' (PJH and myself) influence on patient care by ignoring the information written by us when extracting the data from the case notes. However, it seems inevitable that we have influenced patient care to a certain degree. The research fellows, after having assessed the patients, usually wrote in the case notes, giving a short summary of the history and examination findings. It is possible that what we wrote might have influenced what others wrote. For example, a junior doctor could have simply copied what we wrote without much thought. Alternatively, a junior doctor might have chosen not to document the history or examination findings because we had already done so. The latter might also be a result of a recent national move to reduce the junior doctors' working hours, leading

to many junior doctors being actively discouraged from 'duplicating effort' (e.g. re-taking history, re-examining the patient, re-documentation).

Seasonal effects and changes in outcome with time

Evidence from observational studies suggest that all-cause mortality may be influenced by the season of the year (largely explained by the seasonal effects of ischaemic heart disease), but the association between incidence of stroke, stroke deaths, and the season of the year remain unclear (Oberg et al 2000; van Rossum et al 2001). In our study, both the retrospective and prospective data collection lasted exactly nine months (1/6/99 to 29/2/00, and 23/7/00 to 22/4/01). The months and seasons covered by the periods of data collection were very similar between the two groups and hence seasonal variation was unlikely to have significantly affected our results. However, some outcomes might have changed with time. For example, if patient care has gradually improved throughout the hospital during the study, patient outcome might also have improved with time (probably in a linear fashion). In that case, any observed difference in outcome between the comparison groups in this study could simply reflect this change with time, rather than the effects of introducing the ICP.

To check for change in outcome with time, I received statistical advice from the Effective Practice and Organisation of Care (EPOC) Group of the Cochrane Collaboration, which had a special interest in the methodological issues surrounding non-randomised studies, such as interrupted time series analysis. For this purpose, I was advised to examine the results of the retrospective group in this study. This was

done in three stages. Firstly, I divided the entire duration of the data collection (18 months) into six periods of three months. The numbers of patients admitted during each period are reported in **Table 5.23**. Secondly, I assessed for any change in outcome with time for death, discharge destination, occurrence of complication, and CT scanning between days 0 and 2. This was done by comparing the results between the first and third periods, and between all three periods. (see **Table 5.24**). There was no significant difference in outcome between the groups, nor was there any apparent temporal trend, suggesting that the outcomes selected had not been significantly influenced by the passage of time. However, this type of subgroup analysis would not have enough statistical power to provide reliable evidence of effect.

Number of patients and outcome variables

A small sample size can increase the risk of producing false positive (type I error) or false negative results (type II error) (Piantadosi 1997). With a larger sample of patients, the estimate of effect size would have been more precise, but a larger study would have required greater resources (Lau et al 1992). In theory, recruiting a larger sample of patients would have meant that the study had to last longer. This could in turn introduce more potential confounding factors which could affect the reliability of the results, hence further reducing the internal and external validity of the study. To illustrate, **Appendix 3** outlines the large number of changes to the structure of the stroke service in the WGH during the past decade – a longer study may simply mean more changes.

In this study, I assessed the patient care provided in 520 stroke admissions, making it one of the largest studies ever undertaken in testing the effects of an ICP for acute stroke. Even so, the number of patients included in each group was less than 200. During the planning of this study, we estimated that between 400 to 500 patients would be needed if the study was to have sufficient power to detect the effects on the most important outcome measures.

Another issue is the large number of outcome variables that have been assessed in this study. In general, when many variables are assessed, the results of 1/20 of them would be significant at $p<0.05$ purely as a result of the play of chance. Methods of tackling this problem would include recruiting a very large number of patients, or to reduce the significance level (e.g. to 1%, $p<0.01$). However, the present study could be regarded as exploratory and all the trends appeared to be similar for many of the results, indicating that the study was at least internally valid.

Issues regarding outcome measures

Choice of outcome measures

Ideally, outcome measures should be relevant, valid, reliable, and sensitive to change; and their assessment should be accurate and unbiased (Piantadosi 1997). In this study, death and discharge destination were easy to collect and free from bias. For other outcomes, I have defined the terms prior to data extraction to minimise confusion and inaccuracy. However, the important questions is: are the outcomes assessed in this study meaningful and informative?

It would seem sensible to suggest that the outcomes that are most relevant to the patient are death and discharge destination. However, previous studies have provided conflicting evidence on whether outcome data such as case fatality were able to indicate quality of stroke care (Dubois et al 1987; Jessee & Schranz 1990; Kahn et al 1990). There are two main problems of using case fatality as an assessment of quality of care. Firstly, case fatality is substantially influenced by case mix (Davenport et al 1996a). Secondly, differences in case fatality, even after adjusting for case mix, does not reliably differentiate between hospitals which provide clinically important differences in stroke care (Weir & Dennis 2001). In a study of 4223 hospital admissions by Weir and Dennis (2001), four of the five hospitals studied were found to have almost identical six-month adjusted case fatalities, yet the process of care was found to be significantly different. The authors concluded that the use of outcome data alone (e.g. case fatality) to compare quality of care between hospitals was unlikely to be reliable – it is also important to assess the baseline characteristics for case mix as well as meaningful indicators of organisation and process of stroke care (Davenport et al 1996a; Weir & Dennis 2001).

The process of care might also be a good indicator of quality of stroke care because: a) it is relatively easy to measure; and b) for many aspects of care, there are now national standards against which local stroke services can be compared (see **Chapter 1**). In the UK, the recently published National Service Framework for Older People can be used as a benchmark (DoH 2001). Although the assessment of the process of care can be highly susceptible to biases and confounding, studies of ICP can at least provide some useful information on the possible ways that they could affect patient

care. While previous studies have mainly concentrated on the effects of ICPs on mortality and length of stay, some experts have voiced their doubt on how such an ill-defined organisational intervention could possibly reduce the risk of death, dependency or institutionalisation (Professor L Kalra, personal communication, 2001).

Omission of several outcome measures

There were several important outcomes that I did not examined. In particular, I would ideally have liked to have assessed the patients' quality of life, experience of pain, and their satisfaction with the care provided in hospital. In the Cochrane systematic review, evidence from two randomised controlled trials found that ICP care might have adverse effects on the patients' quality of life and satisfaction with their care (Falconer et al 1993; Sulch et al 2000). Examination of these outcomes in this study might have been informative, but there are methodological problems associated with their assessment. For example, they are usually poorly defined, difficult to measure, and difficult to compare between individuals (see **Chapter 1**). I was also unable to include these outcomes in this study because of limited time and resources.

Several important physiological variables have also been omitted in this study. I assessed whether the blood pressure, blood glucose, oxygen saturation, and temperature had been measured immediately, and whether these physiological parameters were deranged (according to pre-specified definitions). I also assessed whether the patient suffered fever during the first five days of admission, and

whether the fever was associated with infections, deep vein thrombosis, pulmonary embolism, or pressure sores. However, I did not assess blood glucose or oxygen saturation during the first five days of admission. This was because blood glucose or oxygen saturation were not routinely monitored except in patients with certain pre-existing medical problems (e.g. pneumonia, diabetes). In the latter group, measurements of blood glucose and oxygen saturation would invariably be more likely to yield deranged values. Since this was a non-interventional study, I was unable to insist on more intensive physiological monitoring of the patients in the stroke unit.

Several other outcomes related to therapy and nursing interventions have also been omitted in this study. They included: positioning of the patient in bed; bowel management; patient education (e.g. risk factor management); use of equipment and adaptations (e.g. walking aids, ankle foot orthoses); and the 'quality' of multidisciplinary team meetings and discharge planning. It was also beyond the scope of this study to assess the approach, amount, or intensity of physiotherapy, occupational therapy or speech therapy during the acute period.

Finally, I did not assess the cost of hospitalisation. Accurate calculation of hospital cost would have required data on the direct costs (e.g. nursing care, medical care, therapy, tests, and drugs) and overheads (e.g. patient services, property maintenance, and administration costs) (Forbes & Dennis 1999). Collection of these data would have required a great deal of time and resources. I did, however, record the length of

stay, which has been shown to be the main determinant of hospital cost (Isard & Forbes 1992).

Assumptions about investigations, pharmacological agents and therapy

I was unable to determine whether every investigation, medication or therapy offered to every patient was actually needed. Similarly, I was unable to determine whether every patient who needed every investigation, medication, or therapy actually received it. This was because whether a test, medication or therapy was offered or not depended on many factors including the doctor's experience and the patient's wishes. For example, even though a patient might have recovered well from an anterior circulation ischaemic stroke, a carotid duplex scan might not be appropriate if the patient does not wish to have a carotid endarterectomy. Another problem was that several patients were admitted more than once. Hence, if a carotid duplex scan had already been performed during the first admission, it might not need to be repeated during the second admission.

Timing of assessing outcomes

I collected outcome data for the first five days of admission. In addition, death was assessed by the end of hospitalisation. One problem of assessing any outcome at the end of hospitalisation period is that certain outcomes (e.g. occurrence of infections) may be a *result* of staying in hospital for a long time, and this may in turn increase the risk of death. Furthermore, like many outcomes, length of stay is influenced by case mix, so that patients with moderate to severe strokes may stay for a long time in hospital, whereas those with very severe strokes may die early leading to a shorter

length of stay. Ideally, it would have been informative to have collected outcome data more frequently and at later time points (e.g. at one month and three months), but this was not possible due to financial and time constraints.

Dichotomisation of outcomes

I dichotomised several outcomes according to the delay to their occurrence. The points of dichotomisation were in accordance with the national standards in the UK (DoH 2001). In particular, the National Service Framework for Older People states that a CT scan should be performed within two days of admission, and multidisciplinary assessment (with formal swallowing assessment) should be undertaken within one day of admission. In the WGH, there were also local guidelines stating that physiotherapy should be started within one working day, which equated to three days if the patient was admitted on a Friday. Consequently, I dichotomised physiotherapy to 'any', '0-1 day' and '0-3 days'.

Interpretation of results

From the before-and-after study, what can I conclude about the effects of introducing the integrated care pathway in the stroke unit?

The unadjusted comparisons of SU-before-ICP and SU-after-ICP groups did not provide evidence that introducing the ICP has reduced the risk of death or discharge to an institution. However, the confidence intervals were wide and included the possibility of both benefit and harm. After adjustment for baseline stroke severity, the point estimates appeared more favourable for ICP care, but again were not statistically significant. The study, however, has provided some evidence that the introduction of the ICP would not worsen outcome and might improve certain

aspects of patient care and documentation. I recognise that the study was under-powered for these comparisons, and perhaps all one can conclude is that, for these outcomes, the results are compatible with moderate benefit and do not provide clear evidence of harm.

Did the introduction of the integrated care pathway improve compliance with national standards?

I did not specifically set out to assess the compliance to a particular set of national standards for stroke care. However, several outcomes were related to the standards set by the National Service Framework for Older People and the National Clinical Guidelines for Stroke, and their assessment in this study could be used as indicators of compliance (DoH 2001; RCP 2001b). There were four standards that could be assessed by this study:

1. ***Standard 1. "A brain scan should be performed within 48 hours"***

   Patients in the SU-after-ICP group were more likely to have a CT scan within two days.

2. ***Standard 2. "Multidisciplinary assessment (including formal swallowing testing) within 24 hours of admission"***

   Physiotherapy was more likely to be started in the SU-after-ICP group, but there was no difference in physiotherapy given within one or three days of admission. There was also no difference in the performance of formal swallowing assessment within one day of admission.

3. ***Standard 3. "Existing antihypertensive medication should be continued"***

There was no significant difference in the likelihood of continuing the patients' existing antihypertensive medication between the two groups.

4. ***Standard 4. "Immediate management should include management of fever"***

   There was no significant difference in the use of antipyretic medication between the two groups.

Looking at the above standards, only one out of four standards was more likely to have been met after the introduction of the ICP. More formal assessment of compliance with national standards should be included in future studies.

What was the influence of compliance on the results?

1. Did the <u>use</u> of the different sections of the integrated care pathway influence the results?

To explore this question, I analysed the data using treatment-received analysis. For this analysis, I excluded the 34 patients who were not managed with the ICP from the SU-after-ICP group. I further specified the comparison groups according to which sections of the ICP had been used (see **Table 5.25**). For example, I hypothesised that the use of the doctor's and/or nurses' section (n=163) would influence the occurrence of complications, whereas the use of investigations would only be influenced by the use of the doctor's section (n=147). As I have already reported in **Table 5.12**, there were slight differences in the baseline characteristics between the 34 patients who were not managed with the ICP and the 163 patients who were (in terms of history of hypertension and the median NIHSS). However, there were no significant difference in the baseline characteristics between the patients in the SU-after-ICP group and those who were actually *managed with* the ICP.

In this study, the results derived from treatment-received analysis should represent the maximal effects of the ICP since the patients who were not managed with the ICP would be excluded. However, I found that results derived from treatment-received analysis were not dramatically different from those already presented (see **Table 5.26**). For instance, using treatment-received analysis, patients managed with the ICP were also more likely to receive physiotherapy within three days after admission (p=0.02); and documentation of the level of consciousness and visual inattention were also more thorough (p=0.01 and 0.05).

So what does this mean? The fact that there was no significant difference between the results derived from the two approaches of analysis might mean that it was not the *use* of the ICP that contributed to the observed effects, but the *introduction* of it in the stroke unit. This is certainly plausible because the process of designing and implementing the ICP also involved a great deal of staff education, discussion, and team-building. All these factors might have contributed toward any influence on patient care.

2. Did the completeness of recording of the integrated care pathway influence the results?

To explore this question, I examined all the patients in the SU-after-ICP group who had been admitted to the stroke unit for *the full five days*. I then divided the patients into: a) those who had *both* the doctor's and nurses' sections of the ICP completely recorded (n=32); b) those who had *neither* the doctor's or nurses' sections used

(n=28); and c) the remainder of the group (n=30). The aim was to compare a selection of outcomes between the 'gold standard' (the group with both sections completely recorded) against the other two groups. The outcomes for comparison were the same as those used to check for changes with time (minus those occurring by day 5). They included: death in hospital, discharge to institution, discharge to home, occurrence of any complication, and performance of CT scans within two days of admission. I found no significant difference between the three groups (see **Table 5.27**). Overall, the data suggest that compliance might not be responsible for any observed differences in outcome. It may also suggest that a high level of compliance might not be as important as the actual process of *introducing* the ICP in the stroke unit.

The level of compliance might have been influenced by he level of detail of the ICP. The ICP at the WGH was very detailed and required many answers and signatures. However, it replaced the entire medical and nursing documentation in the case notes. The level of compliance might have been higher if the ICP was simpler and shorter, but it would not have replaced much of the medical and nursing documentation. This balance is an issue that should be addressed in the design and planning stage.

Was the introduction of the integrated care pathway responsible for the observed effects?

There are many reasons why the observed differences in outcomes might not reflect the effects of introducing the ICP. But it remains possible that the introduction of the ICP could have improved organisation and efficiency (both difficult to measure),

leading to better process of care and outcome. It is interesting that the introduction of the ICP appeared to influence several outcome measures related to the immediate management of stroke, even though most of the ICPs were initiated in the stroke unit. Unfortunately, I did not record where the ICP was initiated in this study.

Like stroke unit care, it is very difficult to decipher which components of the ICP are responsible for which observed effects. However, this is an important question because a simpler ICP is theoretically more likely to be used than a more complex one. Thus it is important to identify which components should be included in a simpler ICP and which can be omitted. Since ICPs are unique to the environment in which it is used, studies into the individual components of an ICP would also suffer from similar effects of bias and confounding.

How do the results of this study compare with other studies?

I have conducted one of the largest studies ever performed to test the effects of introducing an ICP in a stroke unit. The only other larger (non-randomised) study is Ross et al (1997), where 554 patients were recruited. The results of the present study were mainly consistent with those of previously published studies and with the conclusions drawn from the Cochrane systematic review (see **Chapter 4**).

In the present study, the effects of introducing the ICP on the process of care are consistent with those found in the Cochrane review in two ways: a) patients in the SU-after-ICP group appeared to be more likely to have a CT scan within one or two days of admission; and b) there was also no significant difference in the length of

hospital stay. The randomised study of ICP for stroke rehabilitation by Sulch et al (2000) also found a significant improvement in the process of care (unpublished data).

Like other studies that have examined death and discharge destination, this study did not find any evidence of net benefit or harm by introducing the ICP (Pasquarello 1990; Hamrin & Lindmark 1990; Odderson & McKenna 1993; Falconer et al 1993; Baker et al 1998; Sulch et al 2000). However, this study did not assess the effects of the ICP on other patient-specific outcomes such as patient satisfaction or quality of life.

Previous randomised and non-randomised studies have found an apparent reduction in urinary tract infections amongst patients managed with an ICP, and this was also found in the present study (Pasquarello 1990; Odderson & McKenna 1993; Bowen & Yaste 1994; Crawley 1996). The frequency of specific complications in the present study were also largely in keeping with those from previous reports published in the last decade (see **Table 5.28**) (Dromerick & Reding 1994; Kalra et al 1995; Davenport et al 1996b; Johnston et al 1998; Langhorne et al 2000; Roth et al 2001). However, it is not possible to compare the frequencies of complications in a meaningful way because I have assessed the occurrence of complications during the first five days in this study, whereas other studies have recorded complications during stroke rehabilitation (Dromerick & Reding 1994; Kalra et al 1995; Roth et al 2001), or during acute stroke and rehabilitation (i.e. the entire hospital period) (Davenport et al 1996b; Johnston et al 1998; Langhorne et al 2000). It is also

difficult to compare the frequencies because the majority of these studies did not assess or reported stroke severity or other factors that could have influenced the findings.

Although the internal and external validity of the present study is limited, it has at least provided a detailed audit of the ICP introduced in the stroke unit at the WGH. This information may be used to improve the design and content of the existing ICP. Furthermore, the findings of the present study may inform the design and sample size calculation of future studies of this kind.

5.8 Summary of this chapter

- In March 2000, an ICP was introduced in the stroke unit at the WGH. It is a multidisciplinary document that was designed to guide stroke management during the first five days after admission.
- I performed a before-and-after study to assess the impact of introducing an ICP in the stroke unit on the following: quality of documentation; process of care; occurrence of complications; discharge destination; and mortality.
- After the introduction of the ICP, there were significant improvements in the quality of documentation and certain aspects of patient care, and the risk of urinary tract infection was reduced. However, there was no significant difference in death or discharge destination.
- The extent to which the results of this study could be generalised is limited because of the many potential sources of bias and confounding factors.
- This study has highlighted the many methodological difficulties with performing a before-and-after study to assess the effects of introducing an ICP for acute stroke.

Table 5.1 Functional scales, stroke severity scales, and stroke classification system used in this study.

Scale or classification	Type of scale
Pre-stroke	
Modified Rankin scale	Global outcome/handicap
Day of first assessment	
OCSP classification of stroke	Clinical classification
Glasgow coma scale	Level of consciousness
National Institute of Health stroke scale	Neurological impairment
5th day after admission	
Glasgow coma scale	Level of consciousness
National Institute of Health Stroke Scale	Neurological impairment
Barthel index	Disability
Modified Rankin scale	Global outcome/handicap

Table 5.2 Items recorded to assess the quality of documentation in this study. These items were adapted from the Royal College of Physicians' national sentinel stroke audit package (Rudd et al 1999).

Neurological examination	Diagnostic description
Level of consciousness	Anatomical site of cerebral lesion
Eye movements	Pathological type of lesion (e.g. infarct
Limb movements	or haemorrhage, OCSP subtype)
Sensation	
Truncal control or gait	
Visual fields	
Visual inattention	
Mental ability (formally tested)	
Communication	
Screening for swallowing disorder	

Table 5.3 Items recorded to assess the process of care in this study.

Immediate management	**Within the first 5 days**
Blood pressure measurement	Physiotherapy
Bedside blood glucose measurement	Occupational therapy
Oxygen saturation measurement	Speech therapy
Temperature measurement	Dietician referral
Bedside swallow test	CT brain scanning
Oxygen supplementation	Carotid duplex scanning
Insulin therapy	Echocardiography
Intravenous fluids	Cerebral angiography
Antibiotics	Neurosurgical referral
Intravenous thrombolysis	Other procedures
Blood pressure reduction (new agent)	Use of antiplatelet agents*
Continuation of antihypertensive agent	Use of anticoagulant agents*
Urgent CT brain scanning	Use of antihypertensive agents
Electrocardiography	Use of statin
Chest x-ray	Use of antipyretic agent
Routine blood tests	Use of antibiotics*
Informing patient/relative of diagnosis	Use of intravenous fluids
and/or plan of management	Urinary catheterisation
	Nasogastric feeding
At the end of hospitalisation	Any feeding
Length of stay	TED stockings

*Items were furthermore broken down according to specific agents or routes of administration.

Table 5.4 Definitions of post-stroke complications used in this study. Some of the definitions have been modified from Langhorne et al 2000.

Complication	Definition
Chest infection	Clinical diagnosis of chest infection (e.g. respiratory crackles, new purulent sputum), or radiological evidence.
Urinary tract infection	Clinical diagnosis of urinary tract infection (e.g. dysuria, frequency), or positive urine culture.
Pressure sore	Any skin break or necrosis resulting from pressure or trivial trauma (not skin trauma as a direct result of a fall).
Deep vein thrombosis	Clinical diagnosis of deep vein thrombosis (e.g. painful and swollen calf), or radiological evidence.
Pulmonary embolism	Clinical diagnosis of pulmonary embolism (e.g. dyspnoea, haemoptysis), or radiological evidence.
Fall	Any documented falls, regardless of cause.
Constipation	Any documented constipation, regardless of cause.
Seizure	Clinical diagnosis of focal and/or generalised seizure (not "funny turn" or simple loss of consciousness from vasovagal attack or syncope).
Pyrexia	Temperature greater than 37.5^{0}C, regardless of method of measurement. 1. *Pyrexia – all*: refers to any documented episode of pyrexia. 2. *Pyrexia – no cause*: refers to episodes of pyrexia for which no cause was found (i.e. without infection, deep vein thrombosis, pulmonary embolism or pressure sore).
Mood disturbance	Any documented mood disturbance including low mood, anxiety, emotionalism, excessive mood swings.
Other complications	Any other documented medical or surgical complication resulting in specific intervention or delay in discharge.
Any complication	Any of the above

Table 5.5 Diagnoses of the 65 non-stroke conditions in this study.

Diagnosis	Number of patients
Epileptic seizure	13
Dizzy spell, syncope, or postural hypotension	12
Brain or spinal tumour (primary and secondary)	8
Infections (chest and urinary)	6
Confusional state (acute and acute-on-chronic)	4
Electrolyte imbalance	4
Migraine	3
Labyrinthine pathology	2
Demyelination	1
Alcohol intoxication	1
Others	11

Table 5.6 Baseline characteristics. Also see **Figure 5.3.**

Characteristic	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	GMW (N=88) n (%)
Age: mean (SD)	74.5 (11.7)	74.5 (12.2)	72.0 (13.8)
Age: median (IQ range)	76 (68-83)	77 (68-83)	75.5 (66-82)
Male	77 (50%)	96 (49%)	42 (48%)
Pre-stroke modified Rankin 0-2	108 (70%)	144 (73%)	65 (74%)
Living alone	54 (35%)	72 (37%)	29 (33%)
Risk factors			
Atrial fibrillation	29 (19%)	36 (18%)	12 (14%)
Hypertension	74 (48%)	94 (48%)	44 (50%)
Coronary heart disease	44 (29%)	66 (34%)	33 (38%)
Previous stroke or TIA	52 (34%)	66 (34%)	30 (34%)
Diabetes mellitus	27 (18%)	21 (11%)	8 (9%)
Peripheral vascular disease	9 (6%)	20 (10%)	10 (11%)
Current smoking	34 (22%)	42 (21%)	18 (20%)
Ex-smoking	35 (23%)	42 (21%)	13 (15%)
OCSP classification			
TACS*	28 (18%)	57 (29%)	16 (18%)
PACS*	64 (42%)	60 (30%)	34 (39%)
LACS†	37 (24%)	56 (28%)	15 (17%)
POCS†	17 (11%)	17 (9%)	19 (22%)
OCSP class undeterminable	8 (5%)	7 (4%)	5 (6%)
Stroke severity			
NIHSS: mean (median, IQR) †	No data	9.5 (6, 3-14)	7.0 (4, 1-10)
Pathological type			
Transient ischaemic attack	18 (12%)	13 (7%)	10 (11%)
Stroke: haemorrhage on CT	16 (10%)	17 (9%)	6 (7%)
Stroke: no haemorrhage on CT	115 (75%)	162 (82%)	68 (77%)
Stroke - no CT done	5 (3%)	5 (3%)	4 (5%)
Pre-stroke medication			
Antiplatelet agent(s)	65 (42%)	96 (49%)	37 (42%)
Anticoagulant (warfarin)	10 (6%)	14 (7%)	9 (10%)
Antihypertensive agent(s)	62 (40%)	87 (44%)	40 (45%)

*$p<0.05$ (Chi-square test) comparing SU-before-ICP and SU-after-ICP groups.

†$p<0.05$ (Chi-square test) comparing SU-after-ICP group and GMW group.

Table 5.7 Baseline characteristics (continued). Consequences of stroke – neurological sequelae and physiological disturbances. Table reporting unadjusted and adjusted results.

Physiological disturbances	SU-before-ICP N=154	SU-after-ICP N=197	GMW N=88	SU-before-ICP vs SU-after-ICP p value unadjusted/adjusted	SU-after-ICP vs GMW p value unadjusted/adjusted
Dysphagia	51 (33%)	75 (38%)	24 (27%)	0.40 / 0.92	0.10 / 0.86
Reduced consciousness	35 (23%)	62 (32%)	22 (25%)	0.09 / 0.24	0.33 / 0.88
Incontinence*	64 (42%)	91 (47%)	29 (33%)	0.45 / 0.72	0.05 / 0.39
Hyperglycaemia (BM >11)†	10/103 (10%)	11/160 (7%)	3/68 (4%)	0.55 / 0.41	0.51 / 0.32
Hypoxia (O2 sat <95%)†	27/146 (18%)	43/195 (22%)	13/78 (17%)	0.50 / 0.40	0.41 / 0.37
Fever (temp >37.5)*†	5/149 (3%)	4/190 (2%)	7/85 (8%)	0.50 / 0.43	0.03 / 0.01

*$p<0.05$ (Chi-square or Fisher exact test) comparing SU-after-ICP and GMW groups.

†Denominators used in calculating the percentages = numbers of patients who had the parameters measured on admission.

Table 5.8 Baseline characteristics (continued): pre-stroke place of residence and the need for formal help at home.

Before stroke	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	GMW (N=88) n (%)
Living at home (all)	145 (94%)	184 (93%)	78 (89%)
With no help	111 (72%)	148 (75%)	69 (78%)
With formal help	34 (22%)	36 (23%)	9 (10%)
Living alone	54 (35%)	72 (37%)	29 (33%)
Living in an institution (all)	9 (6%)	13 (7%)	10 (11%)
Rest home	4 (3%)	10 (5%)	7 (8%)
Nursing home	5 (3%)	3 (2%)	3 (3%)

Table 5.9 Recording of date and time of stroke onset and admission.

	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	GMW (N=88) n (%)
Stroke onset			
Date of stroke onset known	154 (100%)	197 (100%)	88 (100%)
Time of stroke onset known*	60 (39%)	118 (60%)	53 (60%)
On waking	39 (25%)	51 (26%)	25 (28%)
Admission to hospital			
Date of admission known	154 (100%)	197 (100%)	88 (100%)
Time of admission known	148 (96%)	191 (97%)	80 (91%)
Dates and times of stroke onset and admission known*	57 (37%)	116 (59%)	49 (56%)

*$p<0.05$ (Chi-square test) comparing SU-before-ICP and SU-after-ICP groups.

Table 5.10 Use of the different parts of the ICP by the three study groups.

Section of the ICP	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	GMW (N=88) n (%)
Doctor's section only	-	18 (9%)	14 (16%)
Nurses' section only	-	16 (8%)	-
Doctor's and nurses' sections	-	129 (65%)	-
Doctor's +/ nurses' (any) section	-	163 (83%)	-
None used	154 (100%)	34 (17%)	74 (84%)

Table 5.11 Possible reasons why 34 patients in the SU-after-ICP group were not managed with the ICP.

Reason	SU-after-ICP but no ICP was used n=34
1. Patient transferred from a general medical ward and ICP not started by staff	23 (68%)
2. Diagnosis of stroke initially unclear	2 (6%)
3. Patient with very severe stroke received only palliative care	2 (6%)
4. No copies of the ICP available when patient arrived	3 (9%)
5. Reasons unknown	4 (12%)

Table 5.12 Baseline characteristics of the patients in the SU-after-ICP group (N=197): those managed with the ICP vs those not managed with the ICP.

Characteristic	SU-after-ICP, ICP used n=163	SU-after-ICP, ICP not used n=34
Age: mean (SD)	74.7 (12.3)	73.4 (12.2)
Age: median (range)	77 (68-83)	76 (65-80)
Male	76 (47%)	20 (59%)
Modified Rankin score 0-2	121 (74%)	23 (68%)
Living alone	61 (37%)	11 (32%)
Risk factors		
Atrial fibrillation	28 (17%)	8 (24%)
Hypertension*	87 (53%)	7 (21%)
Coronary heart disease	50 (31%)	16 (47%)
Previous stroke or TIA	54 (33%)	12 (35%)
Diabetes mellitus	17 (10%)	4 (12%)
Peripheral vascular disease	17 (10%)	3 (9%)
Current smoking	38 (23%)	4 (12%)
Ex-smoking	32 (20%)	10 (29%)
OCSP classification		
TACS	46 (28%)	11 (32%)
PACS	53 (33%)	7 (21%)
LACS	47 (29%)	9 (26%)
POCS	12 (7%)	5 (15%)
OCSP class undeterminable	8 (5%)	2 (6%)
Stroke severity		
NIHSS: mean (median, IQR)*	9 (6, 3-11)	13 (12, 5-20)
Pathological type		
Transient ischaemic attack	12 (7%)	1 (3%)
Stroke: no haemorrhage on CT	135 (83%)	27 (79%)
Stroke: haemorrhage on CT	12 (7%)	5 (15%)
Stroke - no CT done	4 (2%)	1 (3%)
Pre-stroke medication		
Antiplatelet agent(s)	79 (48%)	17 (50%)
Anticoagulant (warfarin)	11 (7%)	3 (9%)
Antihypertensive agent(s)*	81 (50%)	6 (18%)

*$p<0.05$ (Chi-square test).

Table 5.13 Completeness of recording of the ICP in the SU-after-ICP group (N=197). Definitions of the 'complete' and 'partially complete' can be found in the main text of the chapter.

Section of the ICP	Number of patients (%)
Doctor's section (n=147)	
Complete	97 (66%)
Partially complete	50 (34%)
Nurses' section (n=145)	
Complete	82 (57%)
Partially complete	63 (43%)

Table 5.14 Distribution of the six variables in the model which was used to adjust for case mix. Table reporting the number (%) of patients with each variable in each group. There was no significant difference between the three groups.

Model variables	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	GMW (N=88) n (%)	Compare all 3 grps p value
1. Age				
mean (SD)	74.5 (11.7)	74.5 (12.2)	72.0 (13.8)	-
median (range)	76 (68-83)	77 (68-83)	75.5 (66-82)	0.48
2. Living at home alone	54 (35%)	72 (37%)	29 (33%)	0.84
3. Independent pre-stroke	108 (70%)	144 (73%)	65 (74%)	0.77
4. Able to lift both arms up	117 (76%)	134 (68%)	70 (80%)	0.08
5. Able to walk without help	44 (29%)	57 (29%)	36 (41%)	0.09
6. Normal verbal GCS score	101 (66%)	119 (60%)	60 (68%)	0.38

Table 5.15 Results of SU-before-ICP vs SU-after-ICP. Documentation within 24 hours; n (%) represents the number (percentage) of patients who had adequate documentation for each of the items. Also see **Figure 5.5**.

Documentation	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	Risk difference % (95% CI)
Neurological examination			
Level of consciousness	141 (92%)	188 (95%)	3% (-1, 9)
Eye movements	132 (86%)	162 (82%)	-4% (-11, 4)
Limb movements	152 (99%)	196 (100%)	1% (-1, 3)
Sensation*	87 (56%)	138 (70%)	14% (3, 24)
Truncal control or gait*	32 (21%)	134 (68%)	47% (38, 56)
Visual fields	102 (66%)	130 (66%)	0% (-10, 10)
Visual inattention	85 (55%)	116 (59%)	4% (-7, 14)
Mental ability (formal test)*	37 (24%)	87 (44%)	10% (10, 30)
Communication	131 (85%)	167 (85%)	0% (-8, 7)
Swallowing ability*	91 (59%)	140 (71%)	12% (2, 22)
Diagnostic description			
Anatomical site of lesion*	88 (57%)	164 (83%)	26% (17, 36)
Pathological type*	87 (56%)	150 (76%)	20% (10, 29)

*$p<0.05$ (Chi-square test).

Table 5.16 Results of SU-before-ICP vs SU-after-ICP. Process of care – immediate management. Also see **Figure 5.6**.

Immediate management	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	Risk difference % (95% CI)
Blood pressure measurement	154 (100%)	197 (100%)	0% (-1, 1)
Blood glucose measurement*	103 (67%)	160 (81%)	14% (5, 24)
O2 saturation measurement*	146 (95%)	195 (99%)	4% (0, 8)
Temperature measurement	149 (97%)	190 (97%)	0% (-4, 4)
Electrocardiogram	152 (99%)	192 (98%)	-1% (-4, 2)
Chest x-ray*	104 (68%)	95 (49%)	-19% (-29, -9)
Routine blood tests	150 (97%)	196 (99%)	2% (-1, 5)
Swallowing assessment	17 (11%)	17 (9%)	-2% (-9, 4)
O2 supplement therapy	19 (12%)	32 (16%)	4% (-3, 11)
Insulin therapy	7 (5%)	7 (4%)	-1% (-5, 3)
IV fluids	58 (38%)	72 (37%)	-1% (-11, 9)
Antibiotics	13 (8%)	8 (4%)	-4% (-10, 1)
Immediate CT scanning	30 (19%)	44 (22%)	3% (-6, 11)
Thrombolysis	2 (1%)	7 (3%)	2% (-1, 5)
Continue BP medications†	45/62 (73%)	71/87 (82%)	9% (-5, 23)
Informing patient or relative*	32 (21%)	77 (39%)	18% (9, 28)

*$p<0.05$ (Chi-square test).

†Denominators used in calculating the percentages = numbers of patients who had been on antihypertensive medications before stroke.

Table 5.17 Results of SU-before-ICP vs SU-after-ICP. Process of care – use of investigations. Results after adjustment for case mix are presented in **Figure 5.7**.

Use of investigations	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	Risk difference % (95% CI)
CT scan (all)	143 (93%)	189 (96%)	3% (-2, 8)
CT scan 0-1 day*	111 (72%)	163 (83%)	11% (2, 19)
CT scan 0-2 days*	129 (82%)	182 (91%)	9% (2, 16)
Carotid duplex scan	80 (52%)	96 (49%)	-3% (-14, 7)
Echocardiography	32 (21%)	55 (28%)	7% (-2, 16)
MR or catheter angiography	2 (1%)	2 (1%)	0% (-3, 2)
Neurosurgical referral	3 (2%)	7 (4%)	2% (-2, 5)
≥ 1other procedure	8 (5%)	14 (7%)	2% (-3, 7)

*p<0.05 (Chi-square test).

Table 5.18 Results of SU-before-ICP vs SU-after-ICP. Process of care – use of medications. There was no significant difference between the two groups. Results after adjustment for case mix for the variables (marked with *) are presented in **Figure 5.8**.

Use of medications	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	Risk difference % (95% CI)
Antiplatelet Rx same day†	38/133 (29%)	48/175 (28%)	-1% (-11, 9)
Antiplatelet Rx 0-1 day†	80/133 (60%)	104/175 (59%)	-1% (-12, 10)
Antiplatelet Rx 0-2 days†	101/133 (76%)	133/175 (76%)	0% (-10, 10)
Heparin – subcutaneous	5 (3%)	6 (3%)	0% (-4, 4)
Heparin – IV	5 (3%)	1 (0.5%)	-3% (-6, 0)
New aspirin†	61/133 (46%)	75/175 (49%)	3% (-14, 8)
New dipyridamole†	8/133 (6%)	8/175 (5%)	-1% (-7, 4)
New clopidogrel†	0/133 (0%)	3/175 (2%)	2% (-1, 4)
New antihypertensive Rx	8 (5%)	6 (3%)	-2% (-6, 2)
New warfarin	5 (3%)	4 (2%)	-1% (-5, 3)
New statin	2 (1%)	5 (2%)	1% (-2, 4)
Antipyretic therapy*	17 (11%)	30 (15%)	4% (-3, 11)
Antibiotics – oral*	16 (10%)	17 (8%)	-2% (-8, 4)
Antibiotics – IV*	9 (6%)	24 (12%)	6% (0, 12)
IV fluids*	65 (42%)	81 (41%)	-1% (-11, 9)

†Denominators used in calculating the percentages = numbers of patients who had a non-haemorrhagic stroke (confirmed on CT scan) or a TIA.

Table 5.19 Results of SU-before-ICP vs SU-after-ICP. Process of care – use of therapy and nursing interventions. Results after adjustment for case mix are presented in **Figure 5.9**.

Use of therapy & nursing interventions	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	Risk difference % (95% CI)
Physiotherapy – all*	79 (51%)	138 (70%)	19% (9, 29)
Physiotherapy 0-1 day†	44/79 (56%)	72/138 (52%)	-4% (-17, 10)
Physiotherapy 0-3 days†	69/79 (87%)	129/138 (93%)	6% (-2, 15)
Occupational therapy (all)	36 (23%)	51 (26%)	3% (-7, 12)
Speech therapy (all)	62 (40%)	87 (44%)	4% (-6, 14)
Speech therapy 0-1 day†	35/62 (56%)	39/87 (44%)	-12% (-28, 5)
Dietician (all)	12 (8%)	12 (6%)	-2% (-7, 4)
Urinary catheterisation	30 (19%)	37 (18%)	-1% (-9, 8)
Nasogastric feeding	5 (3%)	5 (2%)	-1% (-4, 3)
Any feeding	129 (84%)	161 (82%)	-2% (-10, 6)
Use of TED stockings	10 (6%)	9 (4%)	-2% (-7, 3)

*$p<0.05$ (Chi-square test).

†Denominators used in calculating the percentages = numbers of patients who received the therapy.

Table 5.20 Results of SU-before-ICP vs SU-after-ICP. Length of stay in the WGH. There was no significant difference between the two groups (p=0.65, Mann-Whitney U test).

	SU-before-ICP (N=154)	SU-after-ICP (N=197)
Mean LOS (SD) in days	13.8 (19.7)	13.4 (15.1)
Median LOS (interquartile range)	8 (4-16)	10 (4-16)
Minimum LOS	0	0
Maximum LOS	164	96

Table 5.21 Results of SU-before-ICP vs SU-after-ICP. Occurrence of complications. There was no significant difference between the two groups. Results after adjustment for case mix are presented in **Figure 5.10.**

Medical complications	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	Risk difference % (95% CI)
Chest infection	16 (10%)	21 (10%)	0% (-6, 7)
Urinary tract infection	15 (10%)	10 (5%)	-5% (-10, 1)
Pressure sore	4 (3%)	5 (3%)	0% (-3, 3)
Deep vein thrombosis	0	2 (1%)	1% (-1, 3)
Fall	12 (8%)	19 (10%)	2% (-4, 8)
Fever – all episodes	42 (27%)	46 (23%)	-4% (-13, 5)
Fever – no cause found	26 (17%)	26 (13%)	-4% (-11, 4)
Constipation	25 (16%)	24 (12%)	-4% (-11, 3)
Mood disturbance	22 (14%)	26 (13%)	-1% (-8, 6)
Seizure	5 (3%)	7 (3%)	0% (-4, 4)
Other complications	14 (9%)	12 (6%)	-3% (-9, 3)
Any complication	92 (60%)	102 (52%)	-8% (-18, 2)

Table 5.22 Results of SU-before-ICP vs SU-after-ICP. Death and discharge destination. There was no significant difference between the two groups. Results after adjustment for case mix are presented in **Figure 5.11**.

Death and discharge destination	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=197) n (%)	Risk difference % (95% CI)
Death			
Death by day 5	9 (6%)	11 (6%)	0% (-5, 5)
Death in hospital	20 (13%)	25 (13%)	0% (-7, 7)
Discharge destination			
Discharge to institution by day 5	13 (8%)	16 (8%)	0% (-6, 5)
Discharge to institution from hospital	56 (36%)	69 (35%)	-1% (-11, 9)
Discharge to home by day 5	32 (21%)	43 (22%)	1% (-8, 10)
Discharge to home from hospital	78 (51%)	103 (53%)	2% (-9, 12)

Table 5.23 Numbers of patients admitted during the six periods of recruitment during the study.

Dates of admission	SU-before-ICP (N=154)	SU-after-ICP (N=197)	GMW (N=88)
Retrospective data			
1/6/99 – 31/8/99	50	-	-
1/9/99 – 30/11/99	61	-	-
1/12/99 – 29/2/00	43	-	-
Prospective data			
23/7/00 – 22/10/00	-	69	36
23/10/00 – 22/1/01	-	65	13
23/1/01 – 22/4/01	-	63	39

Table 5.24 Checking for changes with time for death, discharge destination, occurrence of any complication, and CT scanning <2 days. The numbers denote unadjusted results for the SU-before-ICP group. I compared the results for the first and third periods, and for all the three periods, using Chi-square or Fisher exact test. There was no significant difference between the groups, and there was no obvious common trend for the selected outcome measures.

	SU-before-ICP				
Selected outcome measures	**1/6/99 to 31/8/99 (n=50)**	**1/9/99 to 30/11/99 (n=62)**	**1/12/99 to 29/2/00 (n=43)**	**Comparing 1st & 3rd periods p value**	**Comparing all 3 periods p value**
Death by day 5	3 (6%)	6 (10%)	2 (5%)	0.80	>0.99
Death by the end of hospitalisation	5 (10%)	10 (16%)	5 (12%)	0.81	0.63
Discharge to institution by day 5	6 (12%)	4 (6%)	3 (7%)	0.45	0.54
Discharge to institution by the end of hosp	20 (40%)	25 (40%)	11 (26%)	0.15	0.24
Discharge to home by day 5	15 (30%)	9 (15%)	8 (19%)	0.22	0.13
Discharge to home by the end of hosp	25 (50%)	26 (42%)	27 (63%)	0.23	0.11
Any complication within the first 5 days	30 (60%)	41 (66%)	21 (49%)	0.38	0.20
CT scan 0-2 days	43 (86%)	51 (82%)	39 (91%)	0.51	0.48

Table 5.25 Treatment-received analysis. Selection of patients for comparison groups according to which section of the ICP had been used.

Outcome measures	SU-before-ICP (N=154)	SU-after-ICP (N=197)
Documentation	All (n=154)	Doctor's section (n=147)
Process of care	All (n=154)	Doctor's section (n=147) or Doctor's +/ nurses' section (n=163)
Complications	All (n=154)	Doctor's +/ nurses' section (n=163)
Functional outcome	All (n=154)	Doctor's +/ nurses' section (n=163)

Table 5.26 Results of the study using treatment-received analysis (comparison groups as shown in **Table 5.25**) – SU-before-ICP vs SU-after-ICP. Only unadjusted results are shown here.

Outcome measures	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=163) n/N as stated (%)	Risk difference % (95% CI)
Death and discharge destination			
Death by day 5	9 (6%)	7/163 (4%)	-2% (-6, 3)
Death in hospital	20 (13%)	20/163 (12%)	-1% (-8, 7)
Discharge to institution by day 5	13 (8%)	15/163 (9%)	1% (-5, 7)
Discharge to institution from hosp	56 (36%)	56/163 (34%)	-2% (-13, 9)
Discharge to home by day 5	32 (21%)	41/163 (25%)	4% (-5, 14)
Discharge to home from hospital	78 (51%)	87/163 (53%)	3% (-8, 14)
Occurrence of complications			
Chest infection	16 (10%)	16/163 (10%)	-1% (-7, 6)
Urinary tract infection	15 (10%)	8/163 (5%)	-5% (-11, 1)
Pressure sore	4 (3%)	5/163 (3%)	0% (-3, 4)
Deep vein thrombosis	0	1/163 (0.6%)	1% (-1, 2)
Fall	12 (8%)	13/163 (8%)	0% (-6, 6)
Fever – all episodes	42 (27%)	36/163 (22%)	-5% (-15, 4)
Fever – no cause found	26 (17%)	21/163 (13%)	-4% (-12, 4)
Constipation	25 (16%)	20/163 (12%)	-4% (-12, 4)
Mood disturbance	22 (14%)	22/163 (13%)	-1% (-8, 7)
Seizure	5 (3%)	2/163 (1%)	-2% (-5, 1)
Other complications	14 (9%)	10/163 (6%)	-3% (-9, 3)
Any complication	92 (60%)	82/163 (50%)	-9% (-20, 1)
Immediate management			
Blood pressure measurement	154 (100%)	147/147 (100%)	0% (0, 0)
Blood glucose measurement*	103 (67%)	121/147 (82%)	15% (6, 25)
O2 saturation measurement	146 (95%)	145/147 (99%)	4% (0, 8)
Temperature measurement	149 (97%)	141/147 (96%)	-1% (-5, 3)
Electrocardiogram	152 (99%)	144/147 (98%)	-1% (-4, 2)
Chest x-ray*	104 (68%)	66/147 (45%)	-23% (-34, -12)
Routine blood tests	150 (97%)	147/147 (100%)	3% (0, 5)
Swallowing assessment	17 (11%)	17/147 (12%)	1% (-7, 8)
O2 supplement therapy	19 (12%)	22/147 (15%)	3% (-5, 10)

Outcome measures	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=163) n/N as stated (%)	Risk difference % (95% CI)
Insulin therapy	7 (5%)	4/147 (3%)	-2% (-6, 2)
IV fluids	58 (38%)	48/147 (33%)	-5% (-16, 6)
Antibiotics	13 (3%)	5/147 (3%)	-5% (-10, 0)
Immediate CT scanning	30 (19%)	37/147 (25%)	6% (-4, 15)
Thrombolysis	2 (1%)	7/147 (5%)	3% (0, 7)
Continue BP medications†	45/62 (73%)	58/73 (79%)	7% (-8, 21)
Informing patient or relative*	32 (21%)	63/147 (43%)	22% (12, 32)
Use of investigations			
CT scan (all)	143 (93%)	140/147 (95%)	2% (-3, 8)
CT scan 0-1 day	111 (72%)	118/147 (80%)	8% (-1, 18)
CT scan 0-2 days*	129 (82%)	136/147 (93%)	9% (2, 16)
Carotid duplex scan	80 (52%)	79/147 (54%)	2% (-9, 13)
Echocardiography	32 (21%)	42/147 (29%)	8% (-2, 18)
MR or catheter angiography	2 (1%)	2/147 (1%)	0% (-3, 3)
Neurosurgical referral	3 (2%)	2/147 (1%)	-1% (-3, 2)
≥ 1other procedure	8 (5%)	6/147 (4%)	-1% (-6, 4)
Use of medications			
Antiplatelet Rx same day†	38/133 (29%)	42/134 (30%)	3% (-8, 14)
Antiplatelet Rx 0-1 day†	80/133 (60%)	79/134 (59%)	-1% (-13, 11)
Antiplatelet Rx 0-2 days†	101/133 (76%)	104/134 (78%)	2% (-8, 12)
Heparin – subcutaneous	5 (3%)	5/147 (3%)	0% (-4, 4)
Heparin – IV	5 (3%)	1/147 (0.7%)	-3% (-6, 1)
New aspirin†	61/133 (46%)	65/134 (49%)	3% (-9, 15)
New dipyridamole†	8/133 (6%)	7/134 (5%)	-1% (-6, 5)
New clopidogrel†	0/133 (0%)	2/134 (1%)	1% (-1, 4)
New antihypertensive Rx	8 (5%)	5/147 (3%)	-2% (-6, 3)
New warfarin	5 (3%)	4/147 (3%)	-1% (-4, 3)
New statin	2 (1%)	4/147 (3%)	1% (-2, 5)
Antipyretic therapy	17 (11%)	18/147 (12%)	1% (-6, 8)
Antibiotics – oral	16 (10%)	10/147 (7%)	-4% (-10, 3)
Antibiotics – IV	9 (6%)	14/147 (10%)	4% (-2, 10)
IV fluids	65 (42%)	56/147 (38%)	-4% (-15, 7)
Use of therapy & nursing interven			
Physiotherapy – all*	79 (51%)	118/163 (72%)	21% (11, 32)

Outcome measures	SU-before-ICP (N=154) n (%)	SU-after-ICP (N=163) n/N as stated (%)	Risk difference % (95% CI)
Physiotherapy 0-1 day†	44/79 (56%)	62/118 (53%)	-3% (-17, 11)
Physiotherapy 0-3 days*†	69/79 (87%)	114/118 (97%)	9% (1, 17)
Occupational therapy (all)	36 (23%)	44/163 (27%)	4% (-6, 13)
Speech therapy (all)	62 (40%)	75/163 (46%)	6% (-5, 17)
Speech therapy 0-1 day†	35/62 (56%)	33/75 (44%)	-12% (-29, 4)
Dietician (all)	12 (8%)	9/163 (6%)	-2% (-8, 3)
Urinary catheterisation	30 (19%)	27/163 (17%)	-3% (-11, 6)
Nasogastric feeding	5 (3%)	3/163 (2%)	-1% (-5, 2)
Any feeding	129 (84%)	135/163 (83%)	-1% (-9, 7)
Use of TED stockings	10 (6%)	7/163 (4%)	-2% (-7, 3)
Neurological examination			
Level of consciousness*	141 (92%)	144/147 (98%)	6% (1, 11)
Eye movements	132 (86%)	128/147 (87%)	1% (-6, 9)
Limb movements	152 (99%)	147/147 (100%)	1% (-1, 3)
Sensation*	87 (56%)	108/147 (73%)	17% (6, 28)
Truncal control or gait*	32 (21%)	125/147 (85%)	64% (56, 73)
Visual fields	102 (66%)	101/147 (69%)	2% (-8, 13)
Visual inattention*	85 (55%)	98/147 (67%)	11% (1, 22)
Mental ability (formal test)*	37 (24%)	83/147 (56%)	32% (22, 43)
Communication*	131 (85%)	138/147 (94%)	9% (2, 16)
Swallowing ability*	91 (59%)	115/147 (78%)	19% (9, 29)
Diagnostic description			
Anatomical site of lesion*	88 (57%)	136/147 (93%)	35% (26, 44)
Pathological type*	87 (56%)	124/147 (84%)	28% (18, 38)

*$p<0.05$ using Chi-square test.

†Denominators for these as explained in Tables 5.15 to 5.22.

Table 5.27 Effect of completeness of recording on death, discharge destination, occurrence of any complication and CT scanning <2 days. The numbers denote unadjusted results for the patients managed in the stroke unit for the full five days. There was no significant difference between the three groups (Chi-square or Fisher exact test).

Selected outcomes	Doctor's and nurses' sections completed for all 5 days (n=32)	Doctor's and/or nurses' sections partially completed for 5 days (n=30)	Doctor's and nurses' sections not used for all 5 days (n=28)	Comparing all 3 groups p value
Death by the end of hospitalisation	6 (19%)	4 (13%)	1 (4%)	0.20
Discharge to institution by the end of hosp	13 (41%)	11 (37%)	13 (46%)	0.75
Discharge to home by the end of hosp	13 (41%)	15 (50%)	14 (50%)	0.69
Any complication within the first 5 days	19 (59%)	13 (43%)	17 (61%)	0.32
CT scan 0-2 days	31 (97%)	29 (97%)	26 (93%)	0.68

Table 5.28 Occurrence of complications in the present study compared with other studies in the past decade. Figures are percentages (%) of the total numbers of patients in each study (N).

Complication	Our study SU-after-ICP (N=197) %	Our study SU-before-ICP (N=154) %	Roth 2001 (N=1029) %	Langhorne 2000 (N=311) %	Johnston 1998 (N=279) %	Davenport 1996 (N=607) %	Kalra 1995 (N=245) %	Dromerick 1994 (N=100) %
Chest infection	10	10	4	22	10	12	12	7
Urinary tract infection	5	10	31	23	11	16	25	44
Pressure sore	3	3	4	21	-	18	3	2
Deep vein thrombosis	0.6	0	4	2	2	3	5	4
Pulmonary embolism	0	0	1	1	1	1	1	0
Fall	8	8	11	25	-	22	-	25
Fever – all episodes	22	27	-	-	-	-	-	-
Fever – no cause	13	17	-	-	-	4	-	-
Constipation	12	16	-	-	-	-	-	-
Mood disturbance	13	14	8	16	1	5	31	33
Seizure	1	3	2	3	3	4	4	3
Shoulder pain	-	-	14	9	-	4	-	-
Confusion	-	-	-	36	-	5	-	-
Recurrent stroke	-	-	-	9	18	-	-	-
Any complication	**50**	**60**	**75**	**85**	**95**	**59**	**60**	**96**

Figure 5.1 Patient's pathway through the acute stroke service in the Western General Hospital. Patients were admitted to the Acute Medical Assessment Unit (AMAU) since October 2000. Prior to that date, patients were admitted directly to the stroke unit or a general medical ward. The shaded boxes highlight the most common route through the pathway. The dotted arrows represent the least common route.

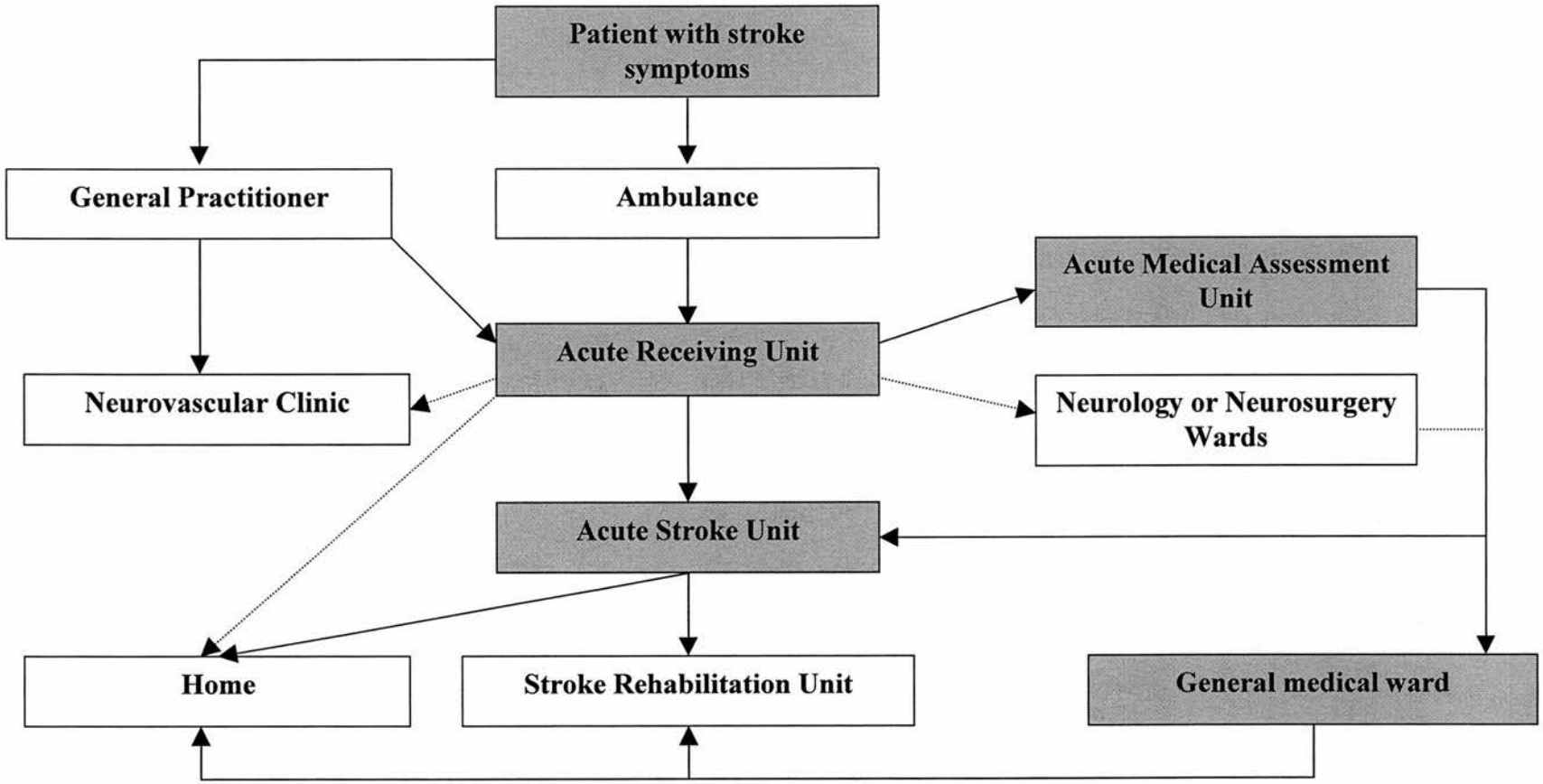


Figure 5.2 Recruitment and inclusion of patients in this study

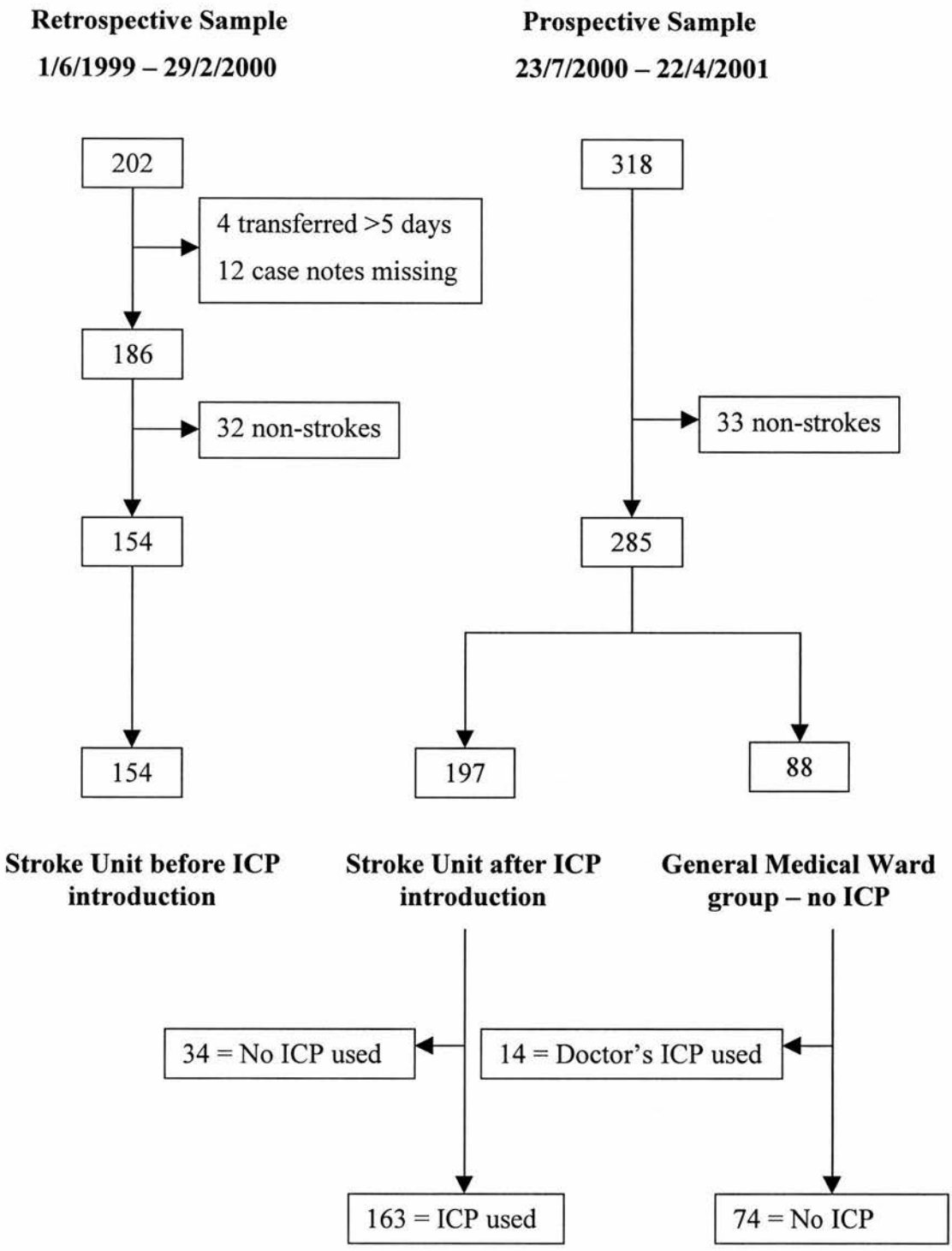


Figure 5.3A Comparing the baseline characteristics between the SU-before-ICP and SU-after-ICP groups. Note: this is a forest plot; OR = odds ratio; black box = point estimate of effect; horizontal line through black box = 95% confidence interval; vertical black line = OR of 1 (line of unity), i.e. the point where the odds of having the characteristic are the same between the two groups. When the 95% CI overlaps the line of unity, then the difference between the groups is *not* statistically significant at $p<0.05$ level; when it does not overlap, then it *is* statistically significant.

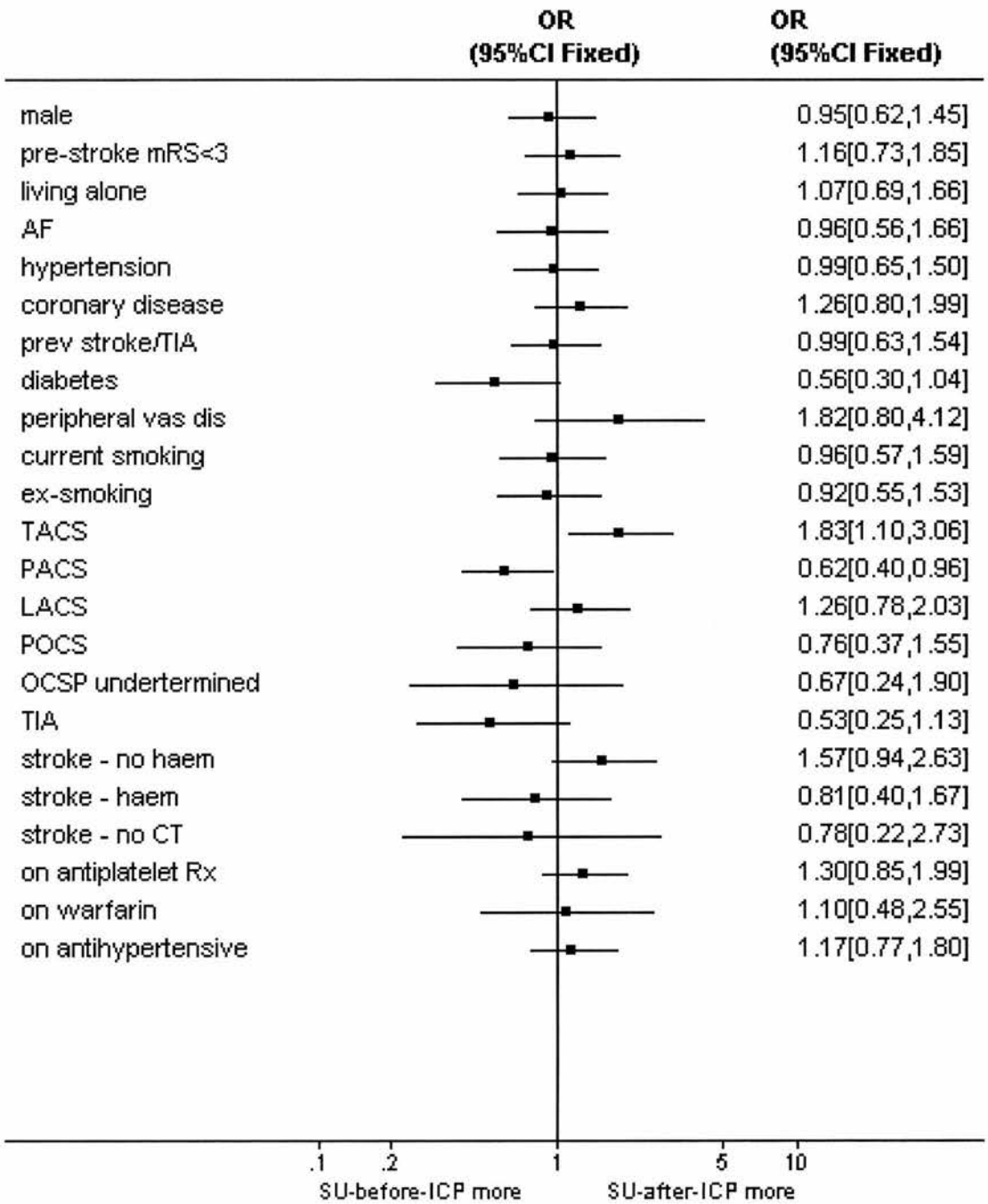


Figure 5.3B Comparing the baseline characteristics between the SU-after-ICP and GMW groups. Notes: see **Figure 5.3A** for explanation regarding the forest plot.

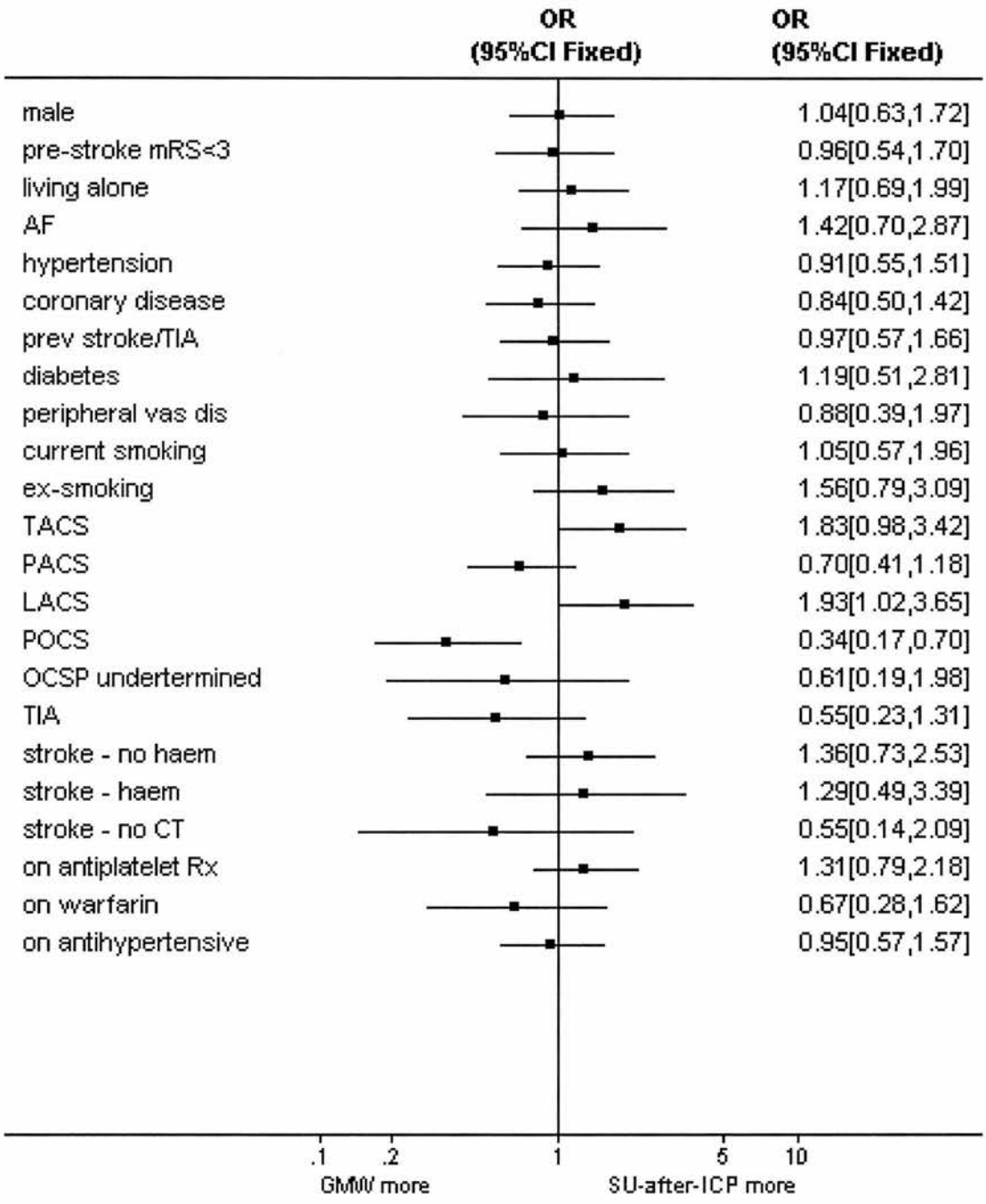


Figure 5.4 Delay from stroke onset to admission in days. There were no significant differences between the three groups (Fisher's exact test).

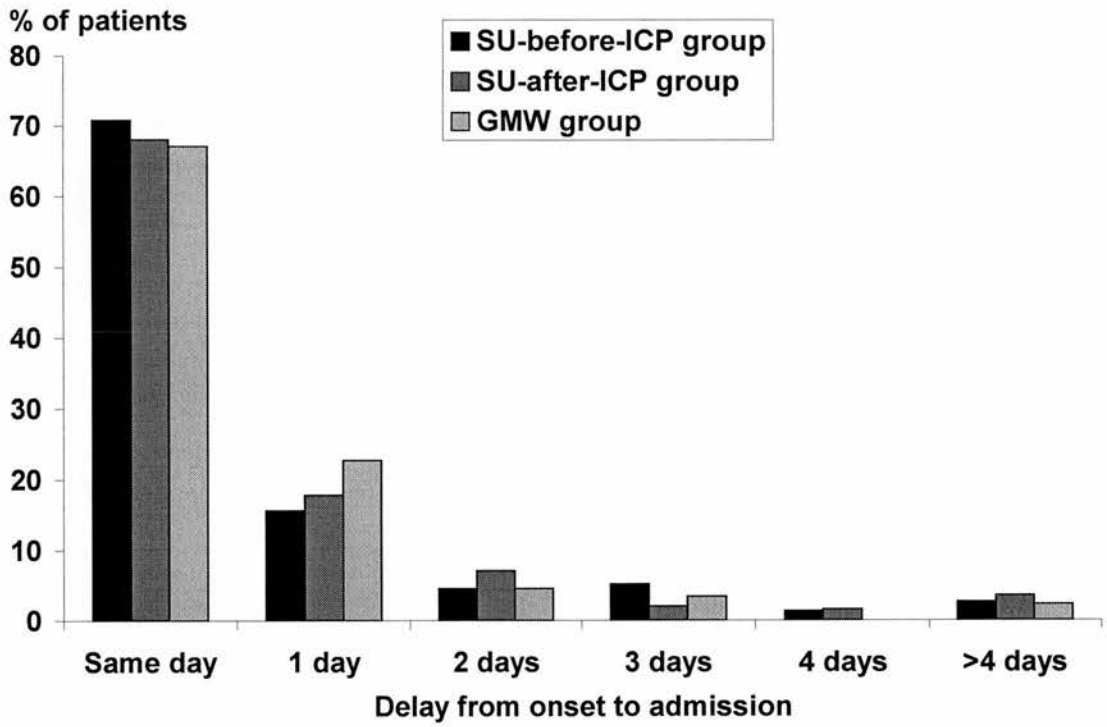


Figure 5.5 Results of SU-before-ICP vs SU-after-ICP. Documentation in the first 24 hours. Note: OR = odds ratio; black box = point estimate of effect; horizontal line through black box = 95% confidence interval; vertical black line = OR of 1 (line of unity), i.e. the point where the odds of the outcome occurring are the same between the two groups. When the 95% CI overlaps the line of unity, then the difference between the groups is *not* statistically significant at $p<0.05$ level; when it does not overlap, then it *is* statistically significant.

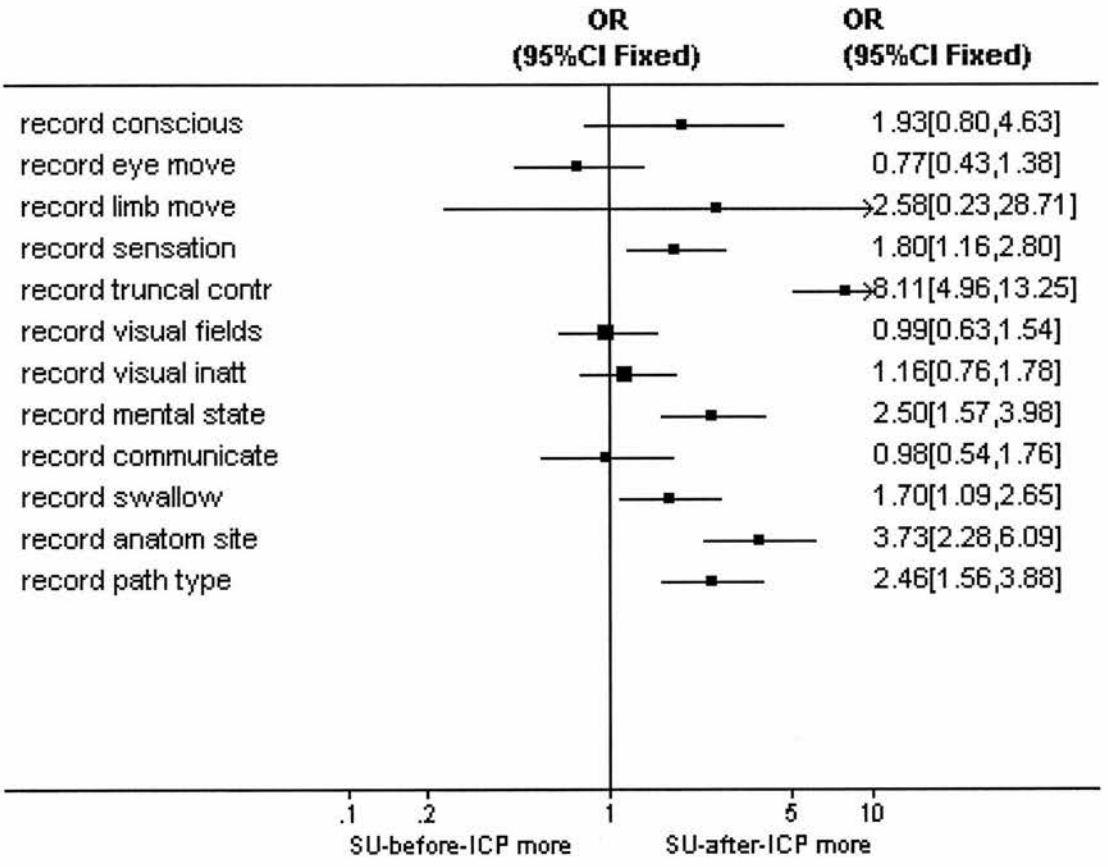


Figure 5.6 Results of SU-before-ICP vs SU-after-ICP. Process of care – immediate management. Notes: see **Figure 5.5** for explanation regarding the forest plot.

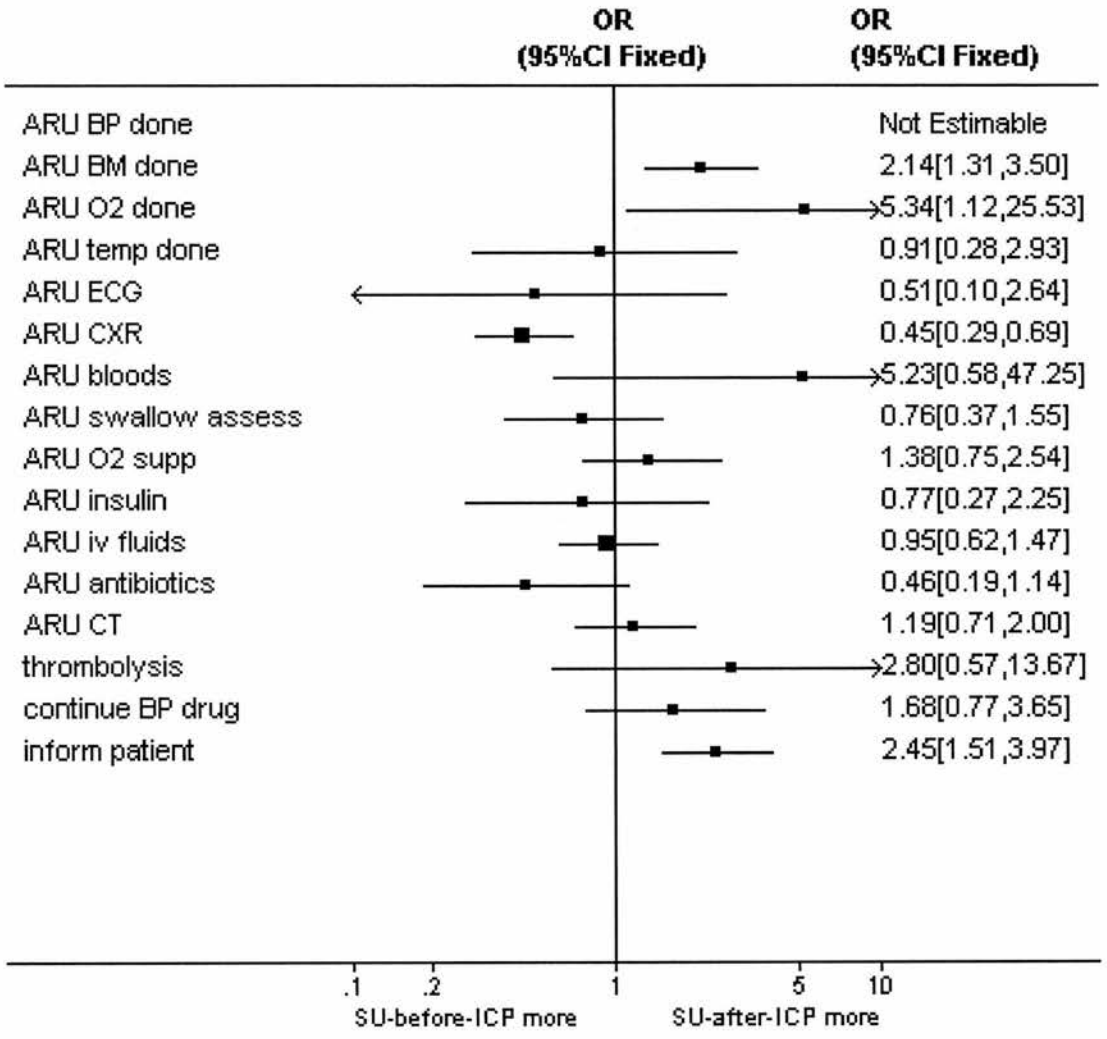
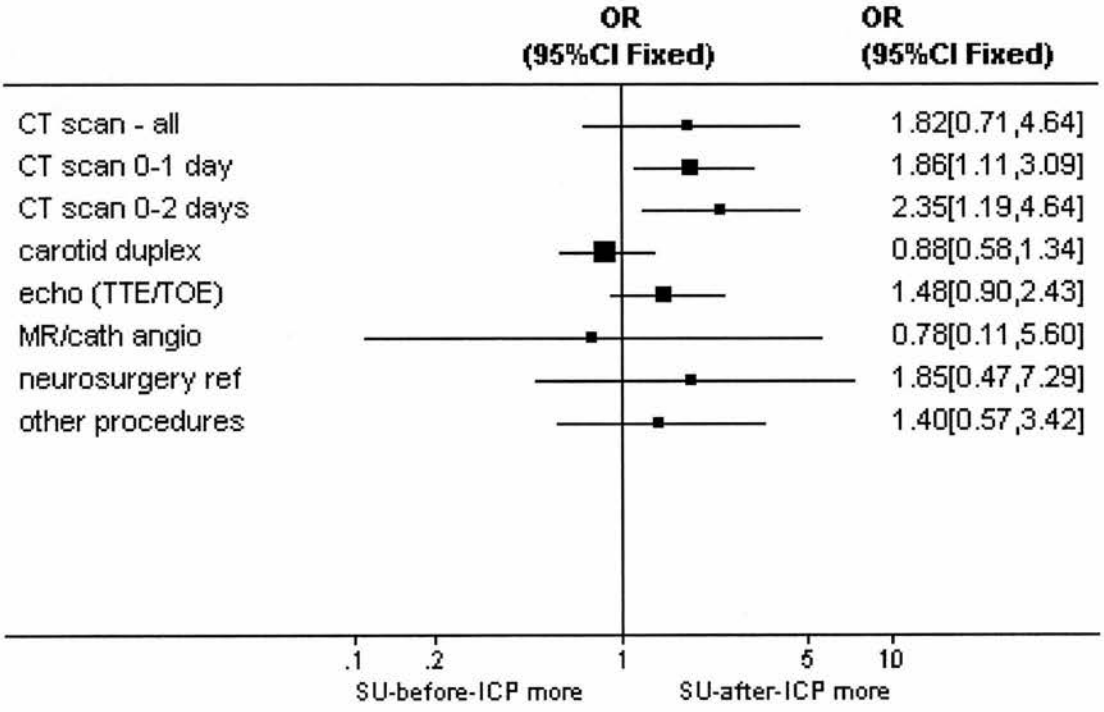


Figure 5.7 Results of SU-before-ICP vs SU-after-ICP. Process of care – use of investigations. Charts showing unadjusted results (top) adjusted results (bottom). Notes: see **Figure 5.5** for explanation regarding the forest plot.

Unadjusted



Adjusted for case mix

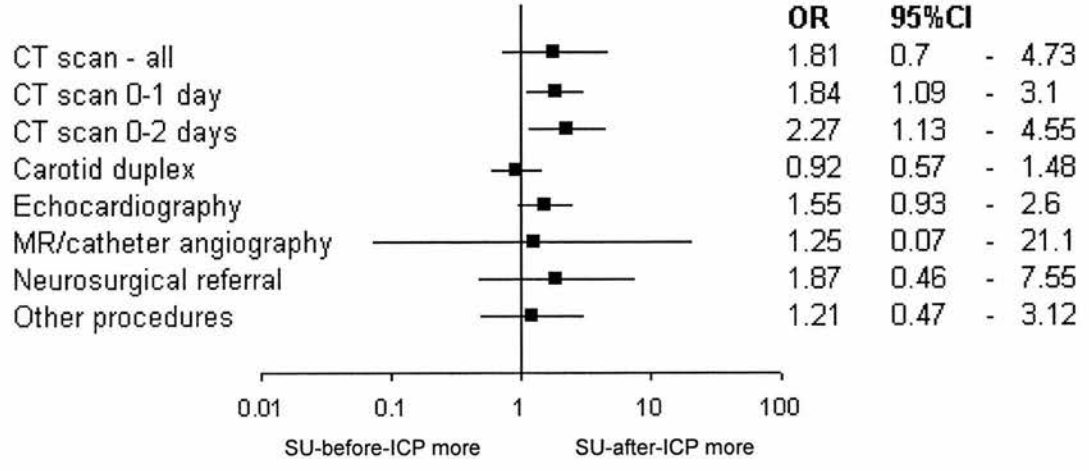
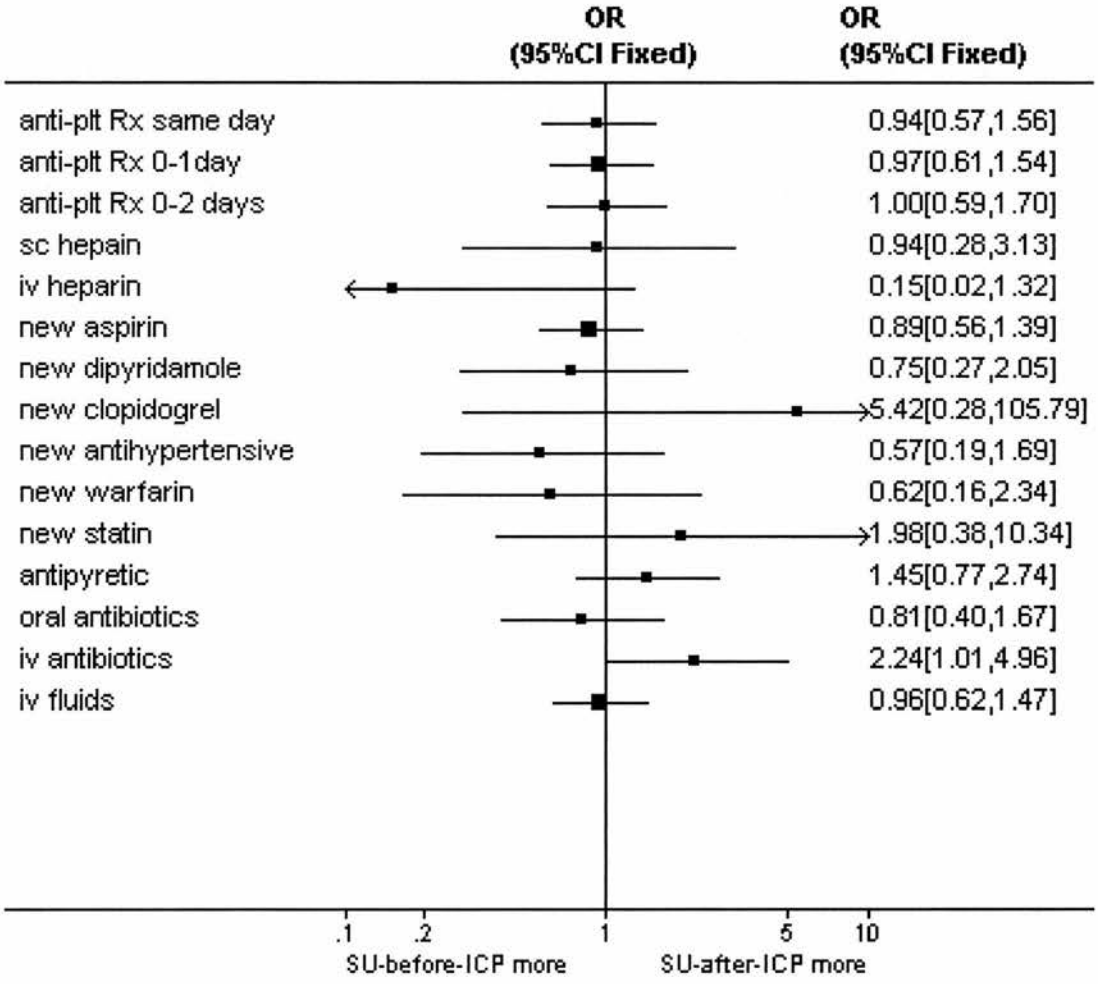


Figure 5.8 Results of SU-before-ICP vs SU-after-ICP. Process of care – use of medications. Charts showing unadjusted results (top) adjusted results (bottom). Notes: see **Figure 5.5** for explanation regarding the forest plot.

Unadjusted



Adjusted for case mix

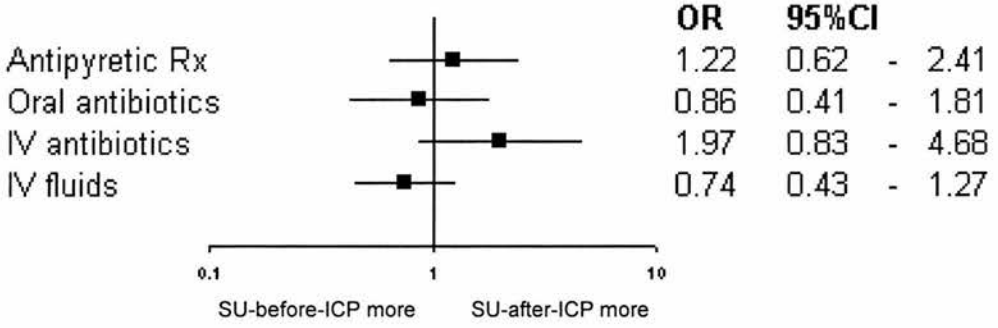
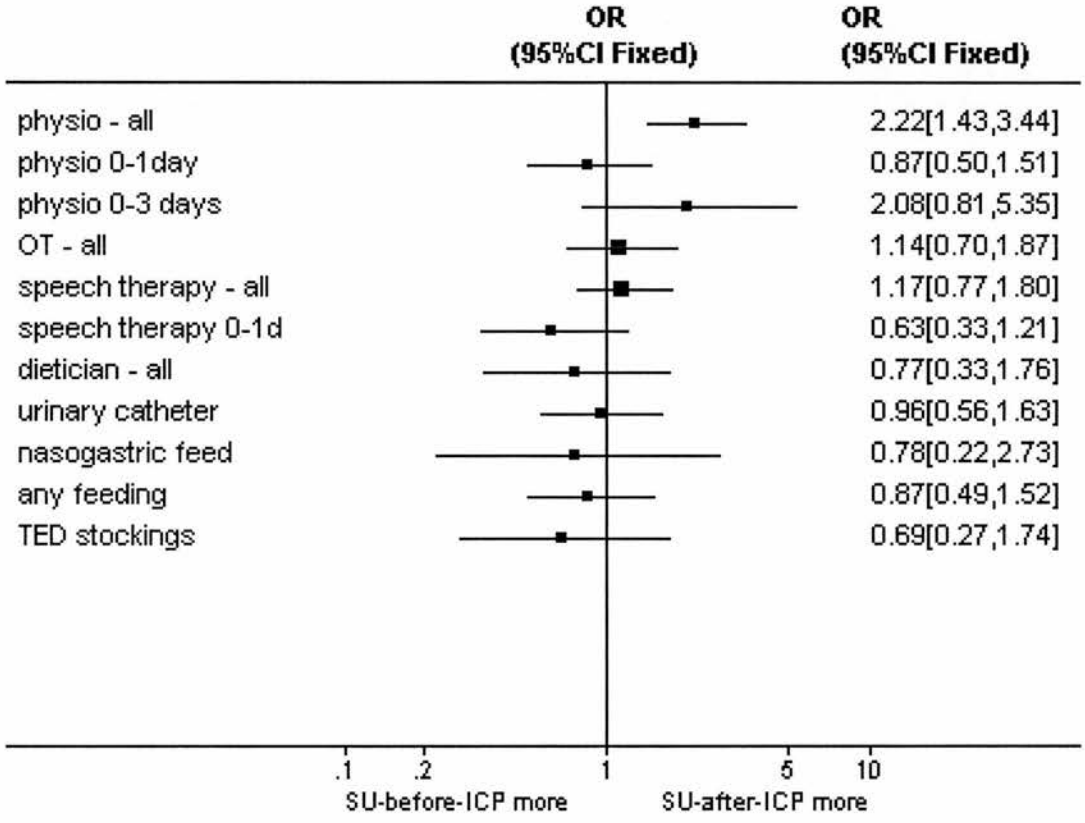


Figure 5.9 Results of SU-before-ICP vs SU-after-ICP. Process of care – use of therapy and nursing interventions. Charts showing unadjusted results (top) adjusted results (bottom). Notes: see **Figure 5.5** for explanation regarding the forest plot.

Unadjusted



Adjusted for case mix

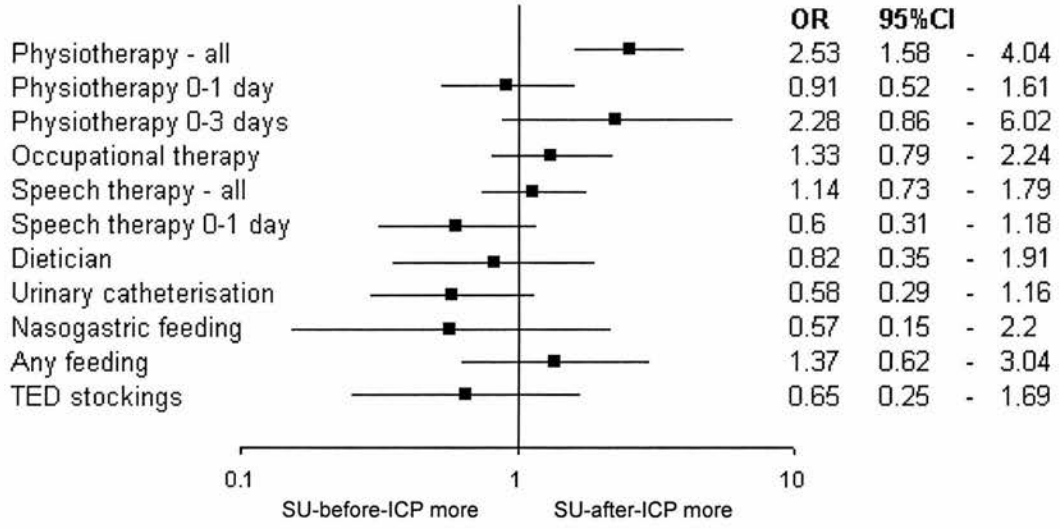
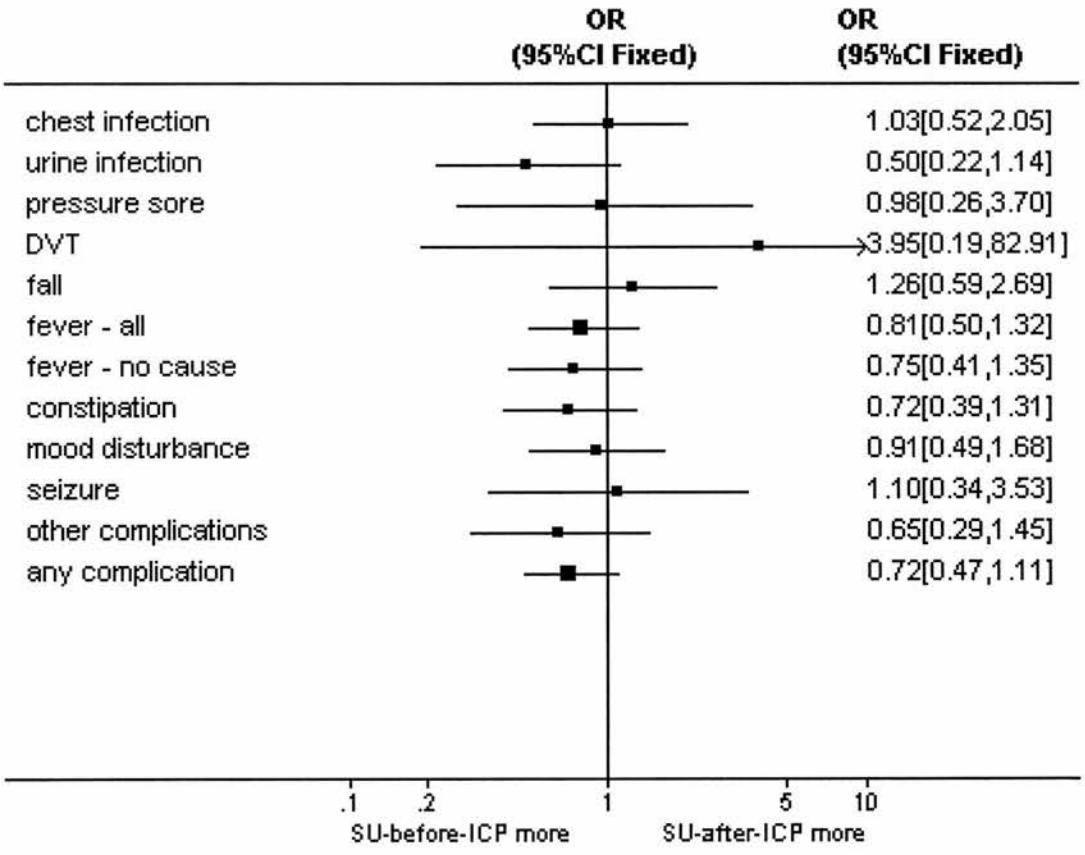


Figure 5.10 Results of SU-before-ICP vs SU-after-ICP. Occurrence of complications. Charts showing unadjusted results (top) adjusted results (bottom). Notes: see **Figure 5.5** for explanation regarding the forest plot.

Unadjusted



Adjusted for case mix

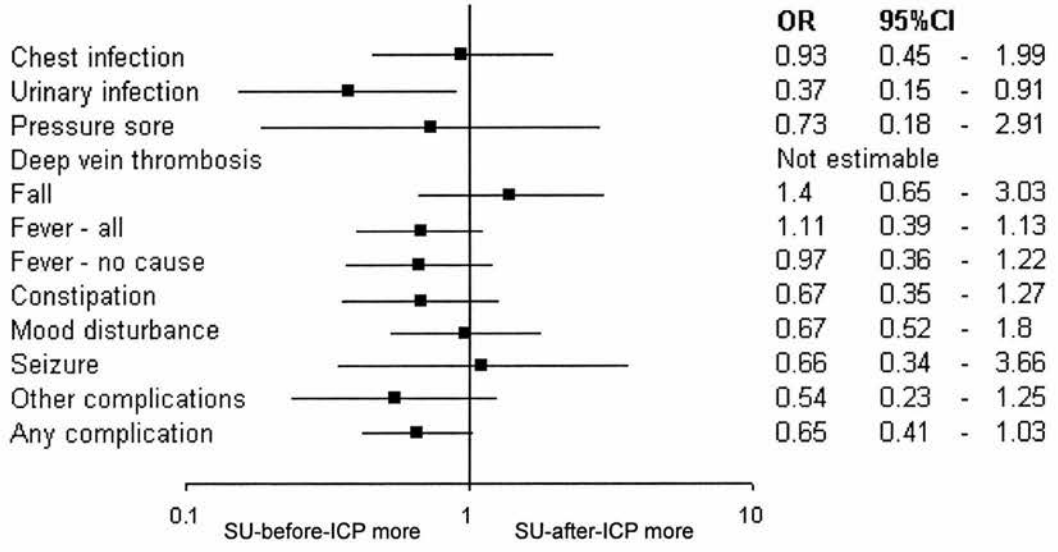
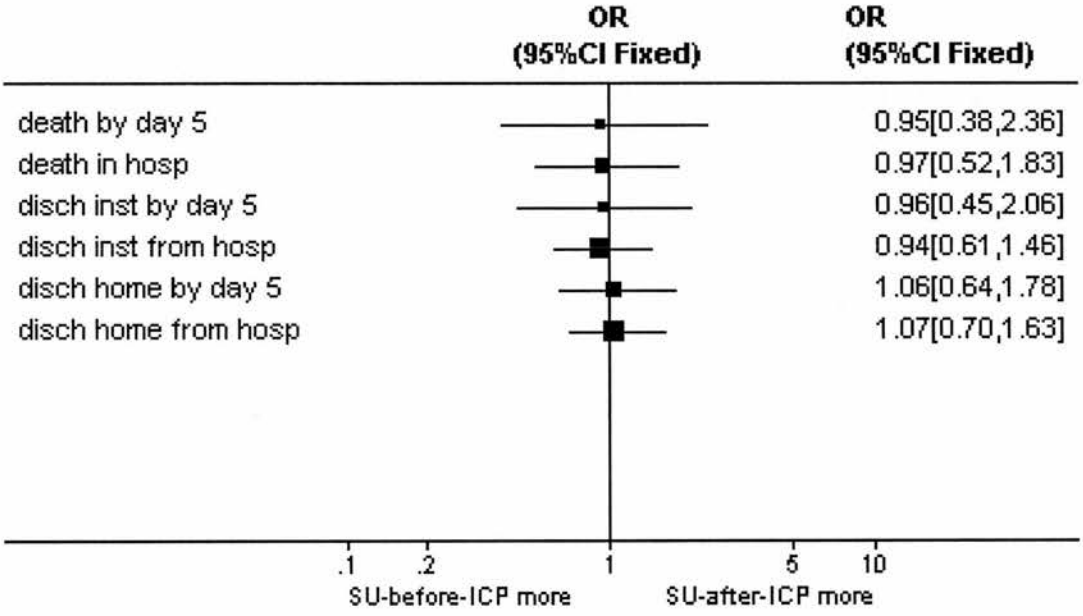
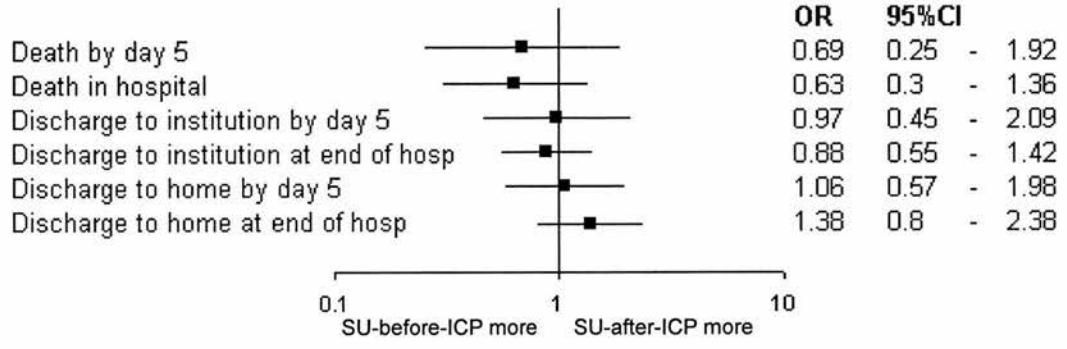


Figure 5.11 Results of SU-before-ICP vs SU-after-ICP. Death and discharge destinations. Charts showing unadjusted results (top) adjusted results (bottom). Notes: see **Figure 5.5** for explanation regarding the forest plot.

Unadjusted



Adjusted or case mix



References for Chapter 5

Al Shahi R, Warlow C. (2000) Using patient-identifiable data for observational research and audit. *The BMJ.* 321(7268):1031-1032.

Anderson CS, Jamrozik KD, Burvill PW et al. (1993) Determining the incidence of different subtypes of stroke: results from the Perth Community Stroke Study, 1989-1990. *Med J Aust.* 158(2):85-89.

Baker CM, Miller I, Sitterding M et al. (1998) Acute stroke patients comparing outcomes with and without case management. *Nurs Case Manag.* 3(5):196-203.

Bamford J, Dennis M, Sandercock P et al. (1990) The frequency, causes and timing of death within 30 days of a first stroke: the Oxfordshire Community Stroke Project. *J Neurol Neurosurg Psychiatry.* 53(10):824-829.

Bamford J, Sandercock P, Dennis M et al. (1991) Classification and natural history of clinically identifiable subtypes of cerebral infarction. *Lancet.* 337(8756):1521-1526.

Bamford J, Sandercock P, Dennis M et al. (1988) A prospective study of acute cerebrovascular disease in the community: the Oxfordshire Community Stroke Project 1981-86. 1. Methodology, demography and incident cases of first-ever stroke. *J Neurol Neurosurg Psychiatry.* 51(11):1373-1380.

Bamford JM, Sandercock PA, Warlow CP et al. (1989) Interobserver agreement for the assessment of handicap in stroke patients [letter]. *Stroke.* 20(6):828.

Bowen J, Yaste C. (1994) Effect of a stroke protocol on hospital costs of stroke patients. *Neurology.* 44(10):1961-1964.

Counsell C. (1999) *The predicting of outcome in patients with acute stroke (MD Thesis).* Cambridge: University of Cambridge.

Crawley WD. (1996) Case management: improving outcomes of care for ischaemic stroke patients. *Medsurg Nurs.* 5:239-244.

Davenport RJ, Dennis M, Warlow C. (1996a) Effect of correcting outcome data for case mix: an example from stroke medicine. *The BMJ.* 312:1503-1505.

Davenport RJ, Dennis M, Wellwood I et al. (1996b) Complications after acute stroke. *Stroke.* 27:415-420.

DoH - Department of Health. (2001) *National Service Framework for Older People.* London: HMSO.

Dromerick A, Reding MJ. (1994) Medical and neurological complications during inpatient stroke rehabilitation. *Stroke.* 25:358-361.

Dubois RW, Rogers WH, Moxley JH, III et al. (1987) Hospital inpatient mortality. Is it a predictor of quality? *N Engl J Med.* 317(26):1674-1680.

Falconer JA, Roth EJ, Sutin JA et al. (1993) The critical path method in stroke rehabilitation: lessons from an experiment in cost containment and outcome improvement [see comments]. *QRB Qual Rev Bull.* 19(1):8-16.

Forbes JF, Dennis MS. (1999) *Costs and health outcomes of stroke patients: a prospective study. Final report to Chief Scientist Office.*

Goldstein LB, Bertels C, Davis JN. (1989) Interrater reliability of the NIH stroke scale. *Arch Neurol.* 46(6):660-662.

Hamrin EKF, Lindmark B. (1990) The effect of systematic care planning after acute stroke in general hospital medical wards. *J Advanced Nurs.* 15:1146-1153.

Isard PA, Forbes JF. (1992) The cost of stroke to the National Health Service in Scotland. *Cerebrovasc Dis.* 2:47-50.

Jennett B, Bond M. (1975) Assessment of outcome after severe brain damage: A practical scale. *Lancet.* 7905:480-484.

Jessee WF, Schranz CM. (1990) Medicare mortality rates and hospital quality: are they related? *Qual Assur Health Care.* 2(2):137-144.

Johnston KC, Li JY, Lyden PD et al. (1998) Medical and neurological complications of ischemic stroke: experience from the RANTTAS trial. *Stroke.* 29(2):447-453.

Kahn KL, Rogers WH, Rubenstein LV et al. (1990) Measuring quality of care with explicit process criteria before and after implementation of the DRG-based prospective payment system. *JAMA.* 264(15):1969-1973.

Kalra L, Yu G, Wilson K et al. (1995) Medical complications during stroke rehabilitation. *Stroke.* 26(6):990-994.

Langhorne P, Stott DJ, Robertson L et al. (2000) Medical complications after stroke: a multicenter study. *Stroke.* 31(6):1223-1229.

Lau J, Antman E, Jimenez-Silva J et al. (1992) Cumulative meta-analysis of therapeutic trials for myocardial infarction. *N Engl J Med.* 327:248-254.

Mahoney FI, Barthel DW. (1965) Functional evaluation: The Barthel Index: a simple index of independence useful in scoring improvement in the rehabilitation of the chronically ill. *Md State Med J.* 14:61-65.

Morrison LG, Lam S, Sutherland M et al. (2001) A unitary patient record improves admission documentation in a medical assessment unit in a major teaching hospital. *Health Bull (Edinburgh).* 59(4):218-223.

Oberg AL, Ferguson JA, McIntyre LM et al. (2000) Incidence of stroke and season of the year: evidence of an association. *Am J Epidmiol.* 152(6):558-564.

Odderson IR, McKenna BS. (1993) A model for management of patients with stroke during the acute phase. Outcome and economic implications. *Stroke.* 24(12):1823-1827.

Pasquarello MA. (1990) Measuring the impact of an acute stroke program on patient outcomes. *J Neurosci Nurs.* 22(2):76-82.

Piantadosi S. (1997) . *Clinical trials. A methodological perspective.* New York: Wiley Interscience.

RCP. (2001a) Consensus conference on stroke treatment and service delivery. *Proceedings of the Royal College of Physicians of Edinburgh.* 31(Supplement 8).

RCP. (2001b) *National Clinical Guidelines for Stroke.* Royal College of Physicians.

Ricci S, Celani MG, La Rosa F et al. (1991) A community-based study of incidence, risk factors and outcome of transient ischaemic attacks in Umbria, Italy: the SEPIVAC study. *J Neurol.* 238(2):87-90.

Ross G, Johnson D, Kobernick M. (1997) Evaluation of a critical pathway for stroke. *J Am Osteopath Assoc.* 97(5):269-6.

Roth EJ, Lovell L, Harvey RL et al. (2001) Incidence of and risk factors for medical complications during stroke rehabilitation. *Stroke.* 32(2):523-529.

Rothwell P, Warlow C. (1995) Is self-audit reliable? *Lancet.* 346:1623.

Rudd AG, Irwin P, Rutledge Z et al. (1999) The national sentinel audit for stroke: a tool for raising standards of care. *J R Coll Physicians Lond.* 33(5):460-464.

Schull DE, Tosch P, Wood M. (1992) Clinical nurse specialists as collaborative care managers. *Nurs Manage.* 23:30-33.

Sulch D, Perez I, Melbourn A et al. (2000) Randomized controlled trial of integrated (managed) care pathway for stroke rehabilitation. *Stroke.* 31(8):1929-1934.

van Rossum CT, Shipley MJ, Hemingway H et al. (2001) Seasonal variation in cause-specific mortality: are there high-risk groups? 25-year follow-up of civil servants from the first Whitehall sudy. *Int J Eidemiol.* 30(5):1109-1116.

Wee AS, Cooper WB, Chatham RK et al. (2000) The development of a stroke clinical pathway: an experience in a medium-sized community hospital. *J Miss State Med Assoc.* 41(7):648-653.

Weir N, Dennis MS. (2001) Towards a national system for monitoring the quality of hospital-based stroke services. *Stroke.* 32(6):1415-1421.

WHO. (1978) *Cerebrovascular disorders: a clinical and research classification.* Geneva: World Health Organisation. Offset Publication No 43.

CHAPTER SIX

EFFECTS OF INTRODUCING AN INTEGRATED CARE PATHWAY IN THE STROKE UNIT AT THE WESTERN GENERAL HOSPITAL: A PROSPECTIVE COMPARATIVE STUDY OF STOKE UNIT AFTER ICP VERSUS GENERAL MEDICAL WARDS

6.1 Aims of the prospective comparative study

This prospective comparative study was performed to address two research questions:

a) What are the differences in patient care and outcome between the stroke unit after the introduction of the ICP and general medical wards where no ICP was used?

b) Are the observed differences in patient care and outcome consistent with the results of the before-and-after study and other previous studies?

6.2 Methods of the prospective comparative study

Study design

From the before-and-after study, prospective identification of patients had found 88 patients who had been admitted to the general medical wards where no ICP was used (i.e. the GMW group). For this prospective comparative study, I compared the outcome measures between the SU-after-ICP and GMW groups.

Other aspects of methodology

The selection criteria, methods of prospective data collection, data extraction and data analysis were the same as that for the before-and-after study, and they have been described in **Chapter 5**. However, there were several important exceptions which I shall outline here:

Additional outcome measures

In addition to the outcome measures that were assessed in the before-and-after study, I also assessed the following two outcomes:

1. Occurrence of complication: stroke progression during the first five days

As I mentioned in **Chapter 1**, stroke progression can be defined as worsening of the initial stroke (Castillo 1999). More recently, objective measures have been used to standardise the diagnostic criteria of stroke progression; for example, change by ≥1 point in the Canadian stroke scale, or ≥2 points in the Scandinavian Stroke Scale or the NIHSS (Davalos et al 1990; Jorgensen et al 1994; Toni et al 1995; Davalos et al

1999; Castillo 1999). In this study, I defined stroke progression as a change by ≥1 point in the NIHSS between day 0 (or as soon after admission as possible) and day 5.

2. Outcome: dependency on day 5

I assessed the dependency of the patients who were still in the WGH on day 5. I defined dependency as the need for regular assistance with activities of daily living. For this, I used the following two indicators of dependency: modified Rankin score of 3 to 5, and Barthel index of 0 to 18. These criteria were the same as those used in the Cochrane systematic review (see **Chapter 4**).

6.3 Baseline characteristics

I have already reported the numbers and baseline characteristics of the patients in both the SU-after-ICP and GMW groups – see **Table 5.6**. In summary, I included 197 in the SU-after-ICP group and 88 in the GMW group. The two groups were similar in terms of demographics, presence of major risk factors for stroke, pre-stroke level of independence, and medications taken before stroke. However, there were differences in the distribution of OCSP subtypes of stroke between the two groups; the SU-after-ICP group had fewer posterior circulation strokes (9% vs 22%, p=0.004), but more lacunar strokes (28% vs 17% p=0.05). Moreover, the patients in the SU-after-ICP appeared to have suffered more severe strokes as compared to the GMW group (median NIHSS 9.5 vs 7, p=0.0005).

Use of the integrated care pathway in the GMW group

The use of the different parts of the ICP in the SU-after-ICP group has been described in **Table 5.10**. Fourteen of the 88 (16%) patients in the GMW group had a doctor's section of the ICP used, probably because the doctor's section was available in the ARU to be used as a clerking proforma. I decided to include these 14 patients in the GMW group for data analysis to retain the intention-to-treat approach, whilst being fully aware of the possible confounding effect that this may have. I shall explore the implication of this approach later in the Discussions.

6.4 Results of the prospective comparative study

In this chapter, I shall report the results of the prospective comparative study in the main text as well as providing summary plots of the absolute numbers and odds ratios (with their 95% confidence intervals) for every outcome measure. For the sake of simplicity, I did not also present the data as tables.

1. Documentation in the first 24 hours

See **Figure 6.1**. Documentation of neurological examination was significantly more thorough in the SU-after-ICP group. This was evident in all but two items that were assessed, including: the level of consciousness ($p=0.0004$), eye movements ($p<0.0001$), truncal control or gait ($p<0.0001$), visual fields ($p=0.04$), visual inattention ($p<0.0001$), formal testing of mental ability ($p=0.01$), communication ($p<0.0001$), and swallowing ($p<0.0001$). Similarly, documentation of the diagnostic description was significantly more thorough in the SU-after-ICP group, in terms of the anatomical site of the lesion ($p<0.0001$) and the pathological type of stroke ($p=0.0004$).

2. Process of care during the first five days

i) Immediate management

See **Figure 6.2**. Patients in the SU-after-ICP group were significantly more likely to: a) have their oxygen saturation measured ($p=0.0002$); b) have an electrocardiogram ($p=0.004$); and c) have their existing antihypertensive medication continued ($p=0.004$); and d) have been informed of their diagnosis and plan of management

(p=0.0004). Overall, there was no significant difference in: a) measurement of blood pressure, blood glucose or temperature; b) use of supplemental oxygen, insulin, iv fluids, antibiotics or thrombolytic therapy; or c) performance of chest x-rays, blood tests, swallowing assessments, or immediate CT scans.

ii) Use of investigations during the first five days

See **Figure 6.3**. I adjusted the use of investigations for case mix. Both the adjusted and unadjusted results showed that patients in the SU-after-ICP group were significantly less likely to be referred to the neurosurgical team (p=0.02), even though there was no significant difference in the proportion of patients with haemorrhagic stroke (7% vs 9%). There were non-significant trends to suggest that patients in the SU-after-ICP group might be more likely to have a CT brain scan within the first one or two days, and less likely to have an echocardiogram. There was no significant difference in the performance of carotid duplex, angiography, or other procedures.

iii) Use of medications during the first five days

See **Figure 6.4**. There was no significant difference in the proportion of patients being *newly* started on antiplatelet agents (aspirin, dipyridamole or clopidogrel), anticoagulation (heparin or warfarin), or statins. However, patients in the SU-after-ICP group were significantly less likely to be started on a new antihypertensive agent during the first five days (p=0.04). There was no significant difference in the proportion of patients with ischaemic stroke who received antiplatelet agent within the first one or two days. Furthermore, I found no significant difference between the

two groups in the use of antipyretic therapy, oral antibiotics, intravenous antibiotics and intravenous fluids, after the results have been adjusted for case mix.

iv) Use of therapy and nursing interventions during the first five days

See **Figure 6.5**. I adjusted the use of therapy and nursing interventions for case mix. After adjustment, patients in the SU-after-ICP group were significantly more likely to receive speech therapy (p=0.006), but there was no significant difference in the provision of other forms of therapy. In terms of nursing interventions, patients in the SU-after-ICP group were significantly less likely to have had a urinary catheter (p=0.003) or TED stockings (p=0.008), but there was no significant difference in the use of nasogastric feeding or any feeding (oral or parenteral).

v) Length of stay at the end of hospitalisation

See **Table 6.1**. The median length of stay in the SU-after-ICP was significantly longer than that in the GMW group (10 vs 5 days, p=0.02, Mann-Whitney U test). The distribution of the data for length of stay was positively skewed for both groups; the maximum length of stay was 96 days for the SU-after-ICP group and 169 days for the GMW group.

3. Occurrence of complication during the first five days

See **Figure 6.6**. I have adjusted the occurrence of complications for case mix. Adjusted results showed that patients in the SU-after-ICP group were significantly less likely to have suffered fever (any fever p=0.048; and fever where no cause was identified p=0.042). There was a non-significant trend to suggest that patients in the

SU-after-ICP group might be less likely to suffer urinary tract infections. Overall, there was no significant difference in the occurrence of other complications including stroke progression, but the general trend was favourable towards ICP care.

4. Outcome: death, discharge destinations, and dependency on day 5

See **Figure 6.7**. I adjusted dependency on day 5, death and discharge destinations for case mix. Both the adjusted and unadjusted results showed no significant difference between the two groups in terms of death or the likelihood of being discharged to institution or to home (by day 5 or at the end of hospitalisation). Furthermore, of the patients who survived the first five days and had the mRS and Barthel index measured, there was no significant difference between the two groups in terms of dependency on day 5 (before and after adjustment for case mix).

6.5 Discussion

Limitations of this study

Many of the potential biases and confounding factors that applied to the before-and-after study would also apply to this prospective comparative study; the exceptions being those related to the changes caused by the passage of time (e.g. seasonal effects, changes in research evidence) – see **Chapter 5**. It is worth noting that, since the number of patients included in this study was smaller than that in the before-and-after study, it would be even more susceptible to random error. I shall now discuss several additional sources of bias and confounding factors that were unique to this study.

Potential sources of bias

Selection bias

Although the intention of the stroke service was for every acute stroke patient to be admitted to the stroke unit (either directly or indirectly), this was not always possible or necessary. In this study, it is possible that some patients, whether intentionally or not, were 'selected' to be admitted to the general medical wards rather than the stroke unit. For example, patients with milder strokes might be more likely to be admitted to the general medical wards, as demonstrated by the finding of a lower median NIHSS in the GMW group. Moreover, though the comparisons were non-significant, patients in the GMW group appeared to be somewhat younger and more likely to live alone, and less likely to have a history of atrial fibrillation or diabetes. So junior doctors might have believed that patients with severe stroke and more

major risk factors were more suitable for the stroke unit. Adjusting for case mix is unlikely to be able to fully correct for such selection bias.

Patients with missing data were excluded

The only missing data in this study came from the 26 patients who could not be clinically assessed by the research fellows on admission because they were admitted while both the research fellows were away. These 26 patients did not have the NIHSS on admission: 20 of the 26 patients were in the SU-after-ICP group and 6 were in the GMW group. On day 5, there were 15 survivors still in the stroke unit and 6 in the general medical ward. I decided not to record their NIHSS because there was no baseline NIHSS for comparison. **Table 6.2** summaries the total numbers of patients who had the NIHSS and functional scores recorded in this study.

For a small number of patients who did not have the NIHSS, the Barthel index was available because it was routinely recorded by the nursing staff, and the modified Rankin score (mRS) could be estimated from the case notes or ICP (e.g. if it was written "patient totally dependent for all activities of daily living", then the score would be 5). I recognise that this could have biased the results because the patients for whom the mRS or Barthel index could be estimated were often those who were very dependent or independent (i.e. those with extreme scores). In retrospect, I should have excluded the functional data for any patient who was not personally examined by the research fellow.

Assessment and reporting bias

As in the before-and-after study, the documentation in patients managed in the stroke unit after the introduction of the ICP was significantly better than those managed in the general medical wards. Consequently, the quality of the extracted data and the reliability of the results could have been severely affected. This bias could have over- or under-estimated any beneficial or harmful effect of the ICP.

Potential confounding factors

Differences in patient care

The major confounding factor in this study is the fact that one cannot differentiate the effects of the ICP from the disparity in patient care between the stroke unit and general medical wards. In this study, patients were admitted to any one of 14 general medical wards, which also included two surgical wards (four patients) and three neurology and neurosurgical wards (11 patients). Although there was a handbook on emergency medical conditions (including stroke) in every general medical ward for reference, this handbook was also available in the stroke unit and a smaller version had been given to every junior doctor. However, I could not exclude the possibility that the junior doctors working in the general medical wards might have used the handbook more often, leading to variation in medical knowledge.

Furthermore, junior doctors frequently rotated between the medical wards including the stroke unit (every one to two months for pre-registration house officers, and every two to four months for senior house officers). During the study, therefore, the knowledge and experience gained by the junior doctors whilst working in the stroke

unit could have been 'carried over' to the general medical wards, leading to cross-contamination of the comparison groups.

Another problem was that the junior doctors from the general medical wards occasionally asked the research fellows for clinical advice on stroke management; for example, whether the patient needed neurovascular clinic follow-up, or whether further neuroimaging was necessary. Although advice regarding specific treatments was rarely sought, provision of any clinical advice might have confounded the results of the study.

Use of the integrated care pathway in GMW group

Intention-to-treat analysis was used in this comparative study. However, there were 14 patients in the medical control group who had the doctor's part of the ICP used. This could have influenced the results of the study by under-estimating the effect of SU-after-ICP care. I did not analyse the data of this study using treatment-received analysis in order to explore the effects of *using* the ICP on the assessed outcomes. This was because: a) the sample size was already low and any subgroup analysis would reduce this number further, hence increasing the risk of random error; and b) there were already many sources of bias and confounding factors that subgroup analyses would be unlikely to generate meaningful or reliable results.

Issues regarding outcome measures

Functional scores: modified Rankin score and Barthel index

I assessed the mRS, NIHSS and the Barthel index in this study. Although these scales can help to describe in greater detail the neurological or functional status of the patient at the time of assessment, they are also objective and their assessment can be problematic (Lyden & Hantson 1998).

The mRS is widely used in clinical trials because researchers regard it as simple and quick to carry out (van Swieten et al 1988; Bamford et al 1989). Although it is intended to be a handicap scale, it is probably more appropriate to regard it as a global functional health index with an emphasis on physical disability (De Haan et al 1995). The Barthel index is a disability scale that is intended to measure physical dependence in personal activities of daily living, and it has been shown to be reliable (Collin et al 1988; Wade & Collin 1988). However, both of these scores are objective and can be influenced by the assessor's personal knowledge of the patient and the assessor's skills at extracting information from the patient, carer or staff. The Barthel index also suffers from the floor and ceiling effects, which can reduce its responsiveness in examining for subtle changes at the extremes of values (Wellwood et al 1995; Duncan et al 1997; van der Putten et al 1999). Furthermore, one can argue that its use in stroke patients may not be entirely valid because it measures only the basic activities of daily living, without any reference to other forms of disability that stroke patients often suffer (e.g. visual loss, communication difficulties) (Pedersen et al 1997).

In this study, I have used the same definition of dependency as that used by the Stroke Unit Trialists' Collaboration and myself in **Chapter 4** (Kwan & Sandercock 2002; Stroke Unit Trialists' Collaboration 2002). However, I recognise that definitions of dependency are not universal and clinical stroke trials often vary in their cut-off points for dichotomisation (for both mRS and Barthel index) in defining dependence (Hacke et al 1998; Sulter et al 1999).

Stroke severity score: NIH stroke score

The NIHSS is widely used in clinical stroke trials to describe stroke severity (Lyden & Hantson 1998). In one clinical trial of thrombolysis for acute stroke, the NIHSS was found to be valid when used serially over time for up to three months, and the scale showed good agreement with other measures of outcome (Lyden et al 1999). The use of the NIHSS also enables a more standardised definition of stroke progression. Although some people define stroke progression as an increase in NIHSS by two or more points, there are others who define it as an increase of three or more points (DeGraba et al 1999; Grotta et al 2001). In this study, I analysed the data using both of these two definitions and found no significant difference. Thus, for the sake of simplicity, I have only presented the results according to the former definition (i.e. increase by two or more points).

The main problem with the NIHSS is that its reliability is dependent on the assessor's clinical skills and familiarity with the scale. In addition, despite the large number (i.e. 15) of items assessed by the scale and a maximal score of 42, the NIHSS is not a continuous scale. In other words, a patient with a score of 20 is not necessary

'more impaired' than a patient with a score of 18. This means comparisons of scores using conventional statistical tests are difficult to interpret. Another problem in this study is that the clinical assessment was not always performed on the day of admission. There was sometimes a delay of one to two days (e.g. if the patient was admitted in the weekend), which may have confounded the results since the NIHSS might have changed during the first few days. In retrospect, I should have noted the date and time when the NIHSS was performed for each patient, but this was not done.

Interpretation of results

What are the differences in patient care and outcome between stroke unit care after the introduction of the integrated care pathway and general medical ward care?

The most striking finding is the substantial difference in the quality of documentation between the two groups. There were also significant differences in several aspects of acute stroke care between the two groups:

- Immediate management (measurement of oxygen saturation, performance of ECGs, continuation of antihypertensive medication, and information provision);
- Use of speech therapy;
- Use of urinary catheters and TED stockings;
- Referral to the neurosurgical team;
- Length of stay in the WGH;
- Occurrence of fever.

Some of these findings are likely to be a result of bias, confounding, or a play of chance. For example, patients in the SU-after-ICP group were less likely to be commenced on new antihypertensive medications within the first five days – there may be many explanations for this finding. Firstly, it may indicate that national guidelines were adhered to more often in the stroke unit (i.e. not to reduce the blood pressure within the first few days of stroke). Secondly, it might indicate that antihypertensive therapy was administered less often in the stroke unit as a secondary preventive measure. Thirdly, it may mean that, in the stroke unit, the blood pressure of more patients declined spontaneously and no active treatment was required. Lastly, it might have occurred by chance.

In this study, I found that fever and urinary tract infections were less likely to occur in the SU-after-ICP group (non-significant). It is possible that these two findings were related to the fact that urinary catheters were significantly less likely to be inserted into the patients of this group. Similarly, in the before-and-after study, I found that urinary tract infections were significantly less likely to occur in the SU-after-ICP group as compared with the SU-before-ICP group. When the data for both studies are combined, I found that having a urinary catheter during the first five days of admission significantly increases the risk of urinary tract infection (OR 4.6, 95% CI 2.12-9.92, $p<0.0002$) and fever (OR 3.54, 95% CI 2.15-5.79, $p<0.0001$) – see **Table 6.3**. The lower usage of urinary catheters might have been the result of introducing the ICP in the stroke unit.

I found that speech therapy was more likely to be given to the patients in the SU-after-ICP group as compared to the GMW group. However, this could be because the patients in the SU-after-ICP group were more likely to present with dysphasia (41% vs 28%, p=0.04) and dysphagia (38% vs 27%, p=0.1), and their median NIHSS was higher (9.5 vs 7, p=0.0005). These differences in the baseline characteristics may also explain other findings such as a shorter median length of stay in the GMW group. The higher usage of TED stockings in the GMW group may be the result of the recommendation in the unitary patient records which were used in the AMAU – there was a section stating that all immobile patients should be considered for TED stockings; there was no such recommendation in the ICP.

Interestingly, I found no evidence to suggest that patient care or outcome were substantially worse in the general medical wards. This is somewhat contrary to my expectation and findings from previous randomised trials and systematic review (Stroke Unit Trialists' Collaboration 2002). Again, this might be explained by the differences in the baseline characteristics between the two groups – if the two groups were balanced in every way, then a genuine difference in patient care or outcome might have been found (i.e. there was type I error in this study).

Other findings may be more difficult to explain, such as the lower risk of developing fever in the SU-after-ICP group. Variations in clinical practice may explain the differences in the immediate management of stroke and the use of TED stockings, although the introduction of the ICP might have had an impact.

In this study, I did not find evidence to suggest that patients managed in the stroke unit after the introduction of the ICP were less likely to be dead, dependent or discharged to an institution. Overall, the results of this study are consistent with those of the before-and-after study, with no evidence that stroke unit care after the introduction of the ICP was associated with any significant harm. However, since the confidence intervals were wide, one cannot exclude the possibility of a moderate disadvantage to the patients in both study groups.

How do the results of the this study compare with other studies?

In the Cochrane review of stroke unit care, the reviewers collated the results of all the randomised controlled trials of stroke unit care versus conventional medical care (Stroke Unit Trialists' Collaboration 2002). Although the review did not specifically examine the effects of ICP care, the reviewers had identified one ongoing study which examined the effects of stroke unit care with an ICP, but the data of this study were not presented (Patel et al). In the Cochrane review, the overall odds ratio (OR) for death by the end of follow-up was 0.83 (95% CI 0.71 to 0.97). In the present study, the OR for death by day 5 was 0.68 (95% CI 0.26 to 1.83), and the OR for death in hospital was 1.28 (95% CI 0.57 to 2.86). The confidence intervals in the present study are much wider than that of the Cochrane review, and they overlap the line of unity (where OR = 1). Therefore, one can only conclude that the finding of the present study was not inconsistent with the finding of the Cochrane review regarding the risk of death, but one cannot exclude the possibility of a higher risk of death in the SU-after-ICP group.

The Cochrane review of ICPs for stroke (see **Chapter 4**) included two before-and-after studies that also recruited "concurrent controls" (Bowen & Yaste 1994; Ross et al 1997). However, these two studies did not describe the setting in which the concurrent controls were managed (e.g. in a general medical ward or stroke unit), and the reasons for not using an ICP to manage them were unclear. I suspect that many of these concurrent controls were highly selected and any comparison of outcome could be severely biased and confounded. I have therefore chosen not to compare the results of the present study with these two studies.

In conclusion, the effects of managing patients in a stroke unit (after the introduction of the ICP) are consistent with what might be expected on the basis of external evidence (Cochrane reviews) and from the evidence of the before-and-after study. Whilst it may be the play of chance, it is of particular interest that patients managed in the general medical wards had more urinary catheters and more urinary tract infections and fever. Thus the systematic avoidance of urinary catheterisation (where possible) may be a contributory factor in the beneficial effects of stroke unit care. Further studies like the present one may help to determine which components of stroke unit care may be effective.

6.6 Summary of this chapter

- I performed a prospective comparative study to explore the differences in patient care and outcome between a stroke unit after the introduction of an ICP and general medical wards where there were no ICPs.
- There were significant differences in the quality of documentation and certain aspects of patient care. However, there was no significant difference in death, dependency, or discharge destination.
- In general, the results of the prospective comparative study are consistent with those of the Cochrane review of stroke unit care, the Cochrane review of ICPs for stroke, and the before-and-after study.
- Combining the data of both non-randomised studies, I found that having a urinary catheter during the first five days of admission significantly increases the risk of urinary tract infection and fever. Thus, the systematic avoidance of urinary catheterisation may possibly be a contributory factor in the beneficial effects of stroke unit care.

Table 6.1 Results of SU-after-ICP vs GMW. Length of stay in the WGH. There was a significant difference in the median length of stay between the two groups (p=0.02, Mann-Whitney U test).

	SU-after-ICP N=197	**GMW N=88**
Mean LOS (SD) in days	13.4 (15.1)	13.6 (23.4)
Median LOS (1^{st}-3^{rd} quartile)	10 (4-16)	5 (2-15)
Minimum LOS	0	0
Maximum LOS	96	196

Table 6.2 Numbers of patients who had the NIHSS and functional scores recorded on admission and on day 5.

	SU-after-ICP N=197	GMW N=88
On admission		
Modified Rankin score done	197 (100%)	88 (100%)
NIH stroke score done	177 (90%)	82 (93%)
Between admission and day 5		
Dead before day 5	11 (6%)	7 (8%)
Discharged before day 5	59 (30%)	37 (42%)
On day 5		
Survivors on day 5	127 (64%)	44 (50%)
Modified Rankin score done	123/127 (97%)	42/44 (95%)
NIH stroke score done	112/127 (88%)	38/44 (86%)
Barthel index done	124/127 (98%)	41/44 (93%)

Table 6.3 Urinary catheterisation and the risk of developing urinary tract infection and fever: combining the data of both non-randomised studies.

Complication	Catheterised No of patients	No catheter No of patients	OR (95% CI)	P value
UTI	15	15	4.60 (2.12, 9.92)	<0.0002
No UTI	73	336		
Fever	42	72	3.54 (2.15, 5.79)	<0.0001
No fever	46	279		

Figure 6.1 Results of SU-after-ICP vs GMW. Documentation in the first 24 hours. Charts showing unadjusted results. Note: OR = odds ratio; black box = point estimate of effect; horizontal line through black box = 95% confidence interval; vertical black line = OR of 1 (line of unity), i.e. the point where the odds of the outcome occurring are the same between the two groups. When the 95% CI overlaps the line of unity, then the difference between the groups is *not* statistically significant at $p<0.05$ level; when it does not overlap, then it *is* statistically significant.

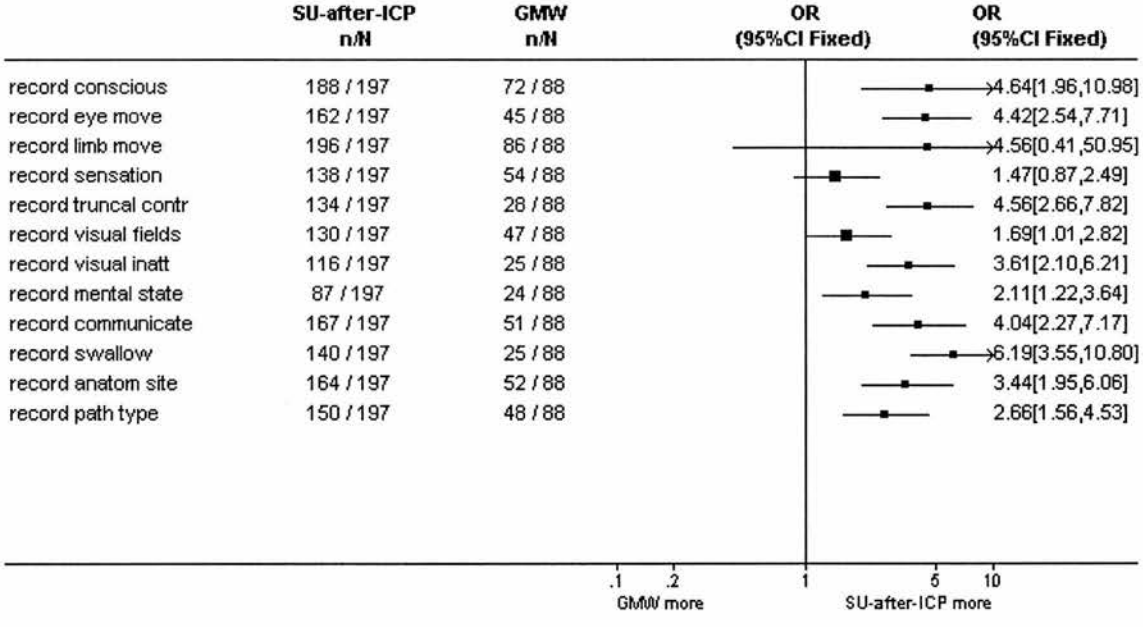


Figure 6.2 Results of SU-after-ICP vs GMW. Immediate management. Charts showing unadjusted results. Notes: see **Figure 6.1** for explanation regarding the forest plot.

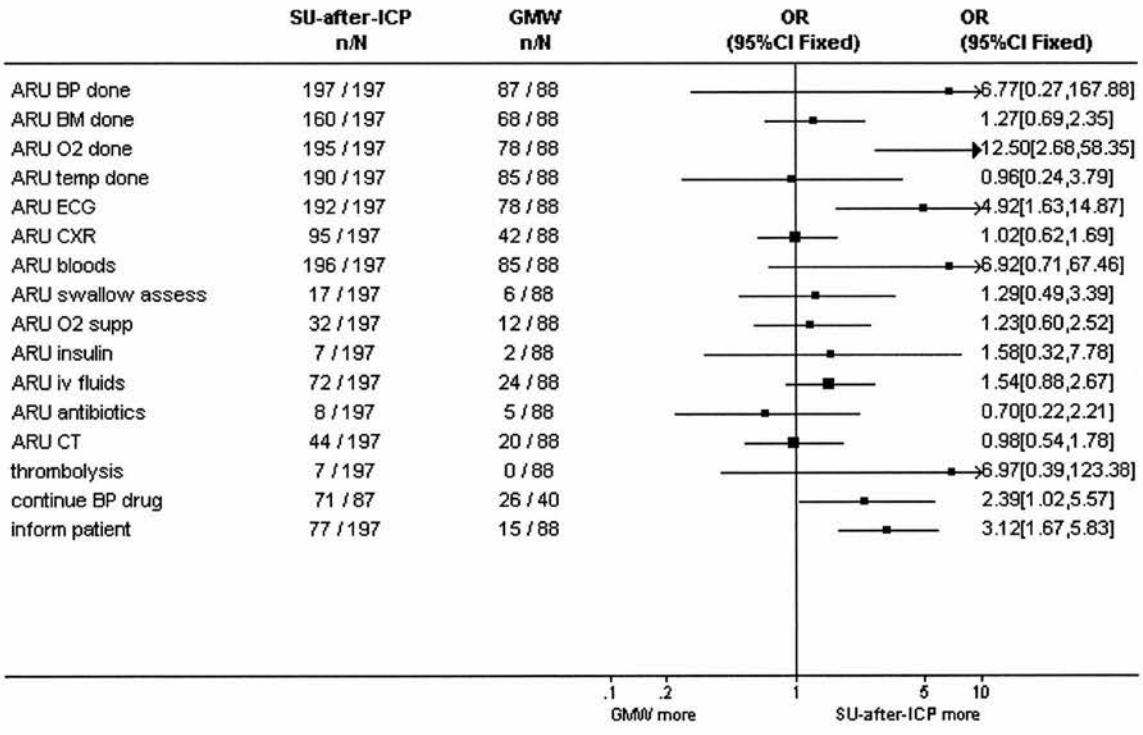
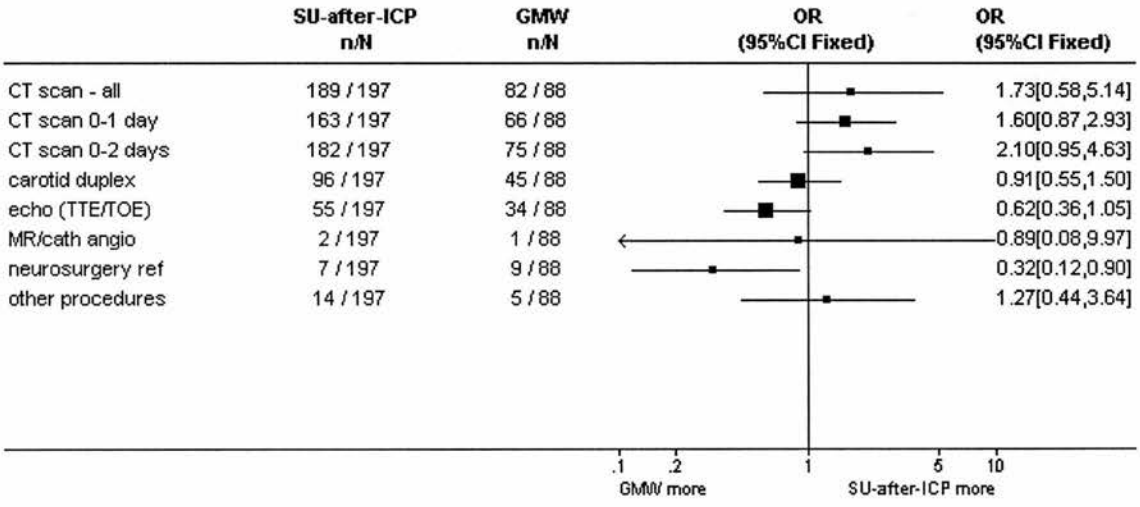


Figure 6.3 Results of SU-after-ICP vs GMW. Process of care – use of investigations. Charts showing unadjusted results (top) and adjusted results (bottom). Notes: see **Figure 6.1** for explanation regarding the forest plot.

Unadjusted



Adjusted for case mix

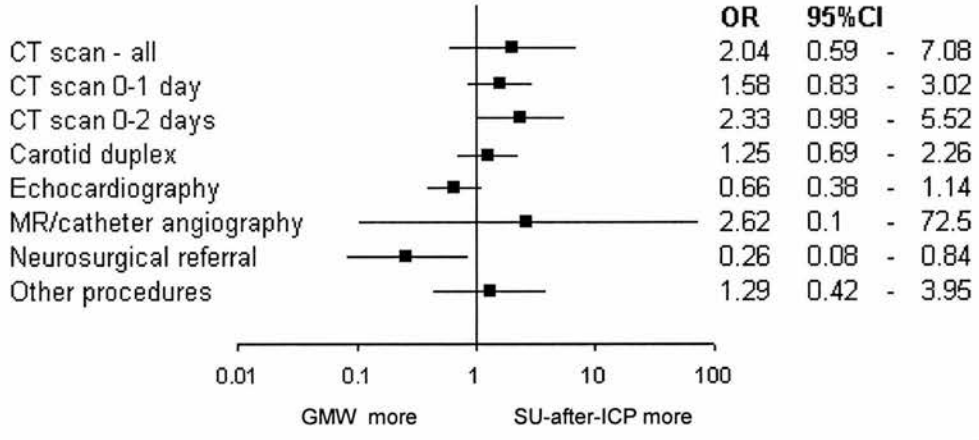
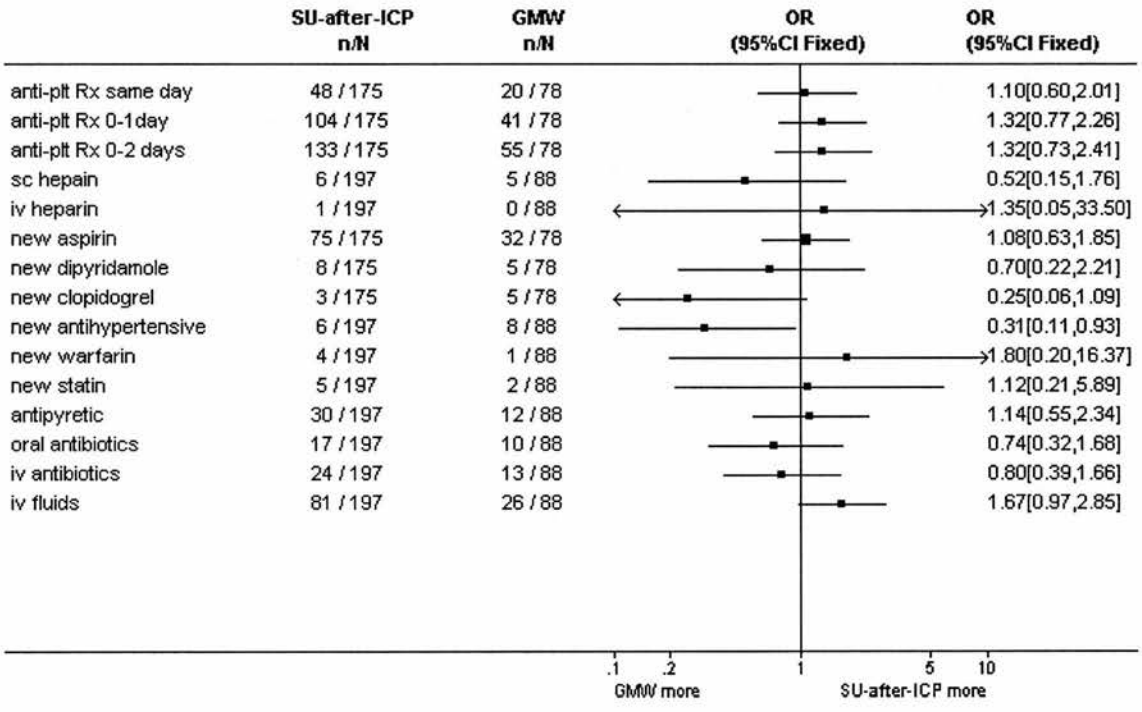


Figure 6.4 Results of SU-after-ICP vs GMW. Process of care – use of medications. Charts showing unadjusted results (top) and adjusted results (bottom). Notes: see **Figure 6.1** for explanation regarding the forest plot.

Unadjusted



Adjusted for case mix

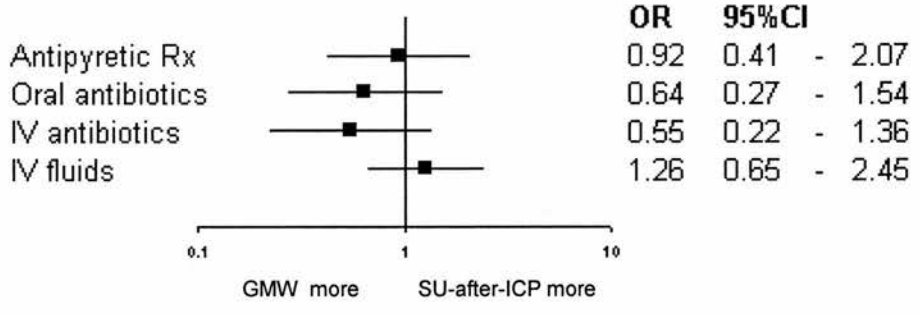
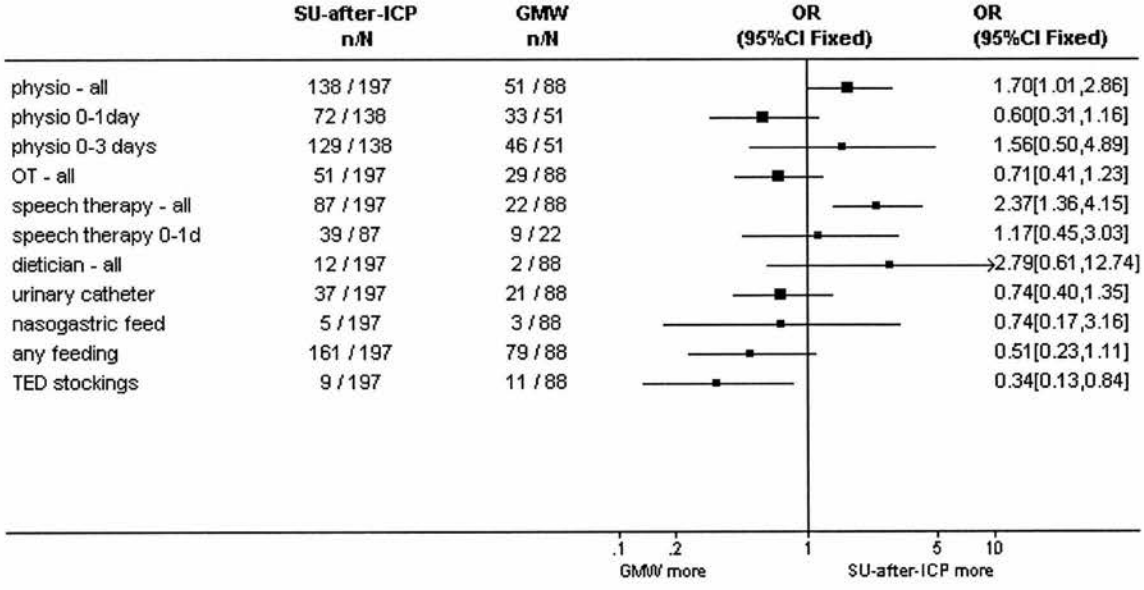


Figure 6.5 Results of SU-after-ICP vs GMW. Process of care – use of therapy and nursing interventions. Charts showing unadjusted results (top) and adjusted results (bottom). Notes: see **Figure 6.1** for explanation regarding the forest plot.

Unadjusted



Adjusted for case mix

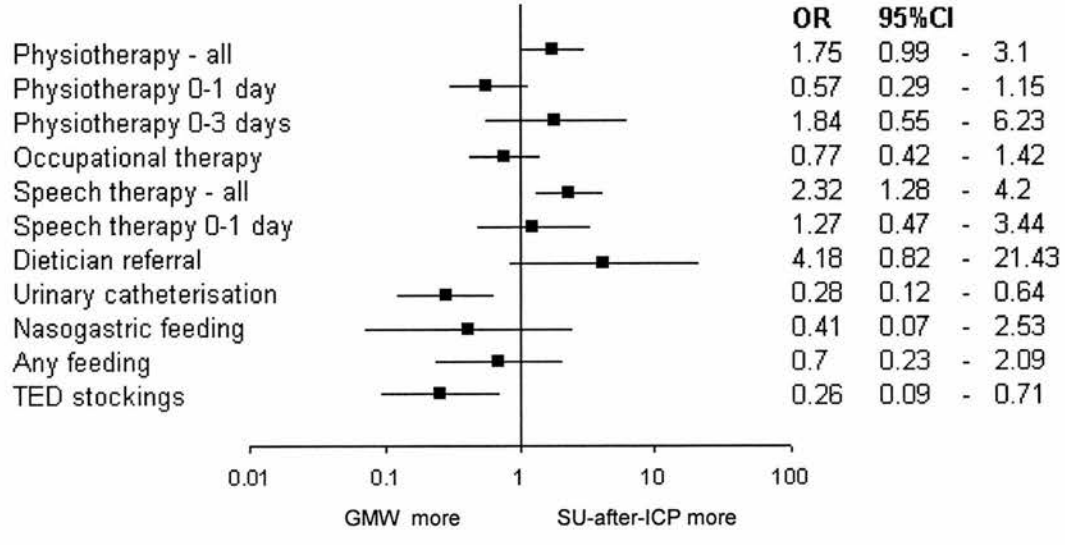
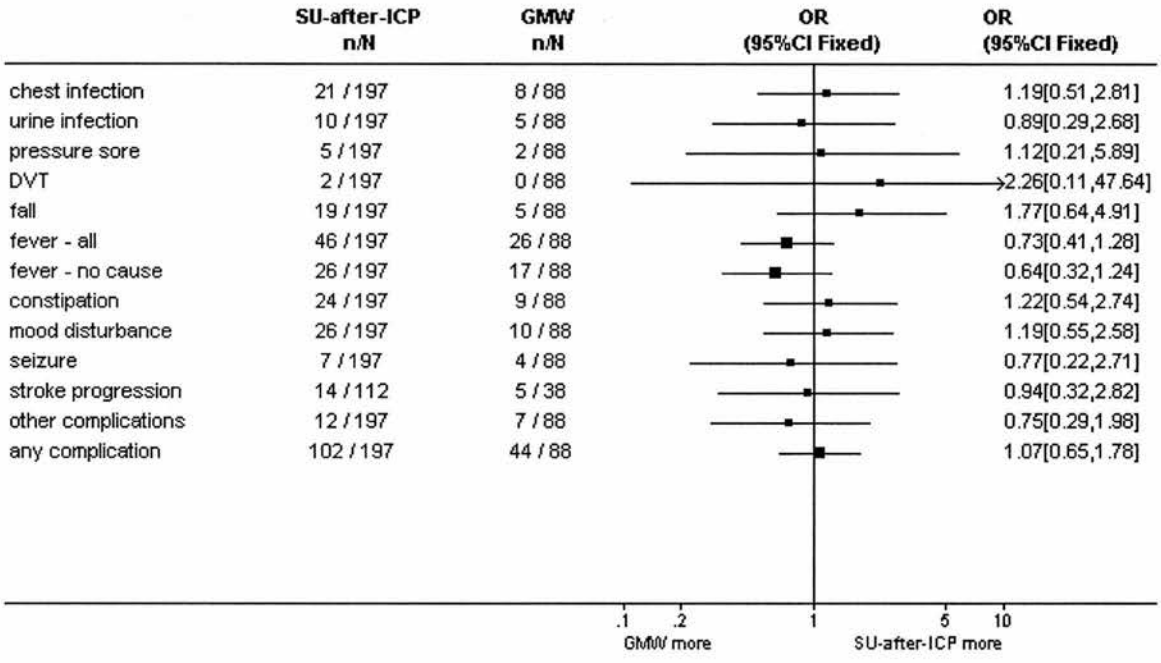


Figure 6.6 Results of SU-after-ICP vs GMW. Occurrence of complications. Charts showing unadjusted results (top) and adjusted results (bottom). Notes: see **Figure 6.1** for explanation regarding the forest plot.

Unadjusted



Adjusted for case mix

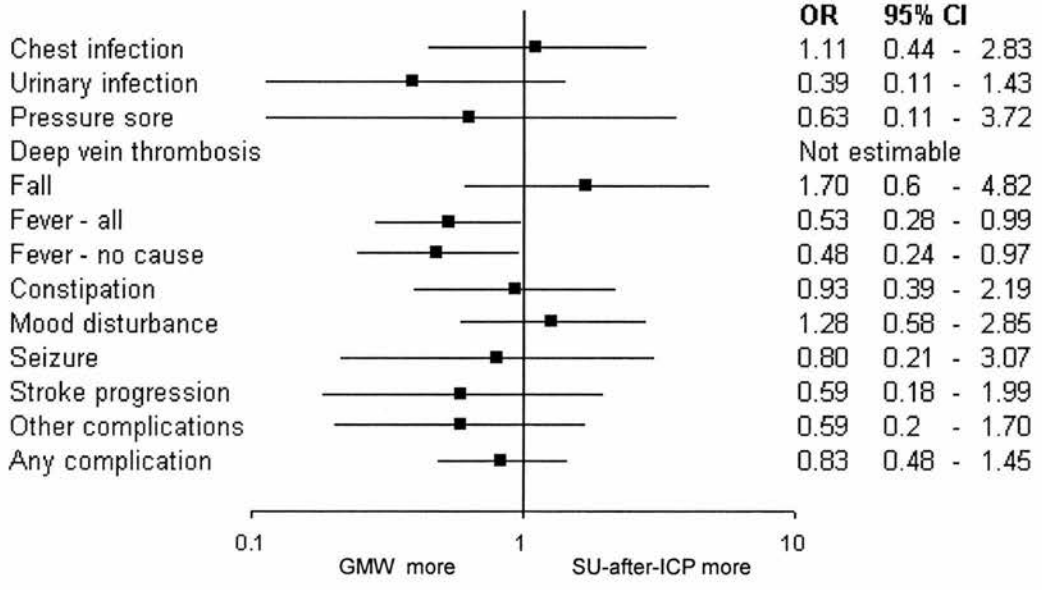
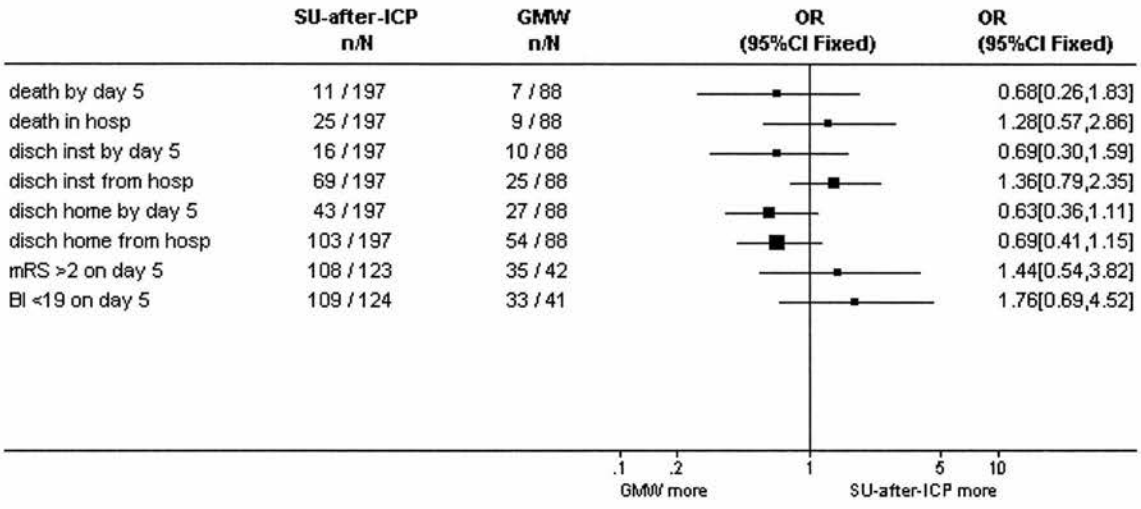
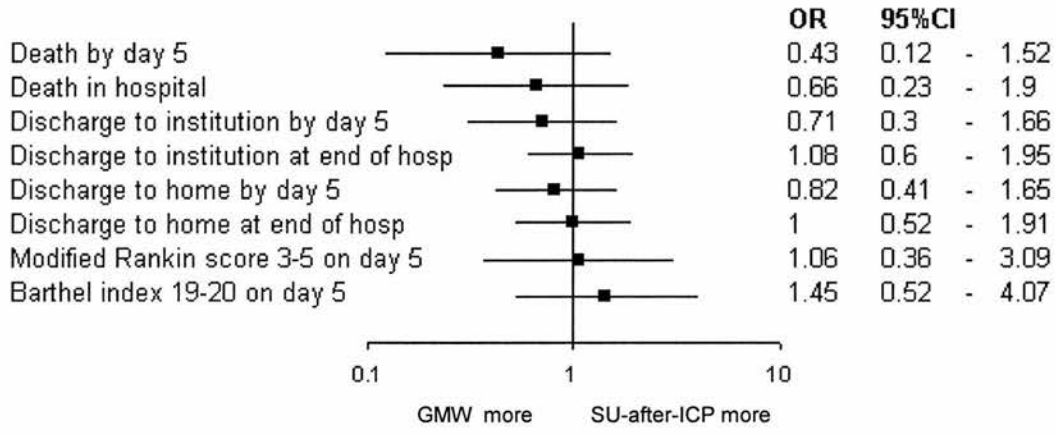


Figure 6.7 Results of SU-after-ICP vs GMW. Death, discharge destination and dependency. Charts showing unadjusted results (top) and adjusted results (bottom). Notes: see **Figure 6.1** for explanation regarding the forest plot.

Unadjusted



Adjusted or case mix



References for Chapter 6

Bamford JM, Sandercock PA, Warlow CP et al. (1989) Interobserver agreement for the assessment of handicap in stroke patients. *Stroke.* 20(6):828.

Bowen J, Yaste C. (1994) Effect of a stroke protocol on hospital costs of stroke patients. *Neurology.* 44(10):1961-1964.

Castillo J. (1999) Deteriorating stroke: diagnostic criteria, predictors, mechanisms and treatment. *Cerebrovasc Dis.* 9(Suppl 3):1-8.

Collin C, Wade DT, Davies S et al. (1988) The Barthel ADL Index: a reliability study. *Int Disabil Stud.* 10(2):61-63.

Davalos A, Cendra E, Teruel J et al. (1990) Deteriorating ischemic stroke: risk factors and prognosis. *Neurology.* 40(12):1865-1869.

Davalos A, Toni D, Iweins F et al. (1999) Neurological deterioration in acute ischemic stroke: potential predictors and associated factors in the European cooperative acute stroke study (ECASS) I. *Stroke.* 30(12):2631-2636.

De Haan R, Limburg M, Bossuyt P et al. (1995) The clinical meaning of Rankin 'handicap' grades after stroke. *Stroke.* 26(11):2027-2030.

DeGraba TJ, Hallenbeck JM, Pettigrew KD et al. (1999) Progression in acute stroke: value of the initial NIH stroke scale score on patient stratification in future trials. *Stroke.* 30(6):1208-1212.

Duncan PW, Samsa GP, Weinberger M et al. (1997) Health status of individuals with mild stroke. *Stroke.* 28(4):740-745.

Grotta JC, Welch KMA, Fagan SC et al. (2001) Clinical Deterioration Following Improvement in the NINDS rt-PA Stroke Trial. *Stroke.* 32(3):661-668.

Hacke W, Bluhmki E, Steiner T et al. (1998) Dichotomized efficacy end points and global end-point analysis applied to the ECASS intention-to-treat data set: post hoc analysis of ECASS I. *Stroke.* 29(10):2073-2075.

Jorgensen HS, Nakayama H, Raaschou HO et al. (1994) Effect of blood pressure and diabetes on stroke in progression. *Lancet.* 344(8916):156-159.

Kwan J, Sandercock P. (2002) In-hospital care pathways for stroke (Cochrane systematic review). In: *The Cochrane Library, Issue 2, 2002.* Oxford: Update Software.

Lyden P, Lu M, Jackson C et al. (1999) Underlying structure of the National Institutes of Health Stroke Scale: results of a factor analysis. NINDS tPA Stroke Trial Investigators. *Stroke.* 30(11):2347-2354.

Lyden PD, Hantson L. (1998) Assessment scales for the evaluation of stroke patients. *J Stroke Cerebrovasc Dis.* 7(2):113-127.

Patel N, Louw S, Zwarenstein M.Organised care of acute stroke at Goort Schuur Hospital. *Unpublished.*

Pedersen PM, Jorgensen HS, Nakayama H et al. (1997) Comprehensive assessment of activities of daily living in stroke. The Copenhagen Stroke Study. *Arch Phys Med Rehabil.* 78(2):161-165.

Ross G, Johnson D, Kobernick M. (1997) Evaluation of a critical pathway for stroke. *J Am Osteopath Assoc.* 97(5):269-6.

Stroke Unit Trialists' Collaboration. (2002) Organised inpatient (stroke unit) care for stroke (Cochrane Review). In: *The Cochrane Library, Issue 2, 2002.* Oxford: Update Software.

Sulter G, Steen C, De Keyser J. (1999) Use of the Barthel index and modified Rankin scale in acute stroke trials. *Stroke.* 30(8):1538-1541.

Toni D, Fiorelli M, Gentile M et al. (1995) Progressing neurological deficit secondary to acute ischemic stroke. A study on predictability, pathogenesis, and prognosis. *Arch Neurol.* 52(7):670-675.

van der Putten JJ, Hobart JC, Freeman JA et al. (1999) Measuring change in disability after inpatient rehabilitation: comparison of the responsiveness of the Barthel index and the Functional Independence Measure. *J Neurol Neurosurg Psychiatry.* 66(4):480-484.

van Swieten JC, Koudstaal PJ, Visser MC et al. (1988) Interobserver agreement for the assessment of handicap in stroke patients. *Stroke.* 19(5):604-607.

Wade DT, Collin C. (1988) The Barthel ADL Index: a standard measure of physical disability? *Int Disabil Stud.* 10(2):64-67.

Wellwood I, Dennis MS, Warlow CP. (1995) A comparison of the Barthel Index and the OPCS disability instrument used to measure outcome after acute stroke. *Age Ageing.* 24(1):54-57.

CHAPTER SEVEN

EVALUATION OF THE STROKE UNIT STAFF'S EXPERIENCE OF USING THE INTEGRATED CARE PATHWAY AT THE WGH: RESULTS OF TWO QUESTIONNAIRE SURVEYS

7.1 Background

As I discussed in **Chapter 2**, an ICP can be regarded as a complex intervention and the methodological difficulties associated with evaluating such an intervention can be considerable (Campbell et al 2000). In the light of the results of my assessment of the effects of introducing an ICP at the WGH, it was apparent that the intervention being studied was more than the ICP document itself. Rather, the intervention might be more appropriately regarded as 'ICP care', which includes the use of the ICP document plus the process of its introduction. The process of introducing an ICP provided opportunities for education and training in stroke management, review of current practice and national guidelines, reorganisation, team building, and discussions. These changes – separately or in combination – could significantly influence the process of care and hence patient outcome. Any evaluation of a complex intervention such as an ICP should therefore include a survey of the staff implementing and using the ICP. Qualitative studies such as interviews of staff may provide useful additional information, such as whether the ICP is acceptable and whether it is feasible to implement it across many hospitals.

Staff's attitude and expectation toward an ICP could have an impact on the compliance with the ICP document, and possibly on other aspects of patient care. What the staff expect the ICP to achieve may be very different from what they actually experience. Expectation and experience may also vary between disciplines and different levels of previous training; surveys of this kind should therefore include staff from different backgrounds in order for the results to be generalisable.

With this in mind, I sought to assess: a) what the stroke unit staff expected from using the ICP when it was first introduced; b) their experience of using the ICP; and c) any difference between what was expected and what was experienced.

7.2 Methods of the surveys

Study design

I conducted two cross-sectional questionnaire-based surveys. The first one was conducted one month after the introduction of the ICP (i.e. April 2000), and the second one was conducted six months later (i.e. October 2000). The first survey was designed to assess what the staff expected from using the ICP when it was first introduced. I chose to conduct the first one at one month because the staff would have had some time to become familiar with the ICP and develop some expectations of what it could achieve. The second survey was designed to assess their views once they have had more experience of using the ICP.

Questionnaire design and distribution

I designed the questionnaires for both surveys with the advice of my supervisors. I wrote down a long list of variables that an ICP might in any way influence. I then turned this list of items into a series of simple questions. The questionnaires were then circulated and modified in the light of any comments (see **Appendix 6**).

The one-month survey questionnaire contained 37 questions which explored the staff's expectation in five main areas: a) process of care; b) communication; c) quality of care; d) patient outcomes; e) personal issues; and f) general working environment. There were also four questions about the use of ICPs in general. The seven-month survey questionnaire contained 60 questions which explored the staff's experience in the same areas as the one-month survey (with some additional

questions in each area), plus a new set of questions on the design and implementation of the ICP.

For the majority of the questions, the participants were asked to score each question using a five-point scale; for the four questions on the use of ICPs in general, the three possible answers were 'yes', 'no', or 'don't know'. There was also a section at the end of the questionnaire for the participant to add any free text. The participant was asked to record his or her discipline but remained anonymous.

Every participant received the same questionnaire regardless of his or her discipline. This was because I aimed to assess everyone's opinion about each other's, as well as their own, discipline. For each survey, one questionnaire was sent to each participant with a personalised and signed cover letter explaining the aims of the study. The participant was asked to answer every question and not leave any blanks, even though not every question would be directly relevant to his or her discipline. The participant was given my telephone number for contact if there was any query. If the participant did not reply within one month, I sent a reminder letter. If there was still no reply after one month, no further reminder letter was sent and I counted the participant as a non-responder. It was necessary to do this because time was passing and the time gap between the two surveys would otherwise have become too short.

Participants in the surveys

I surveyed all the permanent members of the nursing and therapy staff (including physiotherapists, occupational therapists, speech therapists, and dieticians) working

on the stroke unit. The junior doctors were not surveyed because the pre-registration house officers rotated through the unit every one to two months, and the senior house officers rotated every two to four months. This meant that, firstly, they would only have had limited experience with using the ICP, and secondly, they could not take part in the seven-month survey. Furthermore, I did not include the two stroke consultants (MSD, RIL) since they were both personally involved in designing and implementing the ICP, as well as ensuring its use on the stroke unit.

Changes in the service structure between the first and second surveys

Between the one-month and seven-month surveys, there was a turnover of nursing and therapy staff. After the one-month survey, two nurses, one physiotherapist, one occupational therapist and one dietician were replaced by new people. In addition, the stroke unit gained an extra physiotherapist.

Statistical methods and reporting of results

The questionnaires were returned by post and I entered the data into an Excel spreadsheet. The data were thoroughly checked before analyses. Missing answers in the questionnaire were scored as missing data. Where the same question had been answered by the same person in both surveys, I calculated the difference in the scores. All calculations were carried out using SPSS for Windows (version 10.1).

In this chapter, I shall report the results of both surveys and the comparison between the two surveys. Because of the small number of participants, and for the sake of clarity of presentation, I have transformed the data from the original five-point scale

to a simpler three-point scale (see **Figure 7.1**). I have also divided the results into two groups: a) nurses and b) therapists – including physiotherapists, occupational therapists, dieticians and speech therapists.

7.3 Results of the surveys

Description of the participants

For the one-month survey, I assessed a total of 17 nurses and eight therapists (four physiotherapists, one occupational therapist, one dietician and two speech therapists). For the seven-month survey, I assessed a total of 17 nurses and nine therapists (one extra physiotherapist). Of the 17 nurses in both surveys, two were senior nurses and 15 were junior nurses (of whom four were permanently on night duty). None of the participants had previously managed stroke patients using ICPs. All the participants were female except one junior nurse. The characteristics of the participants are summarised in **Table 7.1**.

Response rates and completeness of questionnaires

See **Table 7.1**. The response rate for the one-month survey was 100%. The response rate for the seven-month survey was slightly lower at 81% (76% for nurses and 89% for therapists). The majority of the questionnaires were returned within one to two weeks of distribution; the longest delay was six weeks (by a nurse in the one-month survey).

The completeness of the questionnaires was very high; in the one-month survey with 43 questions, the mean (SD) completeness of the questionnaire was 99% (2%); and in the seven-month survey with 60 questions, it was 96% (5%). The medians were 100% and 95%, respectively.

Results of the surveys

The results for the individual questions in each survey, and the comparison between the two surveys, are presented in **Tables 7.2 – 7.5**. In this section, I shall summarise the general themes derived from the results of each survey under the following eight headings.

1. Impact of the ICP on the process of care

When the ICP was first introduced, the nurses and therapists generally expected the ICP to have a positive impact on the process of care. The majority of staff expected the ICP to increase the thoroughness and efficiency of patient care. In particular, they expected the ICP to speed up documentation, performance of routine CT scans, and transfer of patients between the stroke unit and other wards. The majority of staff also expected the ICP to facilitate and improve the quality of audit, multidisciplinary team meetings, and the decision-making process regarding the patient's resuscitation status. However, the staff did not believe that the ICP would affect the speed of discharge or the number of investigations, drug errors or accidents occurring in the unit.

After having used the ICP for seven months, the staff's experience was generally in keeping with what they had expected. Overall, the therapists appeared less impressed than the nurses about the impact of the ICP on the efficiency of patient care (i.e. speed of documentation, performance of CT scans, and transfer of patients between wards). In the seven-month survey, the majority of nurses and therapists thought that active treatments of deranged physiological variables, such as the use of insulin for

hyperglycaemia, were more commonly practised. Moreover, about half of the nurses believed that urinary catheters were used less often, whereas the other half believed that their use have not changed. Overall, the staff did not feel that the ICP had any impact on the overall amount of time treating patients or early mobilisation of patients.

2. Impact of the ICP on the communication in the stroke unit

The majority of nurses and therapists expected the ICP to improve communication between disciplines, as well as between staff, patients and relatives. Furthermore, the staff expected the ICP to improve the quality of information provided for patients and relatives, but they did not believe that the patient's and relatives' expectation would simultaneously increase (which might lead to more complaints).

The seven-month survey showed that the staff's experience was somewhat different from what had been expected. Although 86% of the therapists thought that communication between disciplines had improved, 58% of the nurses did not think so. The majority of nurses and therapists also did not feel that the ICP had any impact on communication between staff and patients or relatives. Nevertheless, 62% of nurses believed that the quality of information provided for patients and relatives had improved. Overall, the staff did not think that the patient's and relatives' expectation, or the number of complaints received by the unit, had changed after the introduction of the ICP.

3. Impact of the ICP on the quality of care

Nearly all of the nurses and therapists expected the ICP to improve the quality of nursing care, medical care, and therapy in the stroke unit, including the care of younger stroke patients and those with unusual strokes (but not those with behavioural or cognitive problems). The quality of discharge planning was also expected to improve, but the quality of stroke care in other medical wards was expected to remain the same.

At seven months, the majority of the staff felt that the quality of nursing and medical care had actually improved, but the quality of therapy was felt not to have changed. The staff did not think that the ICP had improved the quality of care for younger stroke patients or those with unusual strokes, behavioural or cognitive problems. The quality of discharge planning, and the quality of stroke care in the other wards, were thought to have been unchanged. When I compared the results on quality of care from the two surveys, I found that what was experienced was mainly similar as what had been expected.

4. Impact of the ICP on the patient outcomes

When the ICP was introduced, the nurses and therapists did not expect it to have a major impact on patient outcomes including death, disability, or the occurrence of complications. After seven months of using the ICP, this view remained the same. Moreover, the staff did not think that patient satisfaction had been affected.

5. Impact of the ICP on the staff's personal development

In general, the staff expected the ICP to improve their knowledge of stroke, clinical acumen in managing patients, and confidence in explaining clinical information to the patient or relative. Furthermore, the staff expected to be more enthusiastic to learn about stroke and maintain their autonomy in clinical decision-making.

After seven months of using the ICP, the majority of the nurses and therapists thought that the ICP has had no significant impact on their personal development, although the therapists seemed to be slightly more positive than the nurses regarding the impact of the ICP on their knowledge of stroke, clinical acumen, and enthusiasm to learn about stroke. Lastly, 23% of the nurses and 29% of the therapists thought that the introduction of the ICP had increased their overall job satisfaction.

6. Impact of the ICP on the general working environment

There was only one question about the general working environment in the one-month survey; the majority of the nurses, but not the therapists, thought that introducing the ICP would improve the appeal of the stroke unit for healthcare professionals applying for a job on the unit. The seven-month survey found that this view had not changed. In addition, the general morale of the staff and the profile of stroke in the WGH were not believed to have changed after the introduction of the ICP.

7. Opinions on the design and implementation of the ICP

There was a wide variety of opinions regarding the design and implementation of the ICP. In general, the majority of the therapists were satisfied with all the different aspects of design and implementation. Amongst the nurses, the majority were satisfied with the overall design of the ICP, the size of the document, the clinical relevance, and the amount of information contained in the ICP. However, 46-70% of the nurses were dissatisfied with the large number of signatures required and the difficulty with finding information. Almost half of the nurses felt dissatisfied with the low level of involvement in the design process, and a third of the nurses felt dissatisfied with the overall process of implementation – they felt that there was inadequate explanation of why the ICP was introduced, and a lack of practical guidance on how to complete the document.

8. Opinions on the use of ICPs in general

See **Table 7.5**. Questions regarding the use of ICPs in general were asked in the one-month survey only. The responses were very similar between the nurses and therapists. Half of the staff believed that patients should be selected for management using the ICP; for example, patients with rapidly resolving symptoms (i.e. probably a TIA) or those requiring palliative care only should not be managed with an ICP. 82% of the nurses and all the therapists thought that the natural course of stroke was *not* too unpredictable or complicated for ICP care. 80% of the nurses and 75% of the therapists felt that there should be a 'patient pathway', i.e. there should a simplified version of the ICP that is given to the patients and relatives at regular intervals or on

discharge. Opinions were mixed about whether an electronic version of the ICP should be implemented.

Information given as free text

In the one-month survey, 15/25 (60%) participants (12 nurses and three therapists) provided further information using free-text. In the seven-month survey, 11/21 (52%) participants (six nurses and five therapists) did so. I shall now report the general themes that were extracted from the free-text responses, whilst quoting the exact wordings by the participants, so as to minimise any potential bias associated with my own interpretation of the free-text.

Problems with managing patients with multiple pathologies

One nurse remarked that the ICP was not designed to manage patients with multiple medical problems because the ICP *"diverts attention to the stroke only, and other problems are then not focussed upon in the same detail. Perhaps we need optional parts of the ICP which could be included only when a patient presents with other problems besides stroke".*

Problems with patients transferred from the general medical wards

Patients transferred from the AMAU or other general medical wards usually did not have an ICP completed prior to transfer. This initially led to some confusion of whether an ICP should be started in these patients, especially if they had been transferred one or two days after admission.

Confidentiality could be compromised

1. Because the ICP was usually kept by the patient's bedside, four nurses expressed concern that the patient's confidentiality could be compromised. One wrote, *"how do we know whether an unconscious patient would choose to allow a friend or relative to read his or her notes?"*.
2. However, one nurse had a different view; she wrote *"I really like the openness of the access of the ICP to the patient and family, which is empowering for them – it makes them part of the team"*.
3. Because the ICP was kept at the patient's bedside, this might have influenced the information recorded by doctors, nurses and therapists. For example, sensitive information might not have been written down.

Risks of drug error

1. Since the drug chart was part of the ICP document, one nurse commented how drug errors could occur if the ICP was not available during 'drug rounds' (e.g. if the therapist was using it). She recalled two occasions when she *"left the ICP in the treatment room for intravenous drugs to be prepared. The ICP was then taken out of the room by doctors for the ward round"*. She suggested keeping the drug chart separate from the rest of the ICP document.
2. The ICP did not make it clear whether the patient was allergic to any medication.

Problems with transferring patients to the stroke rehabilitation unit

Since the stroke unit was the only ward that used the ICP, one nurse remarked that *"transfer of patients to the rehabilitation unit is more complex as staff there do not understand the ICP – training needed?"*.

Only one person could use the ICP at any one time

Since only one person could write in the ICP at any one time, people sometimes had to wait for their turn. One nurse observed that *"a lot of time is wasted trying to track down ICPs"*.

Patients were screened for dysphagia

One nurse commented that *"you always know if dysphagia screen has been done – if patient failed assessment, they almost always have a venflon and an iv prescription sheet"*.

Referral to the therapists was more efficient

One nurse noticed that referral of patients to occupational therapists, physiotherapists and speech therapists were *"more efficient"*.

Impact of ICP on nursing documentation

One nurse commented that the ICP *"provides a more uniform method of reporting on patient needs, condition and care"*.

Team work was enhanced

One nurse remarked that it was easy to find out what the other members of the multidisciplinary team have recorded, hence facilitating inter-ward transfers.

Design of the ICP could be improved

1. Two nurses remarked that the ICP was not user friendly.
2. Some questions related to nursing and medical treatments were *"difficult or impossible to answer"*.
3. Some information was difficult to extract (e.g. information on the social services' involvement prior to stroke).
4. Some information could not be obtained on admission, for example because the patient was drowsy and there was no family who could answer questions. Reminders of these potential gaps later in the admission could be helpful.
5. Certain sections were difficult to read because the font sizes were too small, but the use of colour-coded pages for different disciplines was welcomed.
6. The design of the ICP should have *"involved more senior staff nurses"*.

Implementation of the ICP could have been better

1. Parts of the ICP required specific training and explanation because of the complexity of the design. Because of this, one therapist thought that this would make the ICP *"less likely to be used by other areas that occasionally admit stroke patients"* and *"less likely to achieve objective of improving patient care"*.

2. One nurse commented that *"staff should have been given ownership (of the ICP) and empowerment to put forward ideas...nursing staff of various grades should have had some say in development, implementation and evaluation".*

Lack of integration of paperwork

Even though the sections of different disciplines were bound together in one folder, the sections remained separate. Three therapists felt that this design led to fragmented documentation and did not encourage truly integrated care. It would have been better to have *"sub-sections related to the patient – not different professions".*

Problems with compliance with the ICP

One therapist remarked that the ICP was a *"brilliant idea presuming people are very meticulous at filling in all the sections".*

Comparing the results of the survey with those of the non-randomised study

Table 7.6 summarises and compares the results of the non-randomised studies with the results of the seven-month survey. For most of the outcome measures, the opinion of the stroke unit staff was similar to the findings of the non-randomised studies. However, for several outcome measures (i.e. use of antipyretic agents, use of nasogastric feeding, risk of developing complications, and the overall chance of recovery), there was a discrepancy between what was experienced and what was found in the studies.

7.4 Discussion

Limitations of the study

Potential sources of bias

Recall bias

When responding to a question about a particular aspect of an intervention, the participant has to recall specific events, abstract the relevant experience, and arrive at a generalised conclusion. These processes could be compromised by memory failure, imprecise recall due to distorted memory, and selective recall due to the frequency, timing and significance of an event (Hughes & Preski 1997). Events that are more frequent or perceived as more significant tend to be over-reported (Huber & Power 1985). For example, nurses in the stroke unit might vividly recall the occurrence of a recent drug error that led to the death of a patient, and even though the frequency of drug errors might not have changed, some nurses might respond by stating that drug errors have become more frequent after the introduction of the ICP. Furthermore, memory could be distorted because of the participants' attitude, preconceptions and group discussions (i.e. nurses or therapists influencing each other).

In the surveys, the participants were also asked to make inferences or conclusions about abstract organisational properties (e.g. communication between disciplines, quality of discharge planning). The cognitive processes required to perform such a task is thought to be more difficult than those required to provide factual information (Hughes & Preski 1997). Recall bias might have influenced the findings of this

survey, but it is unlikely to be significant since **Table 7.6** shows that the survey findings and the non-randomised studies' results were broadly similar.

Non-response bias

Interpretation of survey results should take into account the many possible sources of bias (Hughes & Preski 1997). In this study, although all the participants were unselected and every member of staff was included, not every participant responded. The response rate was 100% for the one-month survey and 81% in the seven-month survey. The non-responders in the second survey were four junior nurses and one physiotherapist. It could be possible that those participants did not respond because they were particularly negative (or less likely, positive) about the use of the ICP, and an absence of such data might have distorted the overall results, especially when such small numbers of nurses and therapists had been surveyed overall. In retrospect, I should have contacted these five members of staff and examined their expectations and experiences (e.g. by telephone). Previous surveys of healthcare professionals have found differences in the characteristics between responders and non-responders to the questionnaires, with possible influence on the survey findings (Hovland et al 1980; Hill et al 1997).

Investigator bias

Surveys based on face-to-face interviews are prone to 'interviewer bias', which is the influence of the interviewer's personal attributes, experience, and preconception on the questioning of the interviewee (Salazar 1990; Rogers et al 1998). However, since this study did not use interviews, this type of bias was absent. Nevertheless,

'investigator bias' could have been present in this study because the wording of the questions were designed by myself. In a previous survey of healthcare professionals on the impact of ICPs, the participants were simply asked whether they agreed or disagreed with a list of statements, such as *"ICPs have reduced the duplication of information"*, or *"ICPs have improved communication between staff and patients"* (Bryson & Browning 1999). In the present study, I did not ask such leading questions. Instead, I asked open questions, such as *"How has the ICP affected the following?"*, and the participants answered using a five-point scale and had an option of additional free-text. The wording of the questions were carefully chosen to minimise ambiguity or bias. The tick-box format was used to standardise the participants' responses and minimise any potential bias associated with the interpretation of answers by the investigator (myself).

Position bias

Position bias refers to the consistent under or over-reporting of events as a result of the participants' rank or grade (Hughes & Preski 1997). For example, responses to questionnaires by junior nurses might be significantly different from responses by more senior nurses. Possible reasons could include: a) junior nurses might be less willing to express negative feelings about a change in policy, in case the senior nurses or consultants are offended; b) junior nurses with less experience might view any situation with lower level of insight and maturity; and c) senior nurses usually have an active role in the implementation of interventions in the ward – this may result in a more positive attitude towards the intervention. Any of these factors might lead to less accurate reporting and biased results. In this study, two senior nurses and

15 junior nurses were surveyed, and it was apparent that one of the senior nurses consistently gave very positive answers; it transpired that this senior nurse was closely involved with the design of the nursing part of the ICP document.

In both surveys, I found that the responses by the therapists to certain questions were significantly different from those by the nurses. This was to be expected because the two disciplines had different roles in the management of stroke patients, and the nurses' and therapists' sections of the ICP were very different. Furthermore, the therapists were more involved with the design than the usage of the ICP.

In this study, it was extremely unlikely that the characteristics of the participants other than their discipline and position would have influenced the responses to the questions (i.e. 'rater-trait interaction' bias). In particular, the age and gender of the participants were unlikely to have played an important role.

Potential confounding factors

Changes in staffing

Between the one-month and seven-month surveys, two nurses and three therapists were replaced and the stroke unit gained an extra physiotherapist. Unfortunately, I did not record how long the new members of staff had been working in the unit before responding to the seven-month survey. If a participant had only been working in the unit for a one or two weeks, he or she might provide invalid and unreliable answers to the survey questions. Moreover, there may be reasons why certain members of staff have been replaced, for example, due to disharmony or

dissatisfaction with the job. It would have been interesting to interview those who had been replaced to examine the reasons for their departure (e.g. was the introduction of the ICP partly responsible?).

Other organisational changes with time

Other changes might have occurred between the one-month and seven-month surveys, such as changes in medical, nursing and therapy policies, opening of the Acute Medical Assessment Unit (AMAU), introduction of a non-stroke unified patient record, and the start of the third International Stroke Trial (see **Chapter 5**). Some or all of these changes might have influenced the general working environment in the stroke unit.

Choice of questions

There are several important issues that have not been investigated by the questions asked in the surveys. These included: a) concerns regarding breach of confidentiality with a bedside record; b) how the ICP could be used as an educational tool; c) how the design and implementation of the ICP could be improved; and d) other factors that could affect the responses to the questions (e.g. level of staffing, training opportunities, previous experience in stroke management). Future surveys of healthcare staff could include such questions.

Interpretation of results

What did the staff think were the effects of introducing the integrated care pathway in the stroke unit at the WGH?

The nurses and therapists in the stroke unit had high expectations for the ICP and hoped that it would improve the process of care, quality of care, communication and their general working environment. It is clearly important to inspire and 'win over' the staff when an ICP is introduced, for example, by promoting its many potential benefits. However, it is also important to be realistic about what could be achieved in practice.

The nurses and therapists realised that, seven months after its introduction, many of their expectations of the ICP had not been realised. In particular, they felt that there had been no substantial improvement in: a) communication with patients and relatives; b) quality of therapy; c) quality of discharge planning; and d) their confidence in explaining information to patients and relatives. However, they felt that the process and quality of care had improved after the introduction of the ICP, and that ICP care was not associated with any obvious harm. The survey was useful in revealing several areas where the design and implementation of the ICP could have been better.

How do the results of this study compare with those of other studies?

The only previously published questionnaire survey of staff on the use of ICPs was conducted at the West Glasgow Hospitals and Law Hospital in 1999 (Bryson & Browning 1999). In this project, which was funded by the Clinical Resource and

Audit Group (CRAG) in Scotland, 422 questionnaires were sent out to healthcare staff in these hospitals to examine their experience of using non-stroke ICPs. This single mail shot achieved a response rate of only 51%; the findings of this CRAG study might therefore have been severely influenced by non-responder bias.

This CRAG study found that nurses were generally much more positive than the doctors and therapists in their opinions regarding the impact of ICPs. Overall, the majority of the nursing staff felt that ICPs could: a) improve the documentation of patient care; b) help to introduce guidelines- and evidence-based practice; c) standardise patient care; and d) be used as an educational tool for new staff. Although the questions in my study were different from those in the previous study, the findings point to similar impact on the process and quality of patient care. Furthermore, both the CRAG study and my study found that the introduction of ICPs did not affect communication between staff and patients, or the staff's autonomy in decision-making. Interestingly, the CRAG study found that 41% of doctors and 23% of nurses and therapists did not think that ICPs should be continued to be used or developed in their Health Trusts.

Unfortunately, meaningful comparisons between the CRAG study and my study cannot be made. The main reason is that the CRAG study did not survey any staff who cared for stroke patients. In addition, the CRAG study did not describe the characteristics of the participants apart from their disciplines, and there was no indication on who the non-responders might be.

Use of the ICP and patient confidentiality

Although the present study did not specifically examine the issues surrounding patient confidentiality, several nurses raised concerns about this issue. Interestingly, the CRAG study also included a questionnaire survey of patients to investigate the issue of confidentiality. In the CRAG study, selected inpatients who were "*well or coherent enough*" were given a questionnaire by the ward staff. Of a total of 600 patients given the questionnaires, only 107 (18%) responded. The following were found by the survey:

- 37% of patients thought that the ICP should be by the bedside, but 38% thought that it should be at the bedside *only* if the patient wished so;
- 71% of patients read the ICP once or twice during the admission, 15% read it frequently;
- 63% of patients said that their relatives had read the ICP, 13% said that other visitors had read the ICP, and 9% said that fellow patients had read their ICP;
- 87% of patients did *not* prefer to have more control over who could look at the ICP;
- 100% of therapists and 54% of nurses thought that having the ICP by the bedside had deterred them from writing sensitive information that they would otherwise have written in the usual case notes.

The conclusion was that the patients were less concerned than the healthcare staff about where the ICP was kept, but the most worrying finding was that a significant proportion of ICPs had been read by people other than the healthcare staff and the patients themselves. This type of practice is clearly in breach of patient

confidentiality and action should be taken to prevent it. Many stroke patients, who often suffer from communication difficulties as a consequence of their stroke, would be unable to express whether they wish their ICPs to be read by their relatives or other visitors. In response to this concern, the policy in the stroke unit (WGH) has changed so that ICPs are now kept in a trolley by the nurses' station.

7.5 Summary of this chapter

- I conducted two questionnaire surveys of the stroke unit staff to assess their experience of using the ICP during the first seven months of its introduction. The first survey was performed at one month after the introduction of the ICP and the second survey was performed six months later.
- The nurses and therapists in the stroke unit had high expectations for the ICP and hoped that it would improve the process of care, quality of care, communication and their general working environment.
- After having used the ICP for seven months, the staff felt that the process and quality of care had improved after the introduction of the ICP, and that ICP care was not associated with any obvious harm.
- After having used the ICP for seven months, the staff did not report any substantial improvement in: communication with patients and relatives; quality of therapy; quality of discharge planning; and their confidence in explaining information to patients and relatives.

Table 7.1 Characteristics of the participants and response rate in each survey.

Survey	Discipline	No. surveyed	No. responded
1-month survey	Nurses (F and G grades)	2	2
(April 2000)	Nurses (D and E grades)	15	15
	Physiotherapists	4	4
	Occupational therapists	1	1
	Speech therapists	2	2
	Dieticians	1	1
	Total	**25**	**25 (100%)**
7-month survey	Nurses (F and G grades)	2	2
(October 2000)	Nurses (D and E grades)	15	11
	Physiotherapists	5	4
	Occupational therapists	1	1
	Speech therapists	2	2
	Dieticians	1	1
	Total	**26**	**21 (81%)**

Table 7.2 Results of the one-month survey. Nurses' (n=17) and therapists' (n=8) expectation of what the ICP could achieve. The highest percentages are lightly shaded.

Question: *"How do you expect the ICP to influence the following?"*	Answer to each question					
	Increase n (%)		No change n (%)		Decrease n (%)	
	Nurse	Therap	Nurse	Therap	Nurse	Therap
Process of care in the stroke unit						
Thoroughness in managing patients	15 (88)	8 (100)	2 (12)	-	-	-
Speed of doctors clerking patients	12 (71)	5 (63)	3 (18)	2 (25)	2 (12)	1 (13)
Speed of N&T completing paperwork	15 (88)	5 (63)	-	1 (13)	2 (12)	2 (25)
Speed of obtaining routine CT scans	12 (71)	3 (38)	5 (29)	4 (50)	-	1 (13)
Speed of discharge to institution	6 (35)	1 (13)	11 (65)	6 (75)	-	1 (13)
Speed & ease of transfer from ARU	15 (88)	6 (75)	1 (6)	2 (25)	1 (6)	-
Speed & ease of transfer to rehab unit	10 (59)	5 (63)	4 (24)	3 (38)	1 (6)	-
Total length of stay in hospital	1 (6)	-	9 (56)	4 (50)	6 (38)	1 (13)
Number of investigations	9 (56)	3 (38)	7 (44)	5 (63)	-	-
Number of drug errors	1 (6)	-	14 (82)	4 (50)	2 (12)	4 (50)
Number of accidents on the unit	1 (6)	1 (13)	12 (71)	3 (38)	4 (24)	4 (50)
Ease of making resuscitation decisions	12 (71)	4 (50)	5 (29)	4 (50)	-	-
Quality & ease of auditing	13 (81)	7 (87)	3 (19)	1 (13)	-	-
Quality of multidisciplinary meetings	16 (93)	6 (75)	1 (6)	2 (25)	-	-
Communication						
Communication between disciplines	15 (88)	8 (100)	2 (12)	-	-	-
Communication with patients/relatives	12 (71)	8 (100)	5 (29)	-	-	-
Quality of information to patients/relat.	16 (93)	8 (100)	1 (6)	-	-	-
Expectation from patients/relatives	6 (35)	3 (38)	11 (65)	5 (63)	-	-
Number of complaints by patients/relat.	1 (6)	-	8 (50)	4 (50)	7 (44)	4 (50)
Quality of care						
Quality of nursing care on the unit	14 (82)	6 (75)	3 (18)	2 (25)	-	-
Quality of medical care on the unit	13 (86)	7 (87)	4 (24)	1 (13)	-	-
Quality of therapy on the unit	13 (86)	5 (63)	4 (24)	3 (38)	-	-
Care of patients with unusual strokes	10 (59)	7 (87)	7 (41)	1 (13)	-	-
Care of younger stroke patients	11 (65)	4 (50)	6 (35)	4 (50)	-	-
Care of pts. with behavioural problems	5 (29)	3 (38)	12 (71)	5 (63)	-	-
Care of pts. with cognitive problems	6 (37)	2 (25)	10 (63)	6 (75)	-	-
Quality of discharge planning	11 (65)	7 (87)	4 (24)	1 (13)	2 (12)	-
Quality of stroke care in other wards	1 (7)	2 (25)	12 (80)	6 (75)	2 (13)	-

Question: *"How do you <u>expect</u> the ICP to influence the following?"*	Answer to each question					
	Increase n (%)		No change n (%)		Decrease n (%)	
	Nurse	Therap	Nurse	Therap	Nurse	Therap
Patient outcomes						
Risk of death or disability at 1 month	3 (18)	-	10 (59)	5 (63)	4 (24)	3 (38)
Risk of death or disability at 1 year	1 (6)	-	12 (71)	7 (88)	4 (24)	1 (13)
Risk of complications	1 (6)	-	8 (50)	4 (50)	7 (44)	4 (50)
Personal issues						
General knowledge of stroke	14 (82)	7 (87)	3 (18)	1 (13)	-	-
Clinical acumen in managing stroke	16 (94)	5 (63)	1 (6)	3 (38)	-	-
Enthusiasm to learn about stroke	12 (71)	5 (63)	5 (29)	3 (38)	-	-
Confidence in explaining information	13 (76)	5 (63)	4 (24)	3 (38)	-	-
Confidence in managing stroke	6 (38)	6 (75)	7 (44)	2 (25)	3 (18)	-
Autonomy in decision-making	8 (47)	1 (13)	8 (47)	7 (88)	1 (6)	-
General working environment						
Appeal of the unit to job applicants	10 (59)	4 (50)	7 (41)	4 (50)	-	-

Notes:

The denominator used to calculate each percentage = number of response for that question (*not* the number of participants surveyed).

Therap. = therapists

N&T = nurses and therapists

Pts. = patients

Relat. = relatives

Table 7.3 Results of the seven-month survey. Nurses' (n=13) and therapists' (n=8) experience of using the ICP on the stroke unit.

Question: ***"From your experience, how has the ICP affected the following?"***	***Answer to each question***					
	Increased n (%)		**No change n (%)**		**Reduced n (%)**	
	Nurse	**Therap**	**Nurse**	**Therap**	**Nurse**	**Therap**
Process of care in the stroke unit						
Thoroughness in managing patients	10 (77)	6 (75)	3 (23)	2 (25)	-	-
Speed of doctors clerking patients	5 (56)	2 (29)	2 (22)	5 (71)	2 (22)	-
Speed of N&T completing paperwork	9 (69)	3 (38)	3 (23)	4 (50)	1 (8)	1 (13)
Speed of obtaining routine CT scans	11 (85)	3 (38)	2 (15)	5 (63)	-	-
Speed of discharge to institution	3 (23)	2 (25)	10 (77)	6 (75)	-	-
Speed & ease of transfer from ARU	8 (61)	2 (25)	4 (31)	5 (63)	1 (8)	1 (13)
Speed & ease of transfer to rehab unit	7 (54)	4 (50)	5 (39)	4 (50)	1 (8)	-
Total length of stay in hospital	-	-	10 (77)	6 (75)	3 (23)	2 (25)
Number of investigations	7 (58)	-	5 (42)	6 (100)	-	-
Number of drug errors	-	-	9 (69)	6 (100)	4 (31)	-
Number of accidents on the unit	-	1 (14)	10 (77)	5 (71)	3 (23)	1 (14)
Ease of making resuscitation decisions	2 (17)	-	3 (25)	3 (43)	7 (58)	4 (57)
Quality of multidisciplinary meetings	6 (50)	6 (86)	6 (50)	1 (14)	-	-
Amount of time treating patients*	2 (15)	-	11 (85)	7 (100)	-	-
Use of O2 when hypoxia*	10 (77)	3 (50)	3 (23)	3 (50)	-	-
Use of insulin when high glucose*	9 (69)	4 (57)	4 (31)	3 (43)	-	-
Use of iv fluids*	10 (77)	4 (57)	3 (23)	3 (43)	-	-
Use of antipyretic when fever*	8 (61)	4 (57)	5 (39)	3 (43)	-	-
Use of urinary catheter*	1 (8)	1 (17)	6 (46)	4 (67)	6 (46)	1 (17)
Use of nasogastric feeding*	8 (61)	4 (57)	4 (31)	3 (43)	1 (8)	-
Treatment with early mobilisation*	9 (69)	1 (14)	4 (31)	6 (86)	-	-
Communication						
Communication between disciplines	5 (42)	6 (86)	7 (58)	1 (14)	-	-
Communication with patients/relatives	4 (31)	3 (38)	9 (69)	5 (63)	-	-
Quality of information to patients/relat.	8 (62)	4 (50)	5 (39)	4 (50)	-	-
Expectation from patients/relatives	3 (23)	3 (38)	10 (77)	5 (63)	-	-
Number of complaints by patients/relat.	-	-	8 (73)	7 (88)	3 (27)	1 (13)
Quality of care						
Quality of nursing care on the unit	7 (54)	4 (57)	6 (46)	3 (43)	-	-
Quality of medical care on the unit	7 (58)	4 (57)	5 (42)	3 (43)	-	-
Quality of therapy on the unit	6 (50)	2 (29)	6 (50)	5 (71)	-	-
Care of patients with unusual strokes	6 (46)	3 (38)	7 (54)	5 (63)	-	-

Question: *"From your experience, how has the ICP affected the following?"*	*Answer to each question*					
	Increased n (%)		No change n (%)		Reduced n (%)	
	Nurse	Therap	Nurse	Therap	Nurse	Therap
Care of younger stroke patients	5 (38)	3 (38)	8 (62)	5 (63)	-	-
Care of pts. with behavioural problems	2 (15)	2 (25)	11 (85)	6 (75)	-	-
Care of pts. with cognitive problems	2 (15)	1 (13)	10 (77)	6 (75)	1 (8)	1 (13)
Quality of discharge planning	6 (46)	5 (63)	7 (54)	3 (38)	-	-
Quality of stroke care in other wards	1 (8)	3 (38)	9 (75)	4 (50)	2 (17)	1 (13)
Patient outcomes						
Overall chance of recovery*	6 (46)	4 (57)	6 (46)	3 (43)	1 (8)	-
Risk of complications	3 (23)	2 (29)	8 (62)	4 (57)	2 (15)	1 (14)
Patient/relative satisfaction*	3 (25)	3 (43)	9 (75)	4 (57)	-	-
Personal issues						
General knowledge of stroke	6 (46)	5 (63)	7 (54)	3 (38)	-	-
Clinical acumen in managing stroke	4 (33)	5 (63)	8 (67)	3 (38)	-	-
Enthusiasm to learn about stroke	6 (50)	3 (60)	6 (50)	2 (40)	-	-
Confidence in explaining information	6 (46)	2 (25)	7 (54)	6 (75)	-	-
Confidence in managing stroke	3 (23)	2 (25)	10 (77)	6 (75)	-	-
Autonomy in decision-making	5 (39)	2 (25)	6 (46)	6 (75)	2 (15)	-
Overall job satisfaction*	3 (23)	2 (29)	10 (77)	5 (71)	-	-
General working environment						
General morale of staff on the unit*	1 (8)	2 (29)	11 (85)	5 (71)	1 (8)	-
Profile of stroke care in WGH*	1 (8)	4 (50)	12 (92)	4 (50)	-	-
Appeal of the unit to job applicants	7 (54)	3 (38)	6 (46)	5 (63)	-	-
	Satisfactory		**'Midpoint'**		**Unsatisfactory**	
	Nurse	**Therap**	**Nurse**	**Therap**	**Nurse**	**Therap**
Design and implementation of ICP						
Overall design*	5 (42)	4 (50)	4 (33)	2 (25)	3 (25)	2 (25)
Size of document*	6 (46)	6 (75)	6 (46)	2 (25)	1 (8)	-
Number of questions to answer*	6 (46)	4 (50)	2 (15)	3 (38)	5 (39)	1 (13)
Number of signatures required*	2 (15)	5 (63)	2 (15)	2 (25)	9 (70)	1 (13)
Speed and ease of finding information*	5 (39)	3 (38)	2 (15)	2 (25)	6 (46)	3 (38)
Involvement in the design process*	2 (18)	5 (63)	4 (36)	2 (25)	5 (46)	1 (13)
Clinical relevance of questions*	8 (61)	4 (50)	4 (31)	2 (25)	1 (8)	2 (25)
Explanation of aims of ICP*	4 (33)	5 (63)	4 (33)	3 (38)	4 (33)	-
Education on how to use the ICP*	2 (17)	5 (63)	5 (42)	2 (25)	5 (42)	1 (13)
Mechanism for feedback of comments*	3 (23)	5 (63)	7 (54)	3 (38)	3 (23)	-
Overall process of implementation*	3 (27)	4 (50)	4 (36)	3 (38)	4 (36)	1 (13)
Ease of getting used to the ICP*	4 (31)	5 (63)	7 (54)	3 (38)	2 (15)	-

*New questions compared with one-month survey.

Table 7.4 Comparing what was initially expected with what was experienced during the first seven months: comparing the results of nurses (n=12) and therapists (n=5) who have completed both questionnaires.

Item of interest	*During the seven months, what was experienced was...*					
	Higher than what was expected n (%)		Same as what was expected n (%)		Lower than what was expected n (%)	
	Nurse	Therap	Nurse	Therap	Nurse	Therap
Process of care in the stroke unit						
Thoroughness in managing patients	1 (8)	-	6 (50)	1 (20)	5 (42)	4 (80)
Speed of doctors clerking patients	2 (25)	-	2 (25)	1 (20)	4 (50)	4 (80)
Speed of N&T completing paperwork	1 (8)	1 (20)	8 (67)	2 (40)	3 (25)	2 (40)
Speed of obtaining routine CT scans	3 (25)	1 (20)	7 (58)	3 (60)	2 (17)	1 (20)
Speed of discharge to institution	2 (17)	2 (40)	7 (58)	3 (60)	3 (25)	-
Speed & ease of transfer from ARU	-	-	8 (67)	2 (40)	4 (33)	3 (60)
Speed & ease of transfer to rehab unit	2 (17)	-	8 (67)	3 (60)	2 (17)	2 (40)
Total length of stay in hospital	4 (33)	2 (40)	5 (42)	3 (60)	3 (25)	-
Number of investigations	2 (18)	-	6 (55)	2 (40)	3 (27)	3 (60)
Number of drug errors	1 (8)	4 (80)	8 (67)	1 (20)	3 (25)	-
Number of accidents on the unit	3 (25)	4 (80)	7 (58)	-	2 (17)	1 (20)
Ease of making resuscitation decisions	1 (8)	1 (20)	5 (42)	3 (60)	6 (50)	1 (20)
Quality of multidisciplinary meetings	-	1 (20)	5 (46)	1 (20)	6 (55)	3 (60)
Communication						
Communication between disciplines	-	-	5 (46)	3 (60)	6 (54)	2 (40)
Communication with patients/relatives	-	-	8 (67)	1 (20)	4 (33)	4 (80)
Quality of information to patients/relat.	-	-	4 (33)	2 (40)	8 (67)	3 (60)
Expectation from patients/relatives	1 (8)	3 (60)	9 (75)	2 (40)	2 (17)	-
Number of complaints by patients/relat.	3 (27)	3 (60)	6 (55)	2 (40)	2 (18)	-
Quality of care						
Quality of nursing care on the unit	3 (25)	-	4 (33)	3 (60)	5 (42)	2 (40)
Quality of medical care on the unit	3 (27)	-	5 (46)	2 (40)	3 (27)	3 (60)
Quality of therapy on the unit	2 (18)	-	4 (36)	2 (40)	5 (46)	3 (60)
Care of patients with unusual strokes	2 (17)	-	5 (42)	1 (20)	5 (42)	4 (80)
Care of younger stroke patients	1 (8)	-	6 (50)	3 (60)	5 (42)	2 (40)
Care of pts. with behavioural problems	2 (17)	-	6 (50)	4 (80)	4 (33)	1 (20)
Care of pts. with cognitive problems	2 (18)	-	4 (36)	3 (60)	5 (46)	2 (40)
Quality of discharge planning	2 (17)	1 (20)	5 (42)	2 (40)	5 (42)	2 (40)
Quality of stroke care in other wards	2 (22)	2 (40)	6 (67)	2 (40)	1 (11)	1 (20)

Item of interest	*During the seven months, what was experienced was...*					
	Higher than what was expected n (%)		Same as what was expected n (%)		Lower than what was expected n (%)	
	Nurse	Therap	Nurse	Therap	Nurse	Therap
Patient outcomes						
Risk of complications	5 (42)	4 (57)	4 (33)	1 (14)	3 (25)	2 (29)
Personal issues						
General knowledge of stroke	2 (17)	1 (20)	5 (42)	1 (20)	5 (42)	3 (60)
Clinical acumen in managing stroke	-	-	4 (36)	5 (100)	7 (64)	-
Enthusiasm to learn about stroke	2 (17)	2 (40)	6 (50)	1 (20)	4 (33)	2 (40)
Confidence in explaining information	1 (8)	-	7 (58)	1 (20)	4 (33)	4 (80)
Confidence in managing stroke	1 (9)	-	7 (64)	2 (40)	3 (27)	3 (60)
Autonomy in decision-making	1 (8)	1 (20)	7 (58)	4 (80)	4 (33)	-
General working environment						
Appeal of the unit to job applicants	3 (25)	1 (20)	7 (58)	3 (60)	2 (17)	1 (20)

Table 7.5 Answers to the questions about the use of ICPs in general (in the one-month survey only).

Nurses' responses

Do you think...	Yes n (%)	No n (%)	Don't know n (%)
1. patients should be selected to be managed with the ICP?	8 (50)	6 (38)	2 (13)
2. the natural course of stroke is too unpredictable and complicated for management with an ICP?	3 (18)	14 (82)	-
3. there should be an electronic version of the ICP?	6 (35)	4 (24)	7 (41)
4. there should be a 'patient pathway', which is a simplified version of the ICP given to the patient/relatives?	12 (80)	1 (7)	2 (13)

Therapists' responses

Do you think...	Yes n (%)	No n (%)	Don't know n (%)
1. patients should be selected to be managed with the ICP?	4 (50)	3 (38)	1 (13)
2. the natural course of stroke is too unpredictable and complicated for management with an ICP?	-	8 (100)	-
3. there should be an electronic version of the ICP?	3 (38)	2 (25)	3 (38)
4. there should be a 'patient pathway', which is a simplified version of the ICP given to the patient/relatives?	6 (75)	1 (13)	1 (13)

Table 7.6 Comparing the results of the non-randomised studies with those of the seven-month survey. Notes: ↑ indicates a finding of an increase in the outcome measure as a result of introducing the ICP in the stroke unit, ↓ indicates a decrease, and ↔ indicates no change (a combination of these indicates mixed response in the survey). In the middle two columns, NS = non-significant result, otherwise all other results were statistically significant at $p<0.05$.

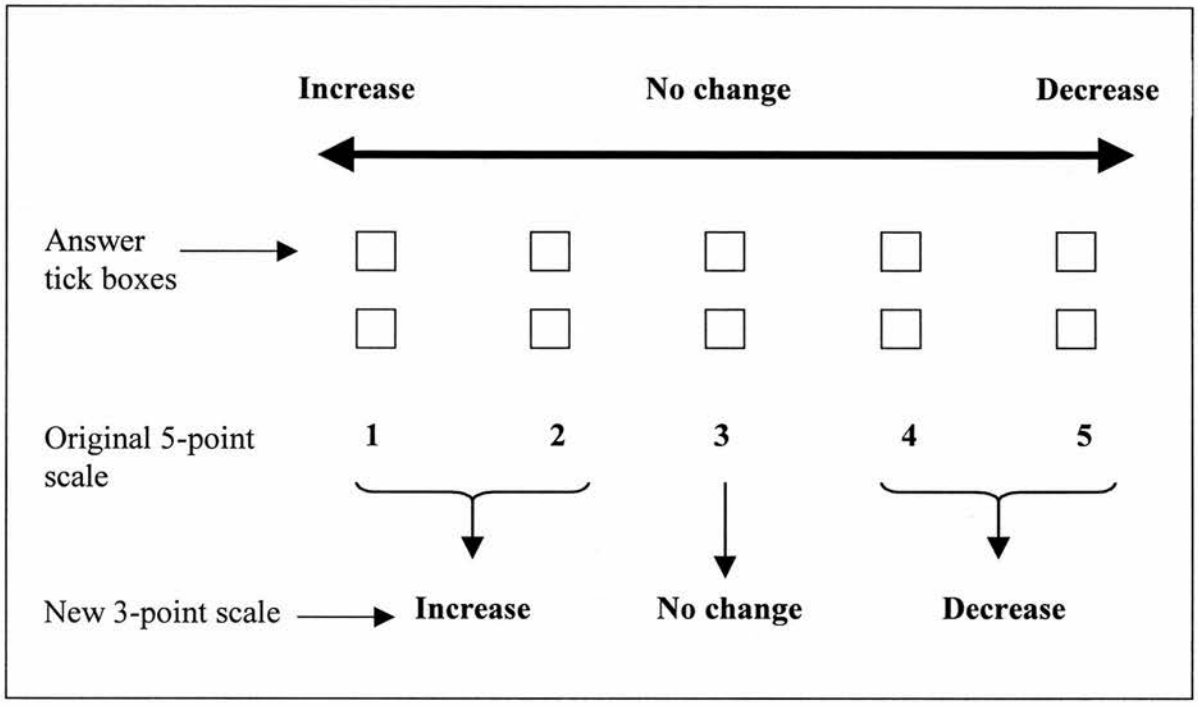
Outcome measure:	Effects of introducing the ICP in the stroke unit		
	Before-and-after study: SU-after-ICP vs SU-before-ICP	**Prospective comparative study: SU-after-ICP vs GMW**	**7-month survey: Majority opinion of 21 members of SU staff**
Speed of obtaining routine CT scans	↑	↑ NS	↑
Length of stay in hospital	↔	↑	↔
Use of iv fluids	↔	↑ NS	↑
Use of antipyretic when fever	↔	↔	↑
Use of urinary catheter	↓ NS	↓	↔ or ↓
Use of nasogastric feeding	↔	↔	↑
Treatment with early mobilisation*	↑	↑	↔ or ↑
Risk of complications†	↓	↓ NS	↔
Overall chance of recovery‡	↔	↔	↔ or ↑

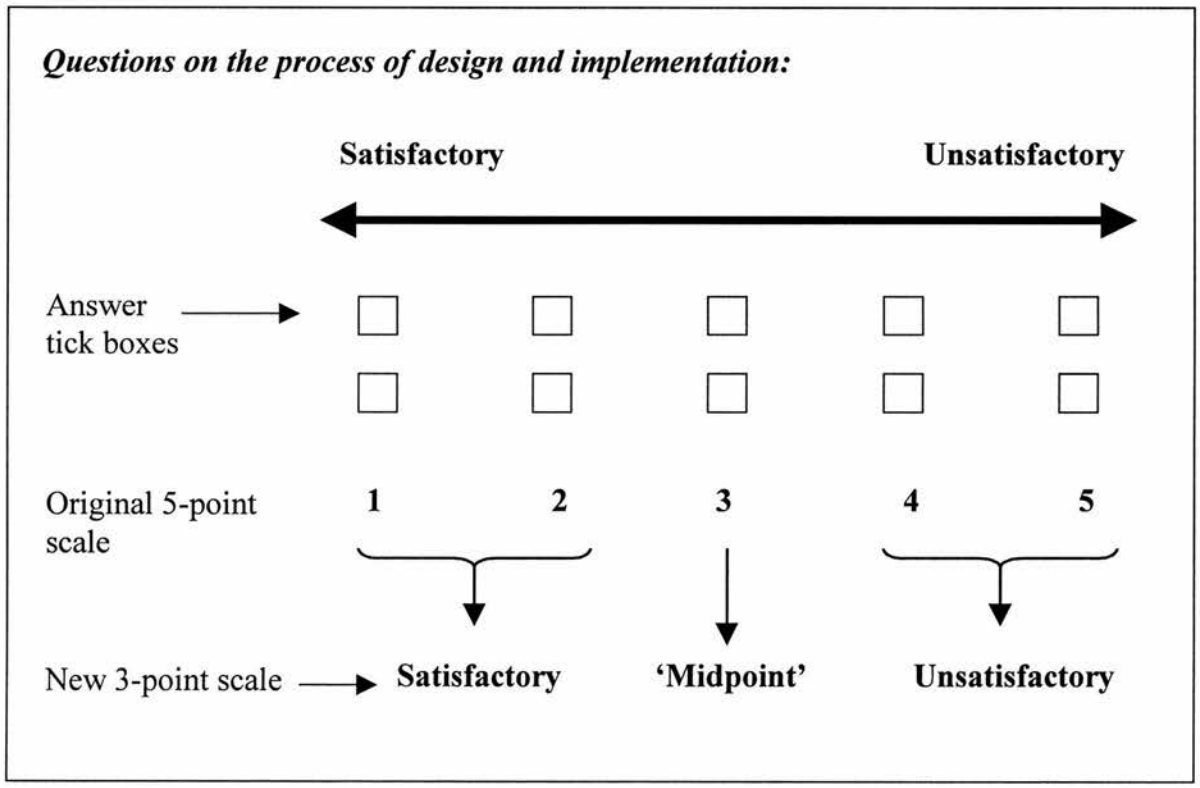
* Physiotherapy only

† Chance of suffering from a urinary tract infection – as an example

‡ Chance of being alive in hospital – as an example

Figure 7.1 Transformation of the five-point scales to three-point scales. Please refer to **Appendix 6** for the layout and wording of the questions.





References for Chapter 7

Bryson A, Browning JD. (1999) *Clinical Audit and quality using integrated pathways of care.* Scottish Executive Health Department.

Campbell M, Fitzpatrick R, Haines A et al. (2000) Framework for design and evaluation of complex interventions to improve health. *The BMJ.* 321(7262):694-696.

Hill A, Roberts J, Ewings P et al. (1997) Non-response bias in a lifestyle survey. *J Public Health Med.* 19(2):203-207.

Hovland EJ, Romberg E, Moreland EF. (1980) Nonresponse bias to mail survey questionnaires within a professional population. *J Dent Educ.* 44(5):270-274.

Huber GP, Power DJ. (1985) Retrospective reports of strategic-level managers: guidelines for increasing their accuracy. *Strategic Manag J.* 6:171-180.

Hughes LC, Preski S. (1997) Using key informant methods in organizational survey research: assessing for informant bias. *Res Nurs Health.* 20(1):81-92.

Rogers SM, Miller HG, Turner CF. (1998) Effects of interview mode on bias in survey measurements of drug use: do respondent characteristics make a difference? *Subst Use Misuse.* 33(10):2179-2200.

Salazar MK. (1990) Interviewer bias. How it affects survey research. *AAOHN J.* 38(12):567-572.

CHAPTER EIGHT

CONCLUSION

1. **Should integrated care pathways be used to manage patients with acute stroke?**
2. **How should the effects of integrated care pathways for acute stroke be evaluated?**
3. **Final remark**

8.1 Should integrated care pathways be used to manage patients with acute stroke?

Evidence from previous studies suggests that hospital management with a stroke ICP may be associated with both beneficial and harmful effects (see **Chapter 4**). Positive effects may include: fewer urinary tract infections; fewer readmissions to hospital; and more patients receiving CT brain scans. Harmful effects may include lower patient satisfaction and quality of life. There is no evidence so far to suggest that ICP care is associated with significant benefit or harm on functional outcome such as death, dependency or discharge destination.

At the WGH, the before-and-after study of 351 patients showed that the introduction of the ICP in the stroke unit was associated with significant benefit on the quality of documentation and several aspects of patient care (see **Chapter 5**). These benefits included: more thorough immediate management of acute stroke (blood glucose and oxygen saturation measurements, and information provision); more patients receiving CT brain scans and physiotherapy; and fewer urinary tract infections. I found no evidence of significant benefit or harm on death or discharge destination.

Also at the WGH, the prospective comparative study of 285 patients showed that, compared with the general medical wards, the introduction of the ICP in the stroke unit was associated with significant benefit on the quality of documentation and several – but slightly different – aspects of patient care (see **Chapter 6**). These benefit included: more thorough immediate management of acute stroke (oxygen

saturation measurements, ECGs, continuation of antihypertensive medication, and information provision); more patients receiving speech therapy; fewer urinary catheterisations, and a lower risk of developing fever. However, there may also be potentially harmful effects such as a lower usage of TED stockings (although the evidence for this is weak) and longer duration of stay in the WGH. Similarly, I found no evidence of significant benefit or harm on functional outcome including death, dependency or discharge destination.

When the nurses and therapists in the stroke unit were surveyed, many of them had high expectations for the ICP and hoped that it would improve the process of care, communication and their general working environment. But after having used the ICP for seven months, many of these expectations (except for process of care) had not been realised (see **Chapter 7**).

Therefore, there is accumulating evidence from these three approaches to suggest that the introduction of an ICP in a stroke unit can lead to better patient care and documentation, even though there may be a small number of potential concerns. The evidence is also concordant in suggesting that ICP care, despite its ability to improve patient care, is unlikely to have an impact on functional outcome.

The introductory chapters have highlighted that an efficient and effective stroke service requires at least a comprehensive structure, a team of enthusiastic and well trained healthcare staff, and good organisation of care (see **Chapters 1 & 2**). From the evidence so far, ICPs certainly have the potential to improve the process of care,

especially during the acute phase of stroke where the process of assessment, investigation, diagnosis and emergency treatment is highly complex, and where speed is an essence if acute treatments such as thrombolysis is to be considered.

But there is a paradox. The design and implementation of an ICP is probably best undertaken where the structure of the stroke service is already in place; for example, where acute stroke patients are routinely admitted to the stroke unit where their management is provided by a dedicated multidisciplinary team (see **Chapter 4**). However, in an already well-structured service, and especially where the patient care is well-coordinated, the ICP is less likely to provide significant additional benefit.

In my opinion, therefore, the beneficial effects of an ICP may be most apparent in hospitals where the basic structure of the stroke service is in place but the patient care is poorly organised. In many hospitals in the UK, this scenario is more applicable to their acute stroke care than stroke rehabilitation. It has to be born in mind, however, that the design and implementation of an ICP necessitates a considerable amount of time, resources and dedication.

I conclude by making the following recommendations:

1. **ICP highly recommended:** in an acute stroke unit where the service structure is in place but organisation is poor.
2. **ICP recommended:** in an acute stroke unit where the service structure is in place and patient care is well organised.
3. **ICP not recommended:** in a stroke rehabilitation unit or general medical ward.

8.2 How should the effects of integrated care pathways for acute stroke be evaluated?

The methodological considerations when evaluating the effects of ICPs have been examined in **Chapter 2**. The limitations of the research designs used to evaluate the ICP for acute stroke in the WGH have also been discussed in detail in **Chapters 5, 6 & 7**. It is clear that there is no ideal research design that will overcome the many problems of bias and confounding. But if future studies are to be carried out, how should they be performed?

Here is a brief outline of one research design that could be used to evaluate the effects of ICPs for acute stroke. This could be a UK-based multicentre before-and-after study involving stroke units that have never used ICPs to manage patients with acute stroke. Data would be collected prospectively, ideally using well-structured methods of data collection and analysis – e.g. the national sentinel audit. Outcome measures should be simple, few, and easy to collect. Each stroke unit would start collecting data before the introduction of an ICP (there may already be several sets of data from the previous rounds of national sentinel audit). The intervention to be introduced should be a very simple ICP for acute stroke, which contains only the core elements that are based on the best-available evidence and national clinical guidelines (e.g. SIGN and RCP guidelines). Each centre is then encouraged to modify the ICP according to local circumstances and policies in order to give them 'ownership', but the original core ICP should not be altered. Each centre would then continue to collect data using the standard data set and collaborative data analysis

would be performed by a third party at the end. Comparison between centres may also be performed under the auspices of the British Association of Stroke Physicians (e.g. the Benchmarking Survey).

As I discussed in **Chapter 2**, the methodology of such a study can be further strengthened by employing a control group before and after the introduction of the ICPs in the intervention group. This control group could consist of a number of hospitals which are similar to the intervention group but without the introduction of the ICPs.

There are several methodological difficulties associated with this type of study. Firstly, it is likely to require many centres that have never introduced an ICP – many hospitals in the UK are already using (or planning to use) ICPs to manage patients with acute stroke. Secondly, it would probably have to last a long time in order to recruit a large enough sample – probably in terms of thousands of patients; this would invariably require a substantial amount of resources and a large team of researchers. Finally, one has to question whether such a study is really necessary – most hospitals are happy to implement a relatively harmless intervention which has many potential benefits.

8.3 Final remark

In this thesis, I used multiple approaches to evaluate the effects of ICPs for acute stroke. These approaches have provided evidence that ICPs may be useful in improving the process of care and quality of documentation, but not functional outcome. However, more information is needed on the impact of ICPs on other important outcomes such as quality of life, patient and carer satisfaction, and the cost of their usage. Qualitative research may also provide additional information on the best method of design, implementation and evaluation of ICPs.

APPENDICES

A1. The integrated care pathway for acute stroke at the WGH

Name:	Cons: **MSD**☐ **RIL**☐ **Other** ☐
Address:	**Other Cons:** *specify*
	Date Admitted to Pathway *(if different to Date of Adm.)*: / /

DOB: / /	**Already I/P?** YES☐, NO☐	Initial Ward number:
Age:		Second Ward number:

Medical Clerking /Admission: Presenting Complaint

History of Presenting Complaint

Symptom onset: Date: / / Time: :

CPR status:

Appropriate for Resuscitation?

YES☐, NO☐

Name (Print .....

& sign): .....

Designation: .....

Date: / /

d.w. Relatives? YES☐, NO☐

Relation to pt:

CHANGE :

Appropriate for Resuscitation?

YES☐, NO☐

Name (Print .....

& sign): .....

Designation: .....

Date: / /

d.w. Relatives? YES☐, NO☐

Relation to pt:

CHANGE :

Appropriate for Resuscitation?

YES☐, NO☐

Name (Print .....

& sign): .....

Designation: .....

Date: / /

d.w. Relatives? YES☐, NO☐

Relation to pt:

Previous Investigations/ Procedures/Operations	Yes	No	If yes, give details	*addressograph*
Carotid endarterectomy/ Angioplasty etc	☐	☐		

Vascular History	Yes	No	If yes, give details
TIAs	☐	☐	
Stroke(s)	☐	☐	
Previous MI(s)	☐	☐	
Angina/Unstable angina	☐	☐	
Arrhythmia (eg AF)	☐	☐	
Heart failure	☐	☐	
Valve disease	☐	☐	
Cardiac surgery	☐	☐	
Peripheral vascular disease	☐	☐	
Diabetes	☐	☐	IDDM ☐ NIDDM ☐
Hypertension	☐	☐	
Migraine with aura	☐	☐	
Epileptic seizures	☐	☐	

Lifestyle	Yes	No	Complete details if requested
Current Smoker (or, Never ☐)	☐	☐	If No,Ex-smoker ☐: ___ cigs/day, for __yrs, Date gave up smoking: ___/___/___ If Yes, ____cigs/day for ___yrs: Type of tobacco: cigs ☐ pipe ☐ cigars ☐
Hypercholesterolaemia	☐	☐	(>5.0mmols/l) Last chol. Result: date:
Family history of IHD or stroke	☐	☐	F< 60 ☐, M<55 ☐
Any Alcohol Intake	☐	☐	Current _____ Units/week, Tick if previous higher intake ☐ (*1 unit = 1 measure spirits/half pint beer/ lager/1 glass wine)
Any other recreational drugs?	☐	☐	

Other Past Medical History / Family History

Drugs on Admission	Dose	Freq.	Drugs on Admission	Dose	Freq.
Source: patient☐ letter☐ GP ☐					

DRUG SENSITIVITIES:

Reviewed by pharmacist ☐ **Pharmacist Signature:**

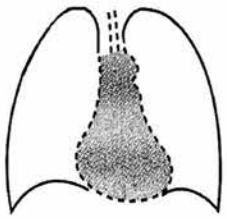
Systems Enquiry	
RESPIRATORY	GASTRO-INTESTINAL
GENITO-URINARY	NEURO-LOCOMOTOR
PSYCHIATRIC	

Physical Examination		Specify Details
General: Jaundice ☐ Pallor ☐ Clubbing ☐ Cyanosis ☐ Corneal arcus ☐ Xanthelasma ☐ ↓Skin turgor ☐ Splinter haemorrhages ☐		
BP: L☐ R☐	/	
Heart rate:	bpm	
Rhythm:	Sinus ☐ Other ☐	
Pulse Volume:	Normal ☐ Reduced☐	
JVP:	cm	
Heart sounds: Normal ☐ Abnormal ☐	Murmur: Yes ☐ No ☐	
Carotid bruits: R. L.	Yes, ☐ No ☐ Yes, ☐ No ☐	
Peripheries: pulses temperature oedema	Norm ☐ Abn ☐ Warm ☐ Cool ☐ Yes ☐ No ☐	

Chest:

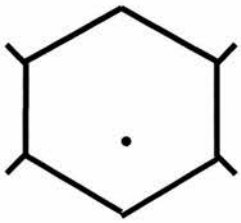
Resp. Rate: /min

Normal pattern? Y/N



R. **L .**

Abdomen:



Locomotion:

Neurological Assessment

Right handed ☐ Left handed ☐ Both ☐ Not known ☐

Glasgow Coma Scale (Ring level for each domain)

Eye opening	- Never	1
	- To pain	2
	- To sound	3
	- Spontaneously	4
Best motor	- None	1
	- Extend to pain	2
	- Abn flex to pain	3
	- Flex to pain	4
	- Localises pain	5
	- Normal	6
Best verbal	- None	1
	- Noises only	2
	- Inappropriate	3
	- Confused	4
	- Normal	5

GCS TOTAL ☐

Visuospatial

(eg neglect, sensory or visual inattention)

Is there evidence of visuospatial dysfunction?
No ☐ Left ☐ Right ☐ Unassessable ☐

Is the patient aware of their neurological deficit?
Yes ☐ No ☐

Draw a clock face **Copy this picture** **Patient**

Mental Test Score (Hodkinson)

(tick correct answers)

Age ☐
Time (nearest hour) ☐
42 West Street (ask patient to recall at end) ☐
Name of Hospital ☐
Year ☐
Recognise two people (eg.Dr & Nurse) ☐
Date of Birth ☐
Dates of World War II ☐
Present Monarch ☐
Count down 20 → 1 ☐
Unable ☐

Total = ☐

(NB: If unable to complete give reason)

Communication

(written if not verbal)

Can the patient communicate normally?

[YES] [NO]

If NO:
Dysphasia? [ ]
Dysarthria? [ ]
Other [ ]
None [ ]

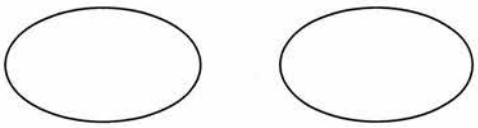
Cranial Nerves:

	R	L
I		
II (Pupils/Acuity)		
Horner's?		
Fundi		
III/IV/VI (Eye movement)		
I		
V II		
III		
VII (Facial)		
VIII (Hearing)		
IX/X (Palate)		
XI (Sternomastoids)		
XII (Tongue)		

Are the visual fields normal?

Yes ☐ No ☐ Unassessable ☐

R eye/fundi L eye/fundi



Nurses should screen for swallowing problem – ask them for the result, so you can write up drugs and fluids appropriately

Limbs:

Grade Power (MRC) ⁄ 5 Grade tone: N/↑/↓

	R	L		R	L
Arms			**Legs**		
Tone			Tone		
Drift					
Fine finger movement					
Power			**Power**		
Shoulder			Hip		
Elbow			Knee		
Wrist			Ankle		
Hand			Co-ordination (Heel/Shin)		
Co-ordination (Finger/Nose)					

Reflexes

	R	L
Jaw jerk	[___]	[___]
Triceps (C7, 8)	[___]	[___]
Biceps (C5, 6)	[___]	[___]
Sup (C5, 6)	[___]	[___]
KJ (L3, 4)	[___]	[___]
AJ (S1, 2)	[___]	[___]
Plantar	[___]	[___]

Grade reflexes

0 = absent
+ = with potentiation
++ = normal
+++ = increased
C = with clonus

Truncal control/gait

		Yes	No
Can patient:	1. Sit?	[___]	[___]
	2. Stand?	[___]	[___]
	3. Walk?	[___]	[___]

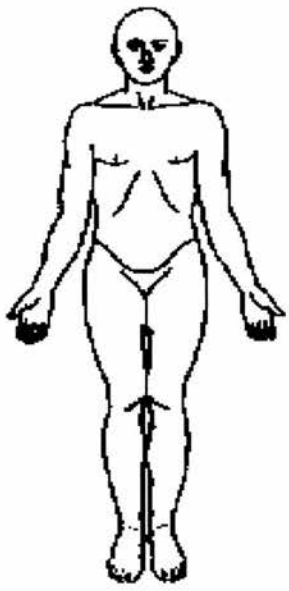
Details:

Sensory Testing

(As a minimum test, PINPRICK or LIGHT TOUCH and JOINT POSITION SENSE. Look for sensory inattention) If not possible to test, give a reason.

Is there any sensory loss?
Yes [__] No [__] Unassessable [__]
(If YES shade affected area on picture →)

Is there sensory inattention?
Yes [__] No [__] Unassessable [__]



Joint Position Sense	**R**	**L**
Fingers		
Toes		

Diagnostic formulation

Summary of neurological deficits

Where is the brain lesion?

Diagnosis		**Location**		**Classification of Stroke/TIA**	
TIA	[_]	L Hemisp/eye	[_]	Total anterior circulation syndrome	[_]
Stroke/brain attack	[_]	R Hemisp/eye	[_]	Partial anterior circulation syndrome	[_]
Amaurosis fugax	[_]	Brainstem	[_]	Lacunar circulation syndrome	[_]
Retinal artery occlusion	[_]	Uncertain	[_]	Posterior circulation syndrome	[_]
Uncertain	[_]			Uncertain	[_]
Other	[_]	Specify:			

Likely causes of cerebrovascular event (eg risk factors)

Prognostic Factors

	Yes	No
Was the patient independent in ADL before stroke?	[ ]	[ ]
Did the patient live alone?	[ ]	[ ]
Can they talk?	[ ]	[ ]
Are they orientated in time, place, person?	[ ]	[ ]
Can they lift both arms off the bed?	[ ]	[ ]
Can they walk without help?	[ ]	[ ]

Investigations: (bold indicates for all patients)

Results should be written on results sheet of ICP

	Requested	Imaging	
FBC	[ ]	**CT**	[ ]
ESR	[ ]	MRI	[ ]
U&Es	[ ]	Duplex	[ ]
LFT's	[ ]	Echocardiogram	[ ]
γGT	[ ]		[ ]
LIPIDS	[ ]		[ ]
TFT's	[ ]		
Glucose	[ ]		
ECG	[ ]		
CXR	[ ]	SOU	[ ]
Urinalysis	[ ]	MSU	[ ]
Syphilis Serology	[ ]	CSU	[ ]
Lupus screen	[ ]	Sputum	[ ]
Thrombophilia screen	[ ]	Stool	[ ]
Auto immune screen	[ ]	Others:	[ ]
	[ ]		[ ]
	[ ]		[ ]
	[ ]		[ ]
	[ ]		[ ]

CT	Date	Echo Result	Date
MR:	Date	Doppler	Date
ECG	Date	CXR	Date
	Date		Date

Immediate Management Plan

	Yes	No			Done	N/A
Cause of stroke uncertain?	[ ]	[ ]	**If yes**	Further investigations organised	[ ]	[ ]
Can patient take adequate fluid orally?	[ ]	[ ]	**If no**	Insert Venflon Prescribe IV fluids (check U&Es at least 2x/week) Consider for FOOD trial – Early NG vs Delay	[ ]	[ ]
					Yes	**No**
Able to take oral medication?	[ ]	[ ]	**If no**	Is it needed?	[ ]	[ ]
			If yes	Alternative route organised	[ ]	[ ]
					Done	**N/A**
Haemorrhage excluded?	[ ]	[ ]	**If yes**	Aspirin 300 mg stat, 75 mg daily (Give by rectal suppository if unable to swallow)	[ ]	[ ]
Haemorrhage on CT?	[ ]	[ ]	**If yes**	Stop any antithrombotic drugs unless prosthetic heart valve	[ ]	[ ]
				Reverse anticoagulation in consultation with haematologist	[ ]	[ ]
Is patient mobile?	[ ]	[ ]	**If no**	Avoid heparin unless previous DVT/PE or other strong indication	[ ]	[ ]
				Consider for Stockings Trial (CLOTS)	[ ]	[ ]
Is O_2 sat <95% on air?	[ ]	[ ]	**If yes**	Prescribe supplemented O_2 with %	[ ]	[ ]
Has the patient a fever? (at any time in 1st 5 days)	[ ]	[ ]	**If yes**	Prescribe regular paracetamol & fan	[ ]	[ ]
				infection screen (think about endocarditis)	[ ]	[ ]
				Give broad spectrum antibiotics if sick	[ ]	[ ]
Is the blood sugar >11 mmol/l)?	[ ]	[ ]	**If yes**	Start GKI infusion with hourly BMs	[ ]	[ ]
Is BP elevated (>160/90)?	[ ]	[ ]	**If yes**	Leave alone unless signs of accelerated phase hypertension	[ ]	[ ]
				Give normal antihypertensive treatment if can swallow and SBP > 120mmHg.	[ ]	[ ]
Have you explained diagnosis, investigations and treatment with patient or relatives?	[ ]	[ ]	**If no**	Do so and document on communication sheet	[ ]	[ ]

If N/A explain on variance sheet

Doctor's Name:

Signature:

Review of Management Plan – Admission +1 or 2 **Date / /**

	Yes	No			Done	N/A
Cause of stroke uncertain?	[ ]	[ ]	**If yes**	Further investigations organised	[ ]	[ ]
Can patient take adequate fluid orally?	[ ]	[ ]	**If no**	Insert Venflon Prescribe IV fluids (check U&Es at least 2x/week) Consider for FOOD trial – Early NG vs Delay	[ ]	[ ]
					Yes	**No**
Able to take oral medication?	[ ]	[ ]	**If no**	Is it needed?	[ ]	[ ]
			If yes	Alternative route organised	[ ]	[ ]
					Done	**N/A**
Haemorrhage excluded?	[ ]	[ ]	**If yes**	Aspirin 300 mg stat, 75 mg daily (Give by rectal suppository if unable to swallow)	[ ]	[ ]
Haemorrhage on CT?	[ ]	[ ]	**If yes**	Stop any antithrombotic drugs unless prosthetic heart valve	[ ]	[ ]
				Reverse anticoagulation in consultation with haematologist	[ ]	[ ]
Is O_2 sat <95% on air?	[ ]	[ ]	**If yes**	Prescribe supplemented O_2 with %	[ ]	[ ]
Has the patient a fever? (at any time in 1st 5 days)	[ ]	[ ]	**If yes**	Prescribe regular paracetamol & fan	[ ]	[ ]
				infection screen (think about endocarditis)	[ ]	[ ]
				Give broad spectrum antibiotics if sick	[ ]	[ ]
Is the blood sugar >11 mmol/l)?	[ ]	[ ]	**If yes**	Start GKI infusion with hourly BMs	[ ]	[ ]
Is BP elevated (>160/90)?	[ ]	[ ]	**If yes**	Leave alone unless signs of accelerated phase hypertension	[ ]	[ ]
				Give normal antihypertensive treatment if can swallow and SBP > 120mmHg.	[ ]	[ ]
Have you explained diagnosis, investigations and treatment with patient or relatives?	[ ]	[ ]	**If no**	Do so and document on communication sheet	[ ]	[ ]

If N/A explain on variance sheet

Doctor's Name:

Signature:

Date	Other problems	Active +/-	Actions	Signature

Addressograph

RECORD OF LABORATORY INVESTIGATIONS										
Date	/	/	/	/	/	/	/	/	/	/
Initials										
Na										
K										
U										
Creat.										
Glucose										
Chol										
Bili										
ALT										
Alk phos										
GGT										
Alb										
Ca										
CK										
CK-MB										
Hb										
MCV										
WBC										
Plat.										
ESR										
PTT										
INR										
H+										
PO_2										
PCO_2										
$StHCO_3$										
URINE										
Dipstick										
MSU										
SOU										
CSU										
Sputum										
Stool										

Date: / / Time: **NURSING ENQUIRY** **Ward:**

Patient name(label or complete)

Hospital number

DOB:

Age:

Religion

Preferred name:

Patient tel number:

Marital status

Single	[ ]	Separated	[ ]
Married/with partner	[ ]		
Divorced	[ ]	Widowed	[ ]

Social circumstances

Siblings	Yes[ ]	No[ ]
Dependants	Yes[ ]	No[ ]

Patient's occupation

Partner's occupation

Driver Yes[ ] No[ ]

Home Circumstances	Yes	No
Lives alone	[ ]	[ ]
District nurse (specify days per week)	[ ]	[ ]
Home help (specify days per week)	[ ]	[ ]
Nursing home	[ ]	[ ]
Residential care	[ ]	[ ]
Other services		

Contact 1 – next of kin

Name:
Address:
Tel:
Relationship:

Contact 2

Name:
Address:
Tel:
Relationship:

Type of admission – tick one only

999 [ ]
GP [ ]
Transfer from other hospital [ ]
Details:

Observations on admission

(if deteriorated from ARU or outwith range, inform doctor)

Is the: -	Yes	No
Temperature - >37.5°C	[ ]	[ ]
Pulse - <50 >100	[ ]	[ ]
Systolic BP - <100 - >200mmHg	[ ]	[ ]
O_2 saturation - <92%	[ ]	[ ]
Respiratory rate - >20 <5	[ ]	[ ]
Glasgow Coma Score (see front sheet)	[ ]	[ ]
Deterioration of >1 point from ARU (inform doctor)	[ ]	
If abnormal, Doctor informed	[ ]	[ ]
Admission Barthel score	[ ]	

Medication	Yes	No
With patient	[ ]	[ ]
Stored in drugs trolley/med cupboard	[ ]	[ ]
Taken home	[ ]	[ ]
Dosette box used	[ ]	[ ]

If a problem, specify:

Refer pharmacist: Yes [ ] No [ ]

Personal belongings	Yes	No
Clothing listed	[ ]	[ ]
Clothing taken home	[ ]	[ ]

Valuables (state location)

Information given

Relatives spoken to	Yes[ ]	No[ ]
Documented on Communication chart	Yes[ ]	No[ ]
Identification band attached	Yes[ ]	No[ ]
Nurse call system explained	Yes[ ]	No[ ]
Information booklet given	Yes[ ]	No[ ]

Named nurse:

Signature: Designation:

Print name: Initials:

NUTRITION

Please circle relevant score. Only select <u>ONE</u> score from each section.
Select the highest score that applies

	SCORE
AGE	
<65	1
65-74	2
78-84	3
>85	4
WEIGHT	
Weight steady, intentional weight loss or weight gain	1
Gradual unexpected weight loss over past 6 months	2
Weight loss over past 4-6 weeks greater than 3.5Kg	3
Rapid weight loss and/or extremely thin and emaciated	4
APPETITE	
Appetite good, able to finish most meals	1
Appetite poor eats only small meals or snacks/requires soft diet	2
Appetite poor manages only fluids or on free fluids	3
Appetite nil or virtually nil/unable to take anything orally has been NBM for <4 meals	4
ABILITY TO EAT OR RETAIN FOOD	
No difficulty eating, able to eat independently	1
Problems handling food, eg needs special cutlery. Frequent regurgitation (or possetting)	2
Problems affecting food intake eg chewing, difficulty swallowing, requires modified consistency, loose dentures, needs special help with feeding (eg physical handicap)	3
Unable to take food orally. Unable to swallow (complete dysphagia)	4
Unable to retain food eg vomiting or diarrhoea	5
MENTAL STATUS	
Alert, Orientated, Co-operative	1
Apathetic, mildly confused	2
Confused, unco-operative, depressed	3
Comatose, unconscious	4

TOTAL SCORE ☐

To include scoring levels for comparison:
5-10 Minimal Risk
11-14 Moderate Risk
15-20 High Risk

Date: / / Time:	NURSING ENQUIRY		Ward:		
Pre admission			**On admission**		
BREATHING					
Domiciliary oxygen	Yes[__]	No[__]	Airway maintained	Yes[__]	No[__]
- nebuliser	Yes[__]	No[__]	Suction required	Yes[__]	No[__]
Poor exercise tolerance	Yes[__]	No[__]	Oxygen required	Yes[__]	No[__]
If yes, specify			If yes – prescribed	Yes[__]	No[__]
			If ≥35% humidify	Yes[__]	No[__]
EYE CARE					
Blind	Yes[__]	No[__]	Spectacles with patient	Yes[__]	No[__]
Partially sighted	Yes[__]	No[__]	If yes, spectacles listed	Yes[__]	No[__]
Wears spectacles/contacts	Yes[__]	No[__]	and marked	Yes[__]	No[__]
- for reading	Yes[__]	No[__]	Specify eye care requirements:		
- for distance	Yes[__]	No[__]			
Wears artificial eye	Yes[__]	No[__]			
ORAL CARE					
Own teeth	Yes[__]	No[__]	Mouth care required	Yes[__]	No[__]
Dentures	Yes[__]	No[__]	Detail specific care		
Specify type:			Frequency		
Regime for cleaning teeth:			If dentures – marked?	Yes[__]	No[__]
			Referred to dentist	Yes[__]	No[__]
			Specify care of dentures		
NUTRITION					
Weight (patient's reported)			Weight (patient's actual)		
Height			Height		
Existing therapeutic diet	Yes[__]	No[__]	If Nutritional Score >15,		
If yes, specify			referred to dietitian?	Yes[__]	No[__]
Appetite:	Poor[_]	Good[_]	Dysphagia screen completed		
Food allergy or intolerance	Yes[__]	No[__]	(see sheet)	Yes[__]	No[__]
Particular foods avoided:	Yes[__]	No[__]	If failed – put NBM		
If yes, specify			- refer to SLT	Yes[__]	No[__]
			- parenteral fluids organised	Yes[__]	No[__]
			- alternative route for oral		
			medication organised	Yes[__]	No[__]
			If passed – needs supervision?	Yes[__]	No[__]
			Fluid balance chart started	Yes[__]	No[__]
SLEEPING					
Sleeps well	Yes[__]	No[__]	Restless	Yes[__]	No[__]
Takes sleeping tablet	Yes[__]	No[__]	Settled	Yes[__]	No[__]
If yes, specify			Sleeping tablet prescribed	Yes[__]	No[__]
Other aid (specify)					
Signature:			Designation:		
Print Name:			Initials:		

DYSPHAGIA SCREENING TEST – ACUTE NEUROLOGICAL PATIENTS

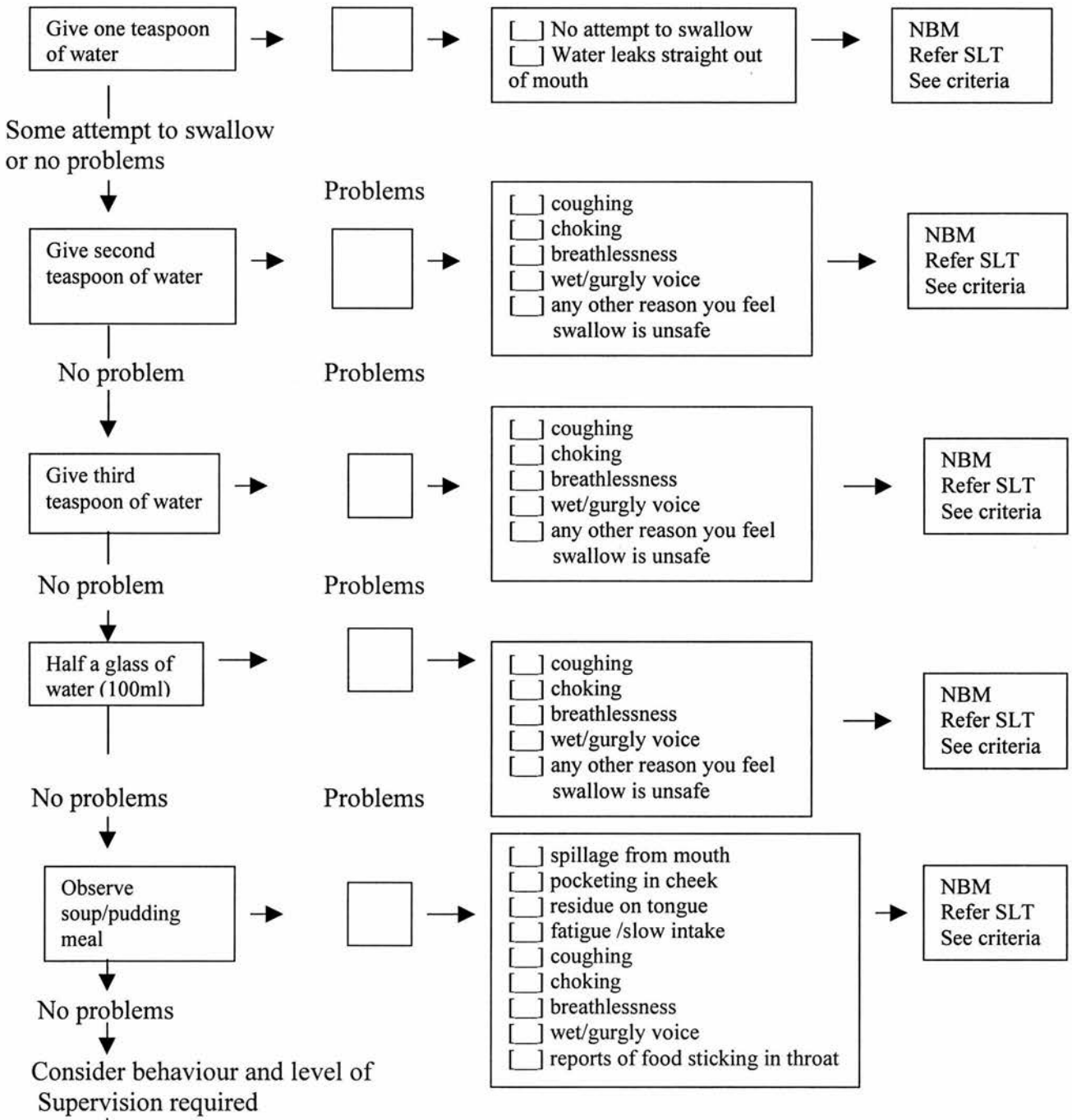
Name: Ward:
Date: Assessor:

Before you start:	Is the patient fully conscious, alert & aware?	Yes[__]No[__]
	Able to produce normal voice and a voluntary cough	Yes[__]No[__]
	Swallow saliva spontaneously	Yes[__]No[__]

If no, see criteria for dysphagia referral

Prepare patient: sit patient up at 90 degrees, supported by pillows if necessary. Ensure neck is not extended

Procedure



Comments:
Signed: Date:

Date: / / Time:	NURSING ENQUIRY	Ward:
Pre admission		**On admission**

MOBILITY

Independent	Yes[ ]	No[ ]	Bed bound	Yes[ ]	No[ ]
Transfers with	1 [ ]	2 [ ]	Mobile	Yes[ ]	No[ ]
Walks with	1 [ ]	2 [ ]	Transfers with 1 [ ]	2 [ ]	Hoist[ ]
Manages stairs	Yes[ ]	No[ ]	Sling colour		
Housebound	Yes[ ]	No[ ]	Walks with	1 [ ]	2 [ ]
Risk of injury	Yes[ ]	No[ ]	Independent	Yes[ ]	No[ ]
If yes, specify			Specific seating required	Yes[ ]	No[ ]
Wears appliance/prosthesis	Yes[ ]	No[ ]	If yes, specify		
If yes, specify			Risk of injury	Yes[ ]	No[ ]
Uses walking stick	Yes[ ]	No[ ]	If yes, specify action		
Uses mobulator	Yes[ ]	No[ ]			
Rec physio before admission	Yes[ ]	No[ ]	Referred to physiotherapist	Yes[ ]	No[ ]

SKIN

Skin intact	Yes[ ]	No[ ]	Waterlow score (see over)	Done[ ]	Not done[ ]
			Skin intact	Yes[ ]	No[ ]
If no, specify treatment			Pressure sore	Yes[ ]	No[ ]
			- Grade:		
Pre-existing skin problem	Yes[ ]	No[ ]	- Size:		
			- Site		
Specify			Specific care plan		

WASHING AND DRESSING

Independent	Yes[ ]	No[ ]	Fully independent	Yes[ ]	No[ ]
Requires assistance	Yes[ ]	No[ ]	Bed bath	Yes[ ]	No[ ]
If yes, specify			Washes top half	Yes[ ]	No[ ]
Totally dependent	Yes[ ]	No[ ]	Washes bottom half	Yes[ ]	No[ ]
Likes bath	Yes[ ]	No[ ]	Dresses top half	Yes[ ]	No[ ]
shower	Yes[ ]	No[ ]	Dresses bottom half	Yes[ ]	No[ ]
Frequency: Daily[ ]	Weekly[ ]	Other[ ]	Requires maximum assistance	Yes[ ]	No[ ]
Aids used	Yes[ ]	No[ ]	- minimum assistance	Yes[ ]	No[ ]
If yes, specify			Referred to OT	Yes[ ]	No[ ]

ELIMINATION

Continent (urine)	Yes[ ]	No[ ]	Continent	Yes[ ]	No[ ]
If no, specify nature of problem/aid used:			Incontinent of urine	Yes[ ]	No[ ]
			Incontinent of faeces	Yes[ ]	No[ ]
Diarrhoea	Yes[ ]	No[ ]	Toileting regime	Yes[ ]	No[ ]
Constipation	Yes[ ]	No[ ]	If yes, specify		
Faecal incontinence	Yes[ ]	No[ ]	Wearing pad and pants	Yes[ ]	No[ ]
Stoma	Yes[ ]	No[ ]	If yes, specify colour		
Aperients used	Yes[ ]	No[ ]	Catheterised	Yes[ ]	No[ ]
If yes, specify			If yes, why		
Other:			- size: - amount of water in balloon:		
			Foley/Silastic		
			Catheter care		
			Urosheath – size		
			Admission specimen of urine obtained	Yes[ ]	No[ ]
			If yes, results		

Signature:	Designation:
Print name:	Initials:

WATERLOW PRESSURE SORE PREVENTION/ TREATMENT POLICY

Ring scores in table, add total – several score per category can be used

Build/weight for height		**Skin type/visual risk areas**		**Sex/age**		**Mobility**	
Average	0	Healthy	0	Male	1	Fully	0
Above average	1	Tissue paper	1	Female	2	Restless/fidget	1
Obese	2	Dry	1	14-49	1	Apathetic	2
Below average	3	Oedematous	1	50-64	2	Restricted	3
		Clammy (temp)	1	65-74	3	Inert/traction	4
		Discoloured	2	75-80	4	Chairbound	5
		Broken spot	3	81+	5		

Continence				**Appetite**			
Complete/ Catheterised	0	Catheter/ Incontinent of faeces	2	Average	0	NBM/anorexic	3
Occasionally Incontinent	1	Doubly incontinent	3	Poor	1		
				NG tube/ Fluids only	2		

Special risks							
Tissue malnutrition eg terminal cachexia	8	Neurological eg diabetes, MS, CVA motor/sensory paraplegia	4 to 6	Major surgery trauma orthopaedic below waist/spinal on table >2 hours	5	Medication cytotoxics high dose steroids anti-inflammatory	4
Cardiac failure	5						
Peripheral vascular Disease	5						
Anaemia	2						
Smoking	1						

Score	10+ AT RISK	15+ HIGH RISK	20+ VERY HIGH RISK

Signature

Designation:

Print Name

Initials:

Date: / /	Time:	ADMISSION +1	Ward:	Initials:

ASSESSMENT	Yes	No		ACTIONS	DONE	N/A	PRINT/SIGN
a Reviewed by medical staff?	[ ]	[ ]	**If yes**	Specify nursing action	[ ]	[ ]	
					[ ]	[ ]	
					[ ]	[ ]	
					[ ]	[ ]	_____
b Airway maintained?	[ ]	[ ]	**If no**	Put in recovery position	[ ]	[ ]	
				Airway inserted	[ ]	[ ]	
				Suction	[ ]	[ ]	
				Monitor oxygen saturations	[ ]	[ ]	
				Inform doctor if <95% on air	[ ]	[ ]	
				Administer oxygen as prescribed	[ ]	[ ]	_____
c Is temp>37.5?	[ ]	[ ]	**If yes**	Inform medical staff	[ ]	[ ]	
				Fan and give regular paracetamol	[ ]	[ ]	
				Obtain sputum	[ ]	[ ]	
				Obtain MSU	[ ]	[ ]	
				Monitor hourly initially	[ ]	[ ]	
				Record 6 hourly	[ ]	[ ]	_____
d Is systolic blood pressure <100 or >200?	[ ]	[ ]	**If yes**	Inform medical staff	[ ]	[ ]	
				Monitor hourly initially	[ ]	[ ]	
				Assess conscious level	[ ]	[ ]	
				Assess pain	[ ]	[ ]	
				Record 6 hourly	[ ]	[ ]	_____
e Has Glasgow Coma Scale fallen?	[ ]	[ ]	**If yes**	Inform medical staff	[ ]	[ ]	
				Record hourly	[ ]	[ ]	
				Record 2 hourly	[ ]	[ ]	
			If no	Record 6 hourly	[ ]	[ ]	_____
f Has dysphagia screen been passed since admission?	[ ]	[ ]	**If no**	Put nil by mouth	[ ]	[ ]	
				Refer to SLT/rpt in 24hrs if drowsy	[ ]	[ ]	
				Parenteral fluids organised	[ ]	[ ]	
				Alternative route for oral medication organised	[ ]	[ ]	
				Fluid balance chart started	[ ]	[ ]	
				If failed because of drowsiness repeat on day Admission +2. If not refer to SLT	[ ]	[ ]	
			If yes	Needs supervision	[ ]	[ ]	_____
g Has the patient a venflon?	[ ]	[ ]	**If yes**	Site checked?	[ ]	[ ]	_____
h Therapeutic diet required?	[ ]	[ ]	**If yes**	Refer to bedside swallowing regime	[ ]	[ ]	
				Specific instructions followed	[ ]	[ ]	
				Oral care given after meal	[ ]	[ ]	_____
i Able to wash independently?	[ ]	[ ]	**If no**	Bed bathed	[ ]	[ ]	
				Assistance given to shower/bath	[ ]	[ ]	_____
j Is patient able to communicate normally?	[ ]	[ ]	**If no**	Refer to Speech and Language Therapy	[ ]	[ ]	_____

ASSESSMENT	Yes	No		ACTIONS	DONE	N/A	PRINT/SIGN
k Able to dress independently?	[ ]	[ ]	**If no**	Assistance given to dress	[ ]	[ ]	
				Referred to OT	[ ]	[ ]	_____
l Waterlow Score>10?	[ ]	[ ]	**If yes**	Inspect skin and change position 2 hourly	[ ]	[ ]	
				Document at risk areas	[ ]	[ ]	
				Consider special mattress/cushion	[ ]	[ ]	_____
m Is patient independently mobile?	[ ]	[ ]	**If no**	Refer to physiotherapist	[ ]	[ ]	
				Specific techniques used for assisting with mobility and transferring identified	[ ]	[ ]	
				If sitting up, specific seating and pressure relieving cushion identified	[ ]	[ ]	
				If on bedrest, limbs positioned according to hemiplegia chart	[ ]	[ ]	
				Safety sides in place to prevent from falling	[ ]	[ ]	_____
n Continent of urine?	[ ]	[ ]	**If no**	Routine specimen tested	[ ]	[ ]	
				Midstream specimen obtained	[ ]	[ ]	
				Toilet 2 hourly	[ ]	[ ]	
				Assisted to use commode/urinals by bedside	[ ]	[ ]	
				Commence bladder record chart	[ ]	[ ]	
				Size for pads and pants and arrange according to manufacturers recommendations	[ ]	[ ]	
				If male appropriate size of urinary drainage sheath applied	[ ]	[ ]	
				Output recorded on fluid balance chart	[ ]	[ ]	
				If Waterlow >10, catheterise if skin at risk	[ ]	[ ]	
				Leg bag applied when sitting up	[ ]	[ ]	
				Overnight bag attached when on bedrest	[ ]	[ ]	_____
o Continent of faeces?	[ ]	[ ]	**If no**	Rectal check performed	[ ]	[ ]	
				Size for pads and pants and arrange according to manufacturers recommendations	[ ]	[ ]	
				Medical staff informed	[ ]	[ ]	
				Specimen obtained if diarrhoea	[ ]	[ ]	
			If yes	Record frequency of bowel movements	[ ]	[ ]	
				Give laxative according to symptomatic relief policy if bowels haven't moved within 3 days	[ ]	[ ]	_____
p Patient unable to sleep at night?	[ ]	[ ]	**If yes**	Assess for pain or discomfort	[ ]	[ ]	
				Give analgesia if required	[ ]	[ ]	
				Alter position in bed	[ ]	[ ]	
				Assess for other complications and document on interdisciplinary communication sheet	[ ]	[ ]	
				Assess need for sedative and consult with doctors	[ ]	[ ]	_____

Date: / /	Time:	ADMISSION +2	Ward:	Initials:

ASSESSMENT	Yes No		ACTIONS	Done N/A	PRINT/SIGN
a Patient is managing own airway?	[ ] [ ]	**If yes**	Remove airway	[ ] [ ]	
			Give suction when required	[ ] [ ]	
			Encourage to cough and expectorate	[ ] [ ]	
			Refer for chest physio	[ ] [ ]	
			Monitor oxygen saturations	[ ] [ ]	
			Continue oxygen therapy as prescribed	[ ] [ ]	
		If no	Follow Admission +1	[ ] [ ]	_____
b Remains pyrexial?	[ ] [ ]	**If yes**	Follow Admission +1	[ ] [ ]	
			Ensure infection screen has been carried out	[ ] [ ]	
		If no	Monitor temp 6 hourly	[ ] [ ]	_____
c Is systolic blood pressure <100 or >200?	[ ] [ ]	**If yes**	Record 2 hourly	[ ] [ ]	
			Continue to follow admission +1	[ ] [ ]	
		If no	Record 6 hourly	[ ] [ ]	_____
d Is Glasgow Coma Scale satisfactory?	[ ] [ ]	**If no**	Follow Admission +1	[ ] [ ]	
		If yes	Record 12 hourly	[ ] [ ]	_____
e Patient is able to swallow safely?	[ ] [ ]	**If no**	Follow Admission +1	[ ] [ ]	
			Venflon reviewed	[ ] [ ]	
			Further assessment by SLT	[ ] [ ]	
			Review results and follow specific instructions on Dysphagia Screening Test	[ ] [ ]	
		If yes	Give free fluids and normal diet	[ ] [ ]	
			Remove venflon if intake over 2 litres	[ ] [ ]	_____
f Patient is able to wash independently?	[ ] [ ]	**If no**	Follow Admission +1	[ ] [ ]	
		If yes	Offer shower, bath or basin at bedside assisting as required	[ ] [ ]	_____
g Patient is able to dress independently?	[ ] [ ]	**If no**	Follow Admission +1	[ ] [ ]	
			Assist and reinforce dressing techniques recommended by occupational therapist	[ ] [ ]	_____

ASSESSMENT	Yes	No		ACTIONS	Done	N/A	PRINT/SIGN
h Waterlow Score>10?	[ ]	[ ]	**If yes**	Follow Admission +1	[ ]	[ ]	
			If no	Record weekly	[ ]	[ ]	_____
i Is patient independent?	[ ]	[ ]	**If no**	Follow Admission +1	[ ]	[ ]	_____
j Continues to be incontinent of urine/faeces?	[ ]	[ ]	**If yes**	Continue to follow Admission +1	[ ]	[ ]	
				Check specimens have been obtained	[ ]	[ ]	
			If no	Ensure buzzer is within reach and toilet needs are met (use of urinal, commode or toilet)	[ ]	[ ]	_____
k Patient is unable to sleep?	[ ]	[ ]	**If yes**	Follow Admission +1	[ ]	[ ]	
				Discuss with doctors needs for sedative	[ ]	[ ]	_____
l Patient is for further rehabilitation?	[ ]	[ ]	**If yes**	Refer to Stroke Rehabilitation Unit	[ ]	[ ]	_____
m Patient/relatives have been informed about diagnosis?	[ ]	[ ]	**If yes**	Review information given on patient/relatives communication sheet to ensure consistency	[ ]	[ ]	
			If no	Arrange appointment with doctor	[ ]	[ ]	_____

:

Date: / /	Time:	ADMISSION +3	Ward:	Initials:

ASSESSMENT	Yes	No		ACTIONS	Done	N/A	PRINT/SIGN
a Patient is managing own airway?	[ ]	[ ]	**If yes**	Encourage deep breathing exercises	[ ]	[ ]	
				Encourage to cough and expectorate	[ ]	[ ]	
			If no	Follow Admission +1	[ ]	[ ]	_____
b Patient is apyrexial?	[ ]	[ ]	**If no**	Follow Admission +1	[ ]	[ ]	
			If yes	Monitor 12 hourly	[ ]	[ ]	_____
c Blood pressure is within set parameters?	[ ]	[ ]	**If no**	Follow Admission +1	[ ]	[ ]	
			If yes	Monitor 12 hourly	[ ]	[ ]	_____
d Glasgow Coma Scale remains satisfactory	[ ]	[ ]	**If no**	Follow Admission +1	[ ]	[ ]	
			If yes	Monitor daily	[ ]	[ ]	_____
e Patient is able to swallow safely?	[ ]	[ ]	**If no**	Follow Admission +1 and refer to Dysphagia Screening Test	[ ]	[ ]	
			If yes	Give normal diet and fluids	[ ]	[ ]	
				Review venflon if still required	[ ]	[ ]	_____
f Patient is able to wash independently?	[ ]	[ ]	**If no**	Follow Admission +1	[ ]	[ ]	
			If yes	Follow Admission +2	[ ]	[ ]	_____
g Patient is able to dress independently?	[ ]	[ ]	**If no**	Follow admission +1 and +2	[ ]	[ ]	_____
h Waterlow Score >10?	[ ]	[ ]	**If yes**	Follow Admission + 1	[ ]	[ ]	
			If no	Record weekly	[ ]	[ ]	_____
i Is patient independent?	[ ]	[ ]	**If no**	Follow Admission +1	[ ]	[ ]	
			If yes	Initiate discharge planning checklist	[ ]	[ ]	_____
j Incontinent of urine/faeces persists?	[ ]	[ ]	**If yes**	Continue to follow Admission +1	[ ]	[ ]	
			If no	Follow Admission +2	[ ]	[ ]	_____
k Patient is unable to sleep?	[ ]	[ ]	**If yes**	Follow Admission +1 and +2	[ ]	[ ]	_____
l Patient and relatives are fully aware of future plans?	[ ]	[ ]	**If no**	Ensure they are informed	[ ]	[ ]	
				Document on patient/relatives communication sheet	[ ]	[ ]	_____
m Discharge planning initiated?	[ ]	[ ]	**If no**	Refer to discharge planning sheet	[ ]	[ ]	_____

Date: / /	Time:	ADMISSION +4	Ward:	Initials:

ASSESSMENT	Yes No		ACTIONS	Done N/A	PRINT/SIGN
a Patient is managing own airway?	[ ] [ ]	**If yes**	Encourage deep breathing exercises	[ ] [ ]	
			Encourage to cough and expectorate	[ ] [ ]	
		If no	Follow Admission +1	[ ] [ ]	_____
b Patient is apyrexial?	[ ] [ ]	**If no**	Follow Admission +1	[ ] [ ]	
		If yes	Monitor 12 hourly	[ ] [ ]	_____
c Blood pressure is within set parameters?	[ ] [ ]	**If no**	Follow Admission +1	[ ] [ ]	
		If yes	Monitor 12 hourly	[ ] [ ]	_____
d Glasgow Coma Scale remains satisfactory	[ ] [ ]	**If no**	Follow Admission +1	[ ] [ ]	
		If yes	Monitor daily	[ ] [ ]	_____
e Patient is able to swallow safely?	[ ][ ]	**If no**	Follow Admission +1 and refer to Dysphagia Screening Test	[ ] [ ]	
		If yes	Give normal diet and fluids	[ ] [ ]	
			Review venflon if still required	[ ] [ ]	_____
f Patient is able to wash independently?	[ ] [ ]	**If no**	Follow Admission +1	[ ] [ ]	
		If yes	Follow Admission +2	[ ] [ ]	_____
g Patient is able to dress independently?	[ ] [ ]	**If no**	Follow admission +1 and +2	[ ] [ ]	_____
h Waterlow Score >10?	[ ] [ ]	**If yes**	Follow Admission + 1	[ ] [ ]	
		If no	Record weekly	[ ] [ ]	_____
i Is patient independent?	[ ] [ ]	**If no**	Follow Admission +1	[ ] [ ]	
		If yes	Initiate discharge planning checklist	[ ] [ ]	_____
j Incontinent of urine/faeces persists?	[ ] [ ]	**If yes**	Continue to follow Admission +1	[ ] [ ]	
		If no	Follow Admission +2	[ ] [ ]	_____
k Patient is unable to sleep?	[ ] [ ]	**If yes**	Follow Admission +1 and +2	[ ] [ ]	_____
l Patient and relatives are fully aware of future plans?	[ ][ ]	**If no**	Ensure they are informed	[ ] [ ]	
			Document on patient/relatives communication sheet	[ ] [ ]	_____
m Discharge planning initiated?	[ ] [ ]	**If no**	Refer to discharge planning sheet	[ ] [ ]	

Date: / /	Time:	ADMISSION +5	Ward:	Initials:

ASSESSMENT	Yes	No	ACTIONS	Done	N/A	PRINT/SIGN
a Patient is managing own airway?	[ ]	[ ]	**If yes** Encourage deep breathing exercises	[ ]	[ ]	
			Encourage to cough and expectorate	[ ]	[ ]	
			If no Follow Admission +1	[ ]	[ ]	_____
b Patient is apyrexial?	[ ]	[ ]	**If no** Follow Admission +1	[ ]	[ ]	
			If yes Monitor 12 hourly	[ ]	[ ]	_____
c Blood pressure is within set parameters?	[ ]	[ ]	**If no** Follow Admission +1	[ ]	[ ]	
			If yes Monitor 12 hourly	[ ]	[ ]	_____
d Glasgow Coma Scale remains satisfactory	[ ]	[ ]	**If no** Follow Admission +1	[ ]	[ ]	
			If yes Monitor daily	[ ]	[ ]	_____
e Patient is able to swallow safely?	[ ]	[ ]	**If no** Follow Admission +1 and refer to Dysphagia Screening Test	[ ]	[ ]	
			If yes Give normal diet and fluids	[ ]	[ ]	
			Review venflon if still required	[ ]	[ ]	_____
f Patient is able to wash independently?	[ ]	[ ]	**If no** Follow Admission +1	[ ]	[ ]	
			If yes Follow Admission +2	[ ]	[ ]	_____
g Patient is able to dress independently?	[ ]	[ ]	**If no** Follow admission +1 and +2	[ ]	[ ]	_____
h Waterlow Score >10?	[ ]	[ ]	**If yes** Follow Admission + 1	[ ]	[ ]	
			If no Record weekly	[ ]	[ ]	_____
i Is patient independent?	[ ]	[ ]	**If no** Follow Admission +1	[ ]	[ ]	
			If yes Initiate discharge planning checklist	[ ]	[ ]	_____
j Incontinent of urine/faeces persists?	[ ]	[ ]	**If yes** Continue to follow Admission +1	[ ]	[ ]	
			If no Follow Admission +2	[ ]	[ ]	_____
k Patient is unable to sleep?	[ ]	[ ]	**If yes** Follow Admission +1 and +2	[ ]	[ ]	
l Patient and relatives are fully aware of future plans?	[ ]	[ ]	**If no** Ensure they are informed	[ ]	[ ]	
			Document on patient/relatives communication sheet	[ ]	[ ]	_____
m Discharge planning initiated?	[ ]	[ ]	**If no** Refer to discharge planning sheet	[ ]	[ ]	_____

WESTERN GENERAL HOSPITAL STROKE SERVICE

Addressograph

DATE OF ASSESSMENT

	Pre-stroke																
DISABILITIES/BOWELS 0 – incontinent/regular enema 1 – occasional accident (<1x/week) 2 – continent																	
BLADDER 0 – incontinent/catheter 1 – occasional accident (<1x24hrs) 2 – continent																	
GROOMING 0 – needs help 1 – independent (face, hair, teeth shaving)																	
TOILET USE 0 – dependent 1 – needs some help 2 – independent (including cleaning)																	
FEEDING 0 – unable 1 – needs help (cutting, spreading) 2 – independent																	
TRANSFER 0 – unable (no sitting balance) 1 – major help, but can sit 2 – minor help (physical or verbal) 3 – independent																	
MOBILITY 0 – immobile 1 – wheelchair independent 2 – walks with help (physical or verbal) 3 – independent but may use aid																	
DRESSING 0 – dependent 1 – needs help (can do half) 2 – independent																	
STAIRS 0 – unable 1 – needs help 2 – independent																	
BATHING 0 – dependent 1 – independent																	
TOTAL BARTHEL SCORE																	

SPEECH AND LANGUAGE THERAPY

Addressograph

Referral to SLT received: / / Date first seen: / /

Problem	Yes	No	Comments
Dysphasia			
Dysarthria			
Dysphagia			

Discharge from SLT: Reason for discharge:

COMMUNICATION – INITIAL ASSESSMENT & PLAN

COMPREHENSION OF LANGUAGE

EXPRESSIVE LANGUAGE

SPEECH

Signature: Date:

Print:	Time:**Swallowing**

Dysphagia Management Status – enter date of change

ORAL	NG	PEG
NBM with IV/subcut. fluids Date: [ ]	NG only with oral hygiene Date: [ ]	PEG only with oral hygiene Date: [ ]
	NG with comfort feeding Date: [ ]	PEG with comfort feeding Date: [ ]
Therapist trials only (IV fluids) Date: [ ]	NG with therapist trials Date: [ ]	PEG with therapist trials Date: [ ]
Restricted oral with strategies and supervision +/- IV Date: [ ]	NG, restricted oral with strategies and supervision Date: [ ]	PEG with restricted oral, strategies and supervision Date [ ]
Restricted oral with strategies +/- IV Date: [ ]	NG with restricted oral strategies Date: [ ]	PEG with restricted oral and strategies Date: [ ]
Restricted oral +/- IV Date: [ ]	NG with restricted oral Date: [ ]	PEG with restricted oral Date: [ ]
Normal oral and strategies Date: [ ]	Randomised in FOOD trial ☐	Allocated ① ②
Normal oral Date: [ ]	Date: / /	

Refer to bedside swallowing regime and SLT notes on interdisciplinary communication sheet for current recommendations

Nutritional/Dietetic Action (tick those that apply)
Referral to Dietitian received: / / Patient seen: / /

Nutritional support	Date started	Texture modification	Date started
Extra snacks/drinks		Liquidised diet	
High protein/fortified diet		Thick puree diet	
Supplements		Minced/mashed diet	
		Soft/easily chewed diet	
		Liquid consistency:	
Enteral feeding – overnight		Liquids: none	
Enteral feeding – total		Liquids: thickened syrup	
		Liquids: thickened custard	
		Liquids: normal	

Food chart required – date:
Discontinued – date:

Trial diet required – date:
Discontinued – date:

Medication --Pharmacist review required on formulation Yes ☐ No ☐

Signature:
Print

Date:
Time:

PHYSIOTHERAPY

Addressograph

Referral received: _____ **Date 1st seen:** _____

	Yes	No	N/A	If no, give reason & date completed
Respiratory Assessment	☐	☐	☐	_____
Swallow Assessment	☐	☐	☐	_____
Neurological Assessment	☐	☐	☐	_____
Hemiplegic Shoulder Pain Assessment	☐	☐	☐	_____
Balance Assessment:				
Sitting Balance	☐	☐	☐	_____
Standing Balance	☐	☐	☐	_____
Transfer Assessment	☐	☐	☐	_____
Gait Assessment	☐	☐	☐	_____
Stair Assessment	☐	☐	☐	_____
Involvement with relatives of treatment	☐	☐	☐	_____
Refer to RVH:				
Verbally	☐	☐	☐	_____
Physio notes filed	☐	☐	☐	_____

Physio signature: _____

Milestones Achieved:	**Yes**	**No**	**Date achieved**
1 min sit	☐	☐	_____
10 sec stand	☐	☐	_____
10 steps	☐	☐	_____
10m walk	☐	☐	_____

N/A – indicates a professional decision that the assessment is not deemed appropriate at that time
YES – indicates that the assessment has been completed
No – indicates that the assessment has not been completed

OCCUPATIONAL THERAPY

Addressograph

Referral to OT: / /

Date first seen: / /

Name & Designation of Referrer:

OT Name:.....

	YES	NO		YES	NO
Proforma Completed	☐	☐	If no reason ..... Date Completed:		
Feeding Assessment	☐	☐	Further input required Date Resolved:	☐	☐
Seating Assessment	☐	☐	Further input required Date Resolved:	☐	☐
Neurological Assessment	☐	☐	Further input required Date Resolved:	☐	☐
Sensory Assessment	☐	☐	Further input required Date Resolved:	☐	☐
Perceptual Assessment	☐	☐	Further input required Date Resolved:	☐	☐
Cognitive Assessment	☐	☐	Further input required Date Resolved:	☐	☐
Washing/Grooming Assessment	☐	☐	Further input required Date Resolved:	☐	☐
Dressing Assessment	☐	☐	Further input required Date Resolved:	☐	☐
Kitchen Assessment	☐	☐	Further input required Date Resolved:	☐	☐

	YES	NO		YES	NO
Bed Transfer Assessment	☐	☐	Further input required Date Resolved:	☐	☐
Chair Transfer Assessment	☐	☐	Further input required Date Resolved:	☐	☐
Toilet Transfer Assessment	☐	☐	Further input required Date Resolved:	☐	☐
Bath Transfer Assessment	☐	☐	Further input required Date Resolved:	☐	☐

Discharge

All issues resolved	☐	☐	If No have appropriate referrals been made?	☐	☐

Details:

Occupational Therapist Signature: .....

Social Work

Addressograph

Date referred to social work:
Date allocated to social worker:
Allocated worker: Contact number:
Does anyone have power of attorney over the patient?

Is patient aware of referral? Yes ☐ No ☐ If no, why not?
Is there a community social worker involved? Give details:

Service Required

Residential/Nursing Home care (please tick)		
	Yes	No
Patient self funding?	☐	☐
Medical form completed?	☐	☐
Is patient Part 4 fit?	☐	☐
Is patient in agreement?	☐	☐

Care at home (please tick)		
	Yes	No
Restart of service required?	☐	☐
Small/simple increase required	☐	☐
Complex package required? See below	☐	☐
Is patient in agreement? Target date:	☐	☐

Date assessment completed:
Date on waiting list for funding:
Date funding awarded:

Details of any unmet needs/future follow up planned:

CARE PLAN – Weekly timetable of tasks & services

Name						Start date	Review date
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Morning							
Mid Day							
Afternoon							
Evening							
Night							

MULTIDISCIPLINARY TEAM MEETINGS

Date: / / Week ☐

Barthel Index: ☐

Addressograph

For CPR: Yes ☐ No ☐

Nursing - Present / Absent

Status

Goals

Actions

Medical – Consultant Present / Absent

Physiotherapy – Present / Absent

Status

Goals

Actions

SLT – Present / Absent

OT – Present / Absent

Status

Goals

Actions

Social Work – Present / Absent

Long term plan

MULTIDISCIPLINARY TEAM MEETINGS

Date: / / Week ☐

Barthel Index: ☐

For CPR: Yes ☐ No ☐

Addressograph

Nursing - Present / Absent

Status

Goals

Actions

Physiotherapy – Present / Absent

Status

Goals

Actions

Medical – Consultant Present / Absent

Status

Goals

Actions

OT – Present / Absent

Status

Goals

Actions

SLT – Present / Absent

Status

Goals

Actions

Social Work – Present / Absent

Status

Goals

Actions

Long term plan

Patient/relative communication:

Addressograph

Date: Time:	Persons name: Relation to patient:	Spoken to by: Witnessed by:	Sign & print name
Date: Time:	Persons name: Relation to patient:	Spoken to by: Witnessed by:	
Date: Time:	Persons name: Relation to patient	Spoken to by: Witnessed by:	
Date: Time:	Persons name: Relation to patient	Spoken to by: Witnessed by:	
Date: Time:	Persons name: Relation to patient	Spoken to by: Witnessed by:	

PHARMACY

Discharge plan – nursing checklist

Action		Date	Time	Signature
Treatment written	☐	/ /		
Send to pharmacy (24 hours required)	☐	/ /		
Pharmacist checked	☐	/ /		
Discharge medication explained to patient	☐	/ /		
Leaflet given	☐	/ /		
Referred to pharmacist	☐	/ /		

A2. Development of the ICP for acute stroke at the WGH

In 1998, the 11-beded stroke unit opened within Ward 15, with a large number of new healthcare staff joining the unit. Dr Dennis had the initial idea to introduce an acute stroke ICP in the unit, and a decision was made to develop an ICP after discussions with Dr Lindley, the nursing sister and the rest of the multidisciplinary team. At that time, the Trust was encouraging the development of ICPs across all the medical and surgical specialities. The stroke team also saw the ICP as a potentially useful method of standardising patient care in a new unit with new staff. Since Dr Dennis has had previous experience in developing a stroke clerking proforma, which has been shown to improve documentation of patient assessment, the team was keen to introduce a similar documentation system. Moreover, it was felt that an ICP using tick boxes would facilitate audit of patient care and outcome within a new unit.

In the WGH, another ICP was being developed by the cardiology department for the management of acute myocardial infarction (AMI) in the coronary care unit (CCU). The stroke team was encouraged by the Department of Clinical Audit and people responsible for developing ICPs to emulate the ICP for AMI. Initially, this seemed sensible since junior medical staff and some nurses rotated between medical wards and the CCU, and having similar formats of ICPs might facilitate their use and enhance compliance. However, soon after the introduction of the ICP for AMI, the document was thought to be badly designed and difficult to use, and it was soon abandoned. It was later replaced by a much shorter and simpler document.

The acute stroke ICP was designed by the members of the multidisciplinary team working on the stroke unit: Drs Dennis and Lindley, Patricia Taylor (nursing sister), Fiona Small (physiotherapist), Sheena Borthwick (speech therapist), and a number of different occupational therapists. There was also input from the dietician, social worker, and other people with an experience of developing ICPs (e.g. a clinical nurse specialist). Team meetings, which were led by Dr Dennis, were held to discuss the planning and design of the ICP. The team decided to focus on the acute stroke period

because clinical assessments and investigations were similar in most stroke patients, and the team's objective was to standardise acute stroke care during this period. After the first few days, because stroke patients varied enormously with their clinical and psychosocial needs, an ICP that delineated specific treatment pathways would have been impractical. The team also explored the possibility of developing a stroke rehabilitation ICP within the stroke rehabilitation unit at the Royal Victoria Hospital, but the healthcare staff there were not enthusiastic and rejected the idea.

Although national guidelines recommendations were used to design the ICP, the team did not need to specifically refer to the guidelines. This was because Drs Dennis and Lindley had been very closely involved in the development of SIGN and RCP guidelines, and they were very familiar with the recommendations. No extra literature search was needed since the guidelines already contained comprehensive systematic reviews of the literature on all the important aspects of stroke care. The team also assessed five other stroke ICPs for comparison (e.g. from Glasgow, Aberdeen and Tyneside), and the good and bad ideas were noted.

The ICP comprised of separate sections relating to the different disciplines. Each discipline was responsible for the content of their section and wrote their own drafts. Some disciplines' sections were integrated into others; for example, the speech therapists' section contained material belonging to the dieticians. The ICP incorporated national guideline recommendations on acute stroke management within the first few days. However, in disciplines such as nursing, where there were few such guidelines, the sections were more difficult to design. After about six team meetings, the first draft of the complete ICP was circulated amongst the team members and comments were fed back to the whole team. This process took some time, especially for the medical and nursing sections because they contained many more items and the documents were longer. When the whole team was satisfied with the final version, it was piloted in real patients. Each discipline was responsible for the implementation and maintenance of their own section of the ICP. For example, Dr Dennis and Lindley were responsible for teaching the junior staff how to use the ICP when they first arrived on the unit. Since the junior doctors turned over every

month, formal induction sessions to large numbers of medical staff would not have been practical. The nurses also held a number of educational sessions to explain how to use the nursing section of the ICP. In general, the time and resources invested into developing the ICP was relatively low, which may be due to the team's high level of experience and background knowledge.

During the pilot phase, several interesting problems were encountered. One problem was that the physiotherapy and occupational therapy departments insisted on retaining their own departmental patient records. This meant that what the therapists wrote in the ICP was only a summary of a more detailed report written in the departmental records. Another problem was that it was difficult to judge how much nurses should write down about patient care in addition to ticking the boxes in the ICP. Some nurses argued that it was important to add in free text about certain aspects of the patient's care, especially when some details were not covered by the tick box questions and answers. Since the implementation, ongoing assessment of the ICP has found that some parts of the ICP have been less well received. The nursing section has also been found to be too complicated and is now being redesigned.

A3. Major developments in the stroke service at the WGH in the past decade

June 1990	Dr Dennis started. There was a 12-bedded medical admission ward (Ward 25) from which patients with stroke were identified. Stroke care was provided by the general physicians on general medical wards (two 30-bedded wards) but there was no specialist stroke team.
Sept 1990	Lothian Stroke Register started - details of consecutive stroke patients were entered into a database.
Nov 1992	Neurovascular clinic and inpatient stroke team were set up.
June 1993	A 15-bedded stroke rehabilitation unit (Ward 14) was set up. Acute stroke care was provided by the stroke tem (led by Dr Dennis) on the general medical wards. The Accident & Emergency Unit closed and was replaced by the Acute Receiving Unit (ARU) and minor trauma unit. The original medical admission unit (Ward 25) was abandoned and it became a cardiology ward.
Nov 1996	Dr Lindley started. Acute stroke care was moved to Ward 11 (a general medical ward) where Drs Dennis and Lindley shared the care. Dr Dennis also managed the stroke rehabilitation unit, while Dr Lindley managed Ward 15 which was a Geriatric Assessment Unit.
June 1998	Stroke rehabilitation Unit was moved to the Royal Victoria Hospital (Ward 8, a 26-bedded unit), where Drs Dennis and Lindley shared the care. All the nursing staff were 'lost' in the subsequent 18 months from that unit. At the same time a 10-bedded acute stroke unit (Ward 15) was opened.
Mar 2000	An ICP was introduced in the acute stroke unit.
Sept 2002	The acute stroke unit was moved from Ward 15 into a purpose built 16-bedded acute stroke unit in another part of the WGH.

A4. Inter-rater study of the clinical assessment of patients with acute stroke

Aim of the study

To assess the inter-rater agreement of history taking, clinical examination, and diagnosis of stroke between three qualified physicians with a special interest in stroke.

Methods

Between February and May 2001, a medical student (JH) carried out an inter-rater study to assess the reliability of the important elements used for clinical assessment of patients with acute stroke. The study included 42 consecutive patients admitted to the WGH with suspected stroke. Patients were assessed within two days of admission. For each patient, two physicians (PJH or BL or myself) took a history and carried out a neurological examination in turn. We then recorded the history findings, clinical signs, and the diagnosis, using specially designed scoring sheets. Agreement between the different assessors was examined using kappa statistics.

Results

Overall, there was moderate to good agreement in the history-related elements (risk factors, neurological symptoms), neurological examination, and the diagnosis of stroke (OCSP classification, anatomical site of lesion), as shown below.

	Kappa value	95% Confidence interval
Risk factors		
Atrial fibrillation	0.62	0.40 – 0.84
Coronary heart disease	0.74	0.55 – 0.93
Hypertension	0.46	0.21 – 0.72
Diabetes	0.77	0.55 – 1.00
Previous stroke or TIA	0.56	0.35 – 0.76
Smoking	0.79	0.61 – 0.98
Peripheral vascular disease	0.50	0.25 – 0.74
History of stroke		
Time of onset	0.51	0.20 – 0.73

	Kappa value	95% Confidence interval
Improvement of symptoms	0.65	0.45 – 0.85
Focal neurological deficit	0.64	0.36 – 0.91
Motor deficit	0.72	0.51 – 0.92
Sensory loss	0.73	0.54 – 0.91
Speech impairment	0.54	0.31 – 0.77
Visual impairment	0.69	0.47 – 0.91
Clinical examination		
Alert	0.81	0.43 – 0.95
Drowsy	0.72	0.28 – 0.92
Arm weakness	0.79	0.51 – 0.92
Hand weakness	0.84	0.59 – 0.95
Facial weakness	0.69	0.40 – 0.85
Leg weakness	0.60	0.30 – 0.79
Problem with walking	0.80	0.54 – 0.92
Hemianopia	0.63	0.40 – 0.86
Dysarthria	0.47	0.20 – 0.74
Dysphasia	0.88	0.72 – 1.00
Sensory loss	0.61	0.40 – 0.83
Visual neglect	0.62	0.41 – 0.83
Sensory neglect	0.67	0.47 – 0.87
Right side of body affected	0.80	0.54 – 0.92
Left side of body affected	0.85	0.60 – 0.95
Diagnosis of stroke		
Stroke or not	0.84	0.38 – 0.97
Left side of brain	1.00	0.81 – 1.00
Right side of brain	0.84	0.57 – 0.94
OCSP classification	0.71	0.53 – 0.89

Conclusion

Agreement between physicians was generally good for history-taking, examination and making a diagnosis of stroke. This finding supports the methodology that I used in the non-randomised studies, which involved the research fellows (PJH or myself) conducting clinical assessments and recording the history and examination findings. It also supports the use of the OCSP classification and stroke scales that were based on clinical findings, such as the NIHSS.

Assessment of Acute Stroke Patients – Day 0

Admission Details (Insert N/A if unsure)

Date of stroke: _____ Time of stroke onset (24 hr clock): ____:____ ☐ on waking
Date of admission: _____ Time of admission (24 hr clock): ____:____
Assessor's initials: _____ Admit to Ward: _____

Patient Characteristics (Enter code in grey boxes)

1. NIH Stroke Scale: _____

2. Abbreviated Scandinavian Stroke Scale (NOW)

Consciousness	Fully conscious	6	
	Somnolent, can be awakened to full consciousness	4	
	Reacts to verbal command, but is not fully conscious	2	
	Coma	0	
Eye Movements	No gaze palsy	4	
	Gaze palsy present	2	
	Conjugate eye deviation	0	
ARM, Motor Power	Normal strength	6	
	Raises arm with reduced strength	5	
	Raises arm with flexion in elbow	4	
	Can move, but not against gravity	2	
	Paralysis	0	
LEG, Motor Power	Normal strength	6	
	Raises leg with reduced strength	5	
	Raises leg with flexion of knee	4	
	Can move, but not against gravity	2	
	Paralysis	0	

3. Glasgow Coma Score (on admission)

1. Eye Opening	Never	1	
	To pain	2	
	To sound	3	
	Spontaneously	4	
2. Best Motor	None	1	
	Extend to pain	2	
	Abnormal flexion to pain	3	
	Flexion to pain	4	
	Localise pain	5	
	Normal	6	
3. Best Verbal	None	1	
	Noises only	2	
	Inappropriate	3	
	Confused	4	
	Normal	5	
	Unable to assess (dysphasic)	9	

4. OCSP clinical stroke syndrome (at patient's WORST)

☐ TACS
☐ PACS
☐ LACS
☐ POCS
☐ Not determinable

5. Side of body with neurological deficit (at patient's WORST)

☐ Can't be lateralised ☐ Right ☐ Left ☐ Both

6. Carl's prognostic variables (on admission)

	Yes	No
1. Was the patient independent before stroke?	☐	☐
2. Can they lift both arms off the bed?	☐	☐
3. Can they walk without help?	☐	☐

7. <u>Pre-stroke</u> modified Rankin score

☐ No symptoms at all
☐ Minor symptoms, but no restriction to lifestyle
☐ Symptoms causing some restriction to lifestyle, but look after themselves
☐ Significant restriction to lifestyle and dependent on others for help
☐ Severe handicap, dependent on others for help, but not requiring constant attention
☐ Severe handicap, totally dependent, requiring attention night and day
☐ Not known

8. <u>Pre-stroke</u> residence and level of support

(Home includes own home, relative's or friend's home, and warden-controlled housing. Support includes home help, meals-on-wheels, and district nurse visits)

☐ Home without social or nursing support
☐ Home with social or nursing support ....**What?** _____
☐ Residential home
☐ Nursing home
☐ Other: _____
☐ Not known

9. If living in "home", did the patient live alone?

☐ Yes ☐ No ☐ Not known

10. Has the patient been on these medications regularly before admission?

	Yes	No	Not known	Name(s)?
♦ **Antiplatelet agent(s)**	☐	☐	☐	_____
♦ **Warfarin**	☐	☐	☐	Target INR:_____
♦ **Antihypertensive agent(s)**	☐	☐	☐	_____

11. Is there a <u>definite</u> previous history of stroke, TIA or subarachnoid haemorrhage?

☐ Yes
☐ No

12. If patient is NOT admitted to the stroke unit, why? (Tick one box only)

☐ Stroke unit is full
☐ Patient is MRSA +ve
☐ Patient needs palliative care only
☐ Diagnosis uncertain
☐ Other: _____
☐ Not known

Day 5 Assessment Form

I. Patient Details & Diagnosis

1. On day 5, where is the patient?

☐ Still in hospital

☐ Discharged

☐ Dead

2. If patient is still in hospital, which ward? _____

3. If patient discharged, what is the discharge residence and level of support?

(**Home** includes own home, relative's or friend's home, and warden-controlled housing. **Support** includes home help, meals-on-wheels, and district nurse visits)

☐ Home without social or nursing support

☐ Home with social or nursing support _____

☐ Residential home

☐ Nursing home

☐ Other: _____

☐ Not known

Date of discharge:

4. If patient has died, when and how?

Date of death: _____

Cause of death if known: _____

5. Has the patient been transferred between wards within the last 5 days?

☐ Yes ……..**From:**_____ **To:** _____ **Date?** _____

☐ No

6. What was the most likely final diagnosis?

☐ Definite stroke

☐ Probable stroke

☐ Possible stroke

☐ TIA

☐ Definite or probably NOT stroke …….. **What?** _____

☐ Not known

PATIENT ASSESSMENT

1. So far during this admission, who has been responsible for the patient's care?

☐ Stroke team – whole of last 5 days

☐ Stroke team – part of last 5 days

☐ General Medical team – whole of last 5 days

☐ Neurologist

☐ Neurosurgical team

2. Has a CT scan or MRI been performed?

☐ Yes ☐ No

3. Date of first brain scan: _____

4. If scanning has been performed, what is the CT or MRI diagnosis?

☐ Infarct

☐ Primary Intracerebral Haemorrhage

☐ Subarachnoid Haemorrhage

☐ Normal scan

☐ Other pathology: _____

5. If scanning has NOT been performed, why?

☐ Still waiting for it

☐ Patient too unwell or died

☐ Diagnosis of TIA was made after admission

☐ Diagnosis of stroke or TIA thought to be unlikely after admission

☐ Other.....**What?** _____

☐ Not known

6. Have the following been specifically recorded in the first 24 hours after admission?

	Yes	**No**
1. Conscious level (GCS, alert/oriented)	☐	☐
2. Eye movements (dolls eye response if drowsy)	☐	☐
3. Limb movements (response to pain if drowsy)	☐	☐

7. Within 24 hours of admission, has a clear diagnostic description been made of:

	Yes	**No**
1. Likely anatomical site of cerebral lesion	☐	☐
2. Pathological type of lesion	☐	☐

(i.e. Infarct, haemorrhage, OCSP syndrome acceptable)

8. If the patient is conscious, have the following been recorded?

For this question, "No, but.." if patient is drowsy or comatose

	Yes	No	No, but..
1. Screening for swallowing disorder (not gag)	☐	☐	☐
2. Communication	☐	☐	☐
3. Truncal control or gait	☐	☐	☐

9. If the patient is alert and able to communicate, is there formal assessment of:

For this question, "No, but.." if patient is drowsy or comatose, or has impaired communication

	Yes	No	No, but..
1. Mental ability (e.g. Mini-mental test)	☐	☐	☐
2. Visual fields	☐	☐	☐
3. Visual inattention	☐	☐	☐
4. Sensation	☐	☐	☐

10. Has the patient had NOTHING to eat or drink for the WHOLE of the last 5 days?

☐ Yes

☐ No

USE OF INTEGRATED CARE PATHWAY

1. Have the following parts of the ICP been filled in?

	Yes – fully	Yes – partially	No
1. ARU admission sheet	☐	☐	☐
2. Doctors clerking proforma	☐	☐	☐
3. Therapists	☐	☐	☐
4. Social Worker	☐	☐	☐

2. If patient managed with nursing ICP, during which days were they used?

	Yes – fully	Yes – partially	No	Discharged/Dead
1. Day of admission	☐	☐	☐	☐
2. Admission + 1	☐	☐	☐	☐
3. Admission + 2	☐	☐	☐	☐
4. Admission + 3	☐	☐	☐	☐
5. Admission + 4	☐	☐	☐	☐
6. Admission + 5	☐	☐	☐	☐

3. If nursing ICP has not been started, why?

☐ Admitted to a medical ward and never transferred to the stroke unit ≤ 5 days

☐ Admitted to a medical ward and subsequently transferred to the stroke unit ≤ 5 days

☐ Admitted to the stroke unit with a TIA

☐ Admitted to the stroke unit but diagnosis unclear or "NOT stroke"

☐ Admitted to the stroke unit but received palliative care only

☐ Other : _____

☐ Not known

5. If the nursing ICP has been started but discontinued before 5th day, why?

☐ Patient died

☐ Patient discharged or transferred to another ward

☐ Diagnosis changed

☐ Other: _____

☐ Not known

IMMEDIATE MANAGEMENT OF PATIENT (IN ARU)

1. Immediate Assessment & Investigation

		Documented	Not Documented
1.	Blood Pressure _____ / _____	☐	☐
2.	Blood Glucose _____	☐	☐
3.	Oxygen Saturation _____ %	☐	☐
4.	Temperature _____ C	☐	☐
5.	Informal Swallowing	☐	☐
6.	ECG AF? Y____ N____	☐	☐
7.	CXR	☐	☐
8.	Blood Tests	☐	☐
9.	Immediate CT Brain	☐	☐

2. Abnormal Physiological Variables

		Yes	No	Not Assessed
1.	Hyperglycaemia (> 11.0 mmol/l)	☐	☐	☐
2.	Hypoglycaemia (< 4.0 mmol/l)	☐	☐	☐
3.	Hypertension (> 160/90 mmHg)	☐	☐	☐
4.	Hypotension (< 100/60 mmHg)	☐	☐	☐
5.	Hypoxia (< 95% on air)	☐	☐	☐
6.	Pyrexia (> 37.5C)	☐	☐	☐
7.	Hypothermia (< 35.0C)	☐	☐	☐
8.	Dehydration (Clinical signs or U&Es)	☐	☐	

3. Immediate Action Taken

		Done+ Doc	No or Not Doc	N/A
1.	GKI IV Infusion	☐	☐	☐
2.	50% Glucose IV	☐	☐	☐
3.	Reduction of BP	☐	☐	☐
4.	Continue usual antihypertensive drug(s)	☐	☐	☐
5.	Supplemental Oxygen	☐	☐	☐
6.	Paracetamol for pyrexia	☐	☐	☐
7.	Antibiotic(s) IV or PO	☐	☐	☐
8.	Fluids IV or SC	☐	☐	

4. Has it been documented that the diagnosis/management/prognosis has been explained to patient and/or relative?

☐ Yes ☐ No

NEUROLOGICAL & FUNCTIONAL STATUS

1. NIH Stroke Scale (NOW).....Patient discharged ☐ Patient died ☐

Total Score: _____

2. Abbreviated Scandinavian Stroke Scale (NOW).....Patient discharged ☐ Patient died ☐

Consciousness	Fully conscious Somnolent, can be awakened to full consciousness Reacts to verbal command, but is not fully conscious Coma	6 4 2 0	
Eye Movements	No gaze palsy Gaze palsy present Conjugate eye deviation	4 2 0	
ARM, Motor Power	Normal strength Raises arm with reduced strength Raises arm with flexion in elbow Can move, but not against gravity Paralysis	6 5 4 2 0	
LEG, Motor Power	Normal strength Raises leg with reduced strength Raises leg with flexion of knee Can move, but not against gravity Paralysis	6 5 4 2 0	

6. Barthel Index (NOW).....Patient discharged ☐ Patient died ☐

Bowels	Incontinent Occasional accident (1 per week) Continent	0 1 2	
Bladder	Incontinent or catheterised & unable to manage Occasional accident (max 1 per 24 hours) Continent for over 7 days	0 1 2	
Grooming	Needs help Independent, face, hair, teeth, shaving	0 1	
Toilet Use	Dependent Needs some help but can do something Independent (on and off, dressing, wiping)	0 1 2	
Feeding	Unable Needs help cutting, spreading butter, etc Independent	0 1 2	
Transfer	Unable Major help (1-2 people, physical) Minor help (verbal or physical) Independent	0 1 2 3	
Mobility	Immobile Wheelchair independent including corners, etc Walks with help of 1 person (verbal or physical) Independent (but may use any aid, e.g. stick)	0 1 2 3	
Dressing	Dependent Needs help but can do half unaided Independent	0 1 2	
Stairs	Unable Needs help (verbal, physical, carrying aid) Independent up and down	0 1 2	
Bathing	Dependent Independent	0 1	

5. Glasgow Coma Score (NOW).....Patient discharged ☐ Patient died ☐

1. Eye Opening	**Never**	**1**	
	To pain	**2**	
	To sound	**3**	
	Spontaneously	**4**	
2. Best Motor	**None**	**1**	
	Extend to pain	**2**	
	Abnormal flexion to pain	**3**	
	Flexion to pain	**4**	
	Localise pain	**5**	
	Normal	**6**	
3. Best Verbal	**None**	**1**	
	Noises only	**2**	
	Inappropriate	**3**	
	Confused	**4**	
	Normal	**5**	
	Unable to assess (dysphasic)	**9**	

3. Glasgow Outcome Score.....Patient discharged ☐

☐ Death

☐ Persistent vegetative state

☐ Severe disability (conscious but disabled)

☐ Moderate disability (disabled but independent)

☐ Resumption of normal life (there may be minor neurological or psychological deficits)

5. Carl's prognostic variables (Tick one box per item).....Patient discharged ☐ Patient died ☐

	Yes	**No**
1. Can they lift both arms off the bed?	☐	☐
2. Can they walk without help?	☐	☐

4. Modified Rankin score (NOW).....Patient discharged ☐

☐ No symptoms at all

☐ Minor symptoms, but no restriction to lifestyle

☐ Symptoms causing some restriction to lifestyle, but look after themselves

☐ Significant restriction to lifestyle and dependent on others for help

☐ Severe handicap, dependent on others for help, but not requiring constant attention

☐ Severe handicap, totally dependent, requiring attention night and day

☐ Dead

☐ Not known

INPATIENT MANAGEMENT (LAST 5 DAYS)

1. Did the patient suffer the following?

	Yes + Doc	No or Not Doc
1. Dysphagia	☐	☐
2. Reduced consciousness	☐	☐
3. Incontinence (of urine or faeces)	☐	☐
4. Bedbound	☐	☐

2. Did the patient suffer the following complication(s)?

	Yes + Doc (1)	No or Not Doc (2)	Date diagnosed
1. Pneumonia (clinical/proven)	☐	☐	_____
2. UTI (clinical/proven)	☐	☐	_____
3. DVT (clinically evident)	☐	☐	_____
4. PE (clinical/proven)	☐	☐	_____
5. Pressure sore (>Grade 2)	☐	☐	_____
6. Fall(s)	☐	☐	_____
7. Seizure (focal/general)	☐	☐	_____
8. Mood disturbance	☐	☐	_____
9. Constipation	☐	☐	_____
10. Pyrexia (> 37.5C)	☐	☐	_____

3. Did the patient receive the following "therapies"?

	Yes + Doc (1)	No or Not Doc (2)	Date 1st assessed
1. Physiotherapy	☐	☐	_____
2. Occupational therapy	☐	☐	_____
3. Speech therapy	☐	☐	_____
4. Dietician review	☐	☐	_____
5. Psychologist review	☐	☐	_____
6. Social worker review	☐	☐	_____

4. Has the patient been given any antiplatelet drug during this admission?

☐ Yes

☐ No

5. When, at what dose, and how was the antiplatelet drug FIRST administered?

Date: _____ **Agent:** _____ **Dose:** _____**mg** **Route:** ☐ **PO** ☐ **PR**

6. If patient had stroke as final diagnosis but did NOT receive ANY antiplatelet drug, why?

☐ Intracranial haemorrhage

☐ Known intolerance (e.g. gastric irritation) or allergy

☐ Too unwell or died soon after admission

☐ Other ..... **What?** _____

☐ Not known

7. Did the patient receive the following "interventions" subsequent to admission (≤ 5 days)?

		Yes + Doc (1)	No or Not Doc (2)	Notes
1.	Subcutaneous Heparin	☐	☐	_____
2.	Intravenous Heparin	☐	☐	_____
3.	Warfarin	☐	☐	_____
4.	Dipyridamole MR	☐	☐	_____
5.	Clopidogrel	☐	☐	_____
6.	Statin	☐	☐	_____
7.	Antihypertensive drug	☐	☐	Date:_____
8.	Oral Antibiotics	☐	☐	_____
9.	Intravenous Antibiotics	☐	☐	_____
10.	Antidepressant	☐	☐	_____
11.	Antipyretic	☐	☐	_____
12.	TED stockings	☐	☐	_____
13.	Nasogastric feeding	☐	☐	Date:_____
14.	PEG feeding	☐	☐	Date:_____
15.	Fluids IV or SC	☐	☐	_____
16.	Urinary catheter	☐	☐	Date:_____
17.	Thrombolysis	☐	☐	IST-3?_____
18.	Referral for neurosurgery	☐	☐	_____

8. Have the following tests been ordered or performed?

		Order + Perform	Order But Not Perform	Not ordered	Date Performed
1.	Carotid Duplex	☐	☐	☐	_____
2.	Transthoracic Echo	☐	☐	☐	_____
3.	Transoesophageal Echo	☐	☐	☐	_____
4.	Transcranial Doppler	☐	☐	☐	_____
5.	MR Angiography	☐	☐	☐	_____
6.	Cerebral Angiography	☐	☐	☐	_____
7.	Other: _____	☐	☐	☐	_____

BLOOD RESULTS ON ADMISSION

1. Biochemistry

	VALUE	DATE
Sodium		
Potassium		
Urea		
Creatinine		
Glucose		
Cholesterol		

2. Haematology

	VALUE	DATE
Haemoglobin		
WCC		
Platelet Count		
ESR		
INR or PT		

3. Waterlow Score on Admission

☐ Known : _____

☐ Not known

NIH Stroke Score

1a LOC Questions	0 1 2 3	Alert – *keenly responsive* Drowsy – *arousable by minor stimulation to obey, answer, or respond* Stuporous – *requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped)* Comatose – *responds only with reflex motor or autonomic effects or totally unresponsive, flaccid*
1b LOC Questions	0 1 2	Answers both correctly Answers one correctly Incorrect Patient is asked to state the month & his/her age
1c LOC Commands	0 1 2	Obeys both correctly Obeys one correctly Incorrect Patient is asked to open & close eyes, grip & release normal hand
2. Best Gaze	0 1 2	Normal Partial gaze palsy – *gaze is abnormal in one or both eyes, no forced deviation/total gaze paresis* Forced deviation – *or total gaze paresis not overcome by oculocephalic manoeuvre*
3. Visual Fields	0 1 2 3	No visual loss Partial hemianopia Complete hemianopia Bilateral Hemianopia – *including cortical blindness*
4. Facial Palsy	0 1 2 3	Normal Minor – *flattened nasolabial fold, asymmetry on smiling* Partial – *total or near total paralysis of lower face* Complete – *absent facial movement in upper and lower face on one or both sides*
5. Best Motor RIGHT ARM	0 1 2 3 4 x	No drift – *holds limb at 90 degrees for full 10 seconds* Drift – *drifts down but does not hit bed* Some effort against gravity No effort against gravity No movement Untestable
6. Best Motor LEFT ARM	0 1 2 3 4 x	No drift – *holds limb at 90 degrees for full 10 seconds* Drift – *drifts down but does not hit bed* Some effort against gravity No effort against gravity No movement Untestable
7. Best Motor RIGHT LEG	0 1 2 3 4 x	No drift – *holds limb at 45 degrees for full 5 seconds* Drift – *drifts down but does not hit bed* Some effort against gravity No effort against gravity No movement Untestable
8. Best Motor LEFT LEG	0 1 2 3 4 x	No drift – *holds limb at 45 degrees for full 5 seconds* Drift – *drifts down but does not hit bed* Some effort against gravity No effort against gravity No movement Untestable
9. Limb Ataxia	0 1 2	Absent Present in 1 limb Present in 2 or more limbs
10. Sensory	0 1 2	Normal Partial loss – *patient feels pinprick is less sharp or is dull on affected side* Dense loss – *patient is unaware of being touched on face, arm, leg*
11. Best Language	0 1 2 3	No dysphasia Mild – moderate dysphasia – *obvious loss of fluency or comprehension, without significant limitation on ideas expressed or form of expression. Makes conversation about provided material difficult or impossible, e.g. examiner can identify picture or naming card from patient's response.* Severe dysphasia – *all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener who carries burden of communication. Examiner cannot identify materials provided from patient response* Mute *no usable speech or auditory comprehension.*
12. Dysarthria	0 1 2 x	Normal articulation Mild – moderate dysarthria – *patient slurs some words, can be understood with some difficulty.* Unintelligible or worse – *speech is so slurred as to be unintelligible or is mute/anarthric* Untestable
13. Neglect	0 1 2	No neglect Partial neglect – *Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities* Complete neglect – *Profound hemi-inattention or hemi-inattention to more than one modality. Does not recognise own hand or orients to only one side of space*

ICP – STAFF QUESTIONNAIRE 1-MONTH (WGH)

Please tick one box per question

Section 1

Are you aware of the integrated care pathway for acute stroke on the ward? Yes ☐ No ☐

Are you a: Nurse (D/E) ☐ Sister (F/G) ☐ Dietician ☐
SALT ☐ OT ☐ Physio ☐

Have you ever worked with an ICP before this one? *Yes – in stroke* ☐ *Yes – not in stroke* ☐ *No* ☐

Section 2

Please select the your answer by ticking the appropriate box. There are no right or wrong answers to these questions. We would just like your honest opinions.

How would you <u>expect</u> the ICP to influence the following?

General	**Higher**		**No Change**		**Lower**
1. your general knowledge of stroke management?	☐	☐	☐	☐	☐
2. the speed of completing paperwork for nurses/physios/OTs/dieticians?	☐	☐	☐	☐	☐
3. the speed of clerking stroke patients and documenting for doctors?	☐	☐	☐	☐	☐
4. your clinical judgement and acumen in managing stroke patients?	☐	☐	☐	☐	☐
5. your enthusiasm to learn about stroke?	☐	☐	☐	☐	☐
Patient & Process Outcomes					
6. the patient's chance of dying or being disabled at 1 month?	☐	☐	☐	☐	☐
7. the patient's chance of dying or being disabled at 1 year?	☐	☐	☐	☐	☐
8. the number of complications (e.g. pneumonia) during hospital stay?	☐	☐	☐	☐	☐
9. the total length of stay in hospital?	☐	☐	☐	☐	☐
10. the speed of getting routine CT scans?	☐	☐	☐	☐	☐
11. the speed patients get discharged to nursing or residential homes?	☐	☐	☐	☐	☐
12. the quality of information given to patients and relatives?	☐	☐	☐	☐	☐
13. the feedback from patients and relatives?	☐	☐	☐	☐	☐
14. your confidence in explaining to patients and relatives about stroke?	☐	☐	☐	☐	☐
15. your confidence in managing stroke in the future <u>without</u> an ICP?	☐	☐	☐	☐	☐
16. the number of investigations (e.g. carotid duplex) performed per patient?	☐	☐	☐	☐	☐
17. the thoroughness in managing a stroke patient?	☐	☐	☐	☐	☐
18. the number of drug errors?	☐	☐	☐	☐	☐

	Higher		No Change		Lower
19. the number of accidents on the ward (e.g. from lifting and handling)?	☐	☐	☐	☐	☐
20. the expectations from patients and relatives?	☐	☐	☐	☐	☐
21. the number of complaints by patients or relatives?	☐	☐	☐	☐	☐
22. the quality of organisation for discharging stroke patients?	☐	☐	☐	☐	☐
Miscellaneous					
23. the quality of care of patients with unusual strokes?	☐	☐	☐	☐	☐
24. the quality of care of younger stroke patients (< 65 years old)?	☐	☐	☐	☐	☐
25. the quality of care of patients with behavioural or emotional problems?	☐	☐	☐	☐	☐
26. the quality of care of patients with cognitive impairment (e.g. dementia)?	☐	☐	☐	☐	☐
27. the ease of making "Do Not Resuscitate" decisions?	☐	☐	☐	☐	☐
28. the attractiveness of the stroke unit for doctors/nurses applying for jobs?	☐	☐	☐	☐	☐
29. the speed and ease of transfer from ARU to stroke unit?	☐	☐	☐	☐	☐
30. the speed and ease of transfer from stroke unit to rehabilitation unit?	☐	☐	☐	☐	☐
31. the quality of stroke care in <u>other</u> wards?	☐	☐	☐	☐	☐
32. your autonomy and decision-making as an individual care-giver?	☐	☐	☐	☐	☐
General Quality of Care					
33. the quality of nursing (stroke) care on the stroke unit?	☐	☐	☐	☐	☐
34. the quality of medical (stroke) care on the stroke unit?	☐	☐	☐	☐	☐
35. the quality of physio/OT/SALT/SW/Dietician care on the stroke unit?	☐	☐	☐	☐	☐
36. the quality and ease of auditing on the stroke unit?	☐	☐	☐	☐	☐
37. the quality of regular multidisciplinary team meetings?	☐	☐	☐	☐	☐
38. the communication/interaction between different disciplines?	☐	☐	☐	☐	☐

Section 3

Here are more general questions about stroke ICPs. Again, please be as frank as possible.

Do you think ...	**Yes**	**No**	**Don't Know**
1. patients should be selected to "go on" an ICP (e.g. not TIAs or "TLC only")?	☐	☐	☐
2. the natural course of stroke is too unpredictable and complicated for ICP?	☐	☐	☐
3. there should be an electronic version of the ICP?	☐	☐	☐
4. there should be a "Patient Pathway", which is a simplified version of the ICP, which can be given to the relatives (and patients)?	☐	☐	☐
5. it is difficult for ICP to make a difference because most of the time-consuming factors (e.g. waiting for investigations) are 'out of our hands'?	☐	☐	☐

Do you have any Other Comments?

Please write as much as you want and use a separate piece of paper if you need

Thank you very much for your time and attention!

Now, please put the completed questionnaire in the box marked "Completed ICP Questionnaires" in the Sister's Office on Ward 15.

Thanks again.

Jo Kwan

Dr Joseph Kwan

Research Fellow in Stroke Medicine

Department of Clinical Neurosciences

Any queries please contact me on **32903** *or Dr Martin Dennis on* **31719**

ICP – STAFF QUESTIONNAIRE 7-MONTHS (WGH)

Please tick one box per question

Have you used the integrated care pathway for acute stroke on the ward? Yes ☐ No ☐

I am a: Nurse (D/E).... ☐ Sister (F/G).... ☐ Dietician.... ☐ Doctor.... ☐
SALT.... ☐ OT .... ☐ Physio.... ☐

Please select the your answer by ticking the appropriate box. There are no right or wrong answers to these questions. We would just like your honest opinions.

From your experience, how has the ICP affected the following?

General	**Increased**		**No Change**		**Reduced**
• Your level of knowledge of stroke management	☐	☐	☐	☐	☐
• The speed of completing paperwork for nurses/physios/OTs/dieticians	☐	☐	☐	☐	☐
• The speed of clerking stroke patients and documenting for doctors	☐	☐	☐	☐	☐
• Your clinical judgement and acumen in managing stroke patients	☐	☐	☐	☐	☐
• Your level of enthusiasm to learn about stroke	☐	☐	☐	☐	☐
Patient & Process Outcomes					
• The patient's chance of recovery	☐	☐	☐	☐	☐
• The number of complications (e.g. pneumonia) during hospital stay	☐	☐	☐	☐	☐
• The number of days patients stay in the stroke unit	☐	☐	☐	☐	☐
• The speed patients get their routine CT brain scans	☐	☐	☐	☐	☐
• The speed patients get discharged to nursing or residential homes	☐	☐	☐	☐	☐
• Likelihood of patients being given oxygen if O2 saturation is below 95%	☐	☐	☐	☐	☐
• Likelihood of patients being given GKI if BM is over 11	☐	☐	☐	☐	☐
• Likelihood of patients being given iv or subcutaneous fluids	☐	☐	☐	☐	☐
• Likelihood of patients being given Paracetamol if temperature is over 37.5	☐	☐	☐	☐	☐
• Likelihood of patients being catheterised (urinary)	☐	☐	☐	☐	☐
• Likelihood of patients being fed by NG or PEG	☐	☐	☐	☐	☐
• Likelihood of patients being mobilised early by physiotherapist	☐	☐	☐	☐	☐
• The quality of information given to patients and relatives	☐	☐	☐	☐	☐
• The amount of feedback from patients and relatives	☐	☐	☐	☐	☐
• Your confidence in explaining to patients and relatives about stroke	☐	☐	☐	☐	☐

	Increased				Reduced
▪ Your confidence in managing stroke in the future <u>without</u> an ICP	☐	☐	☐	☐	☐
• The number of investigations (e.g. carotid duplex) performed per patient	☐	☐	☐	☐	☐
• The thoroughness in managing a stroke patient	☐	☐	☐	☐	☐
• The number of drug errors	☐	☐	☐	☐	☐
• The number of accidents on the ward (e.g. from lifting and handling)	☐	☐	☐	☐	☐
• The expectations from patients and relatives	☐	☐	☐	☐	☐
• The number of complaints by patients or relatives	☐	☐	☐	☐	☐
• The quality of organisation for discharging stroke patients	☐	☐	☐	☐	☐
Miscellaneous					
• The quality of care of patients with unusual strokes	☐	☐	☐	☐	☐
• The quality of care of younger stroke patients (< 65 years old)	☐	☐	☐	☐	☐
• The quality of care of patients with behavioural or emotional problems	☐	☐	☐	☐	☐
• The quality of care of patients with cognitive impairment (e.g. dementia)	☐	☐	☐	☐	☐
• The ease of making "Do Not Resuscitate" decisions	☐	☐	☐	☐	☐
• The attractiveness of the stroke unit for doctors/nurses applying for jobs	☐	☐	☐	☐	☐
• The speed and ease of transfer from ARU or ward 26 to stroke unit	☐	☐	☐	☐	☐
• The speed and ease of transfer from stroke unit to rehabilitation unit	☐	☐	☐	☐	☐
• The quality of stroke care in <u>other</u> wards (e.g. 14, 11)	☐	☐	☐	☐	☐
• Your autonomy in making day-to-day clinical decisions	☐	☐	☐	☐	☐
General Quality of Care					
• The quality of nursing (stroke) care on the stroke unit	☐	☐	☐	☐	☐
• The quality of medical (stroke) care on the stroke unit	☐	☐	☐	☐	☐
• The quality of physio/OT/SALT/SW/Dietician care on the stroke unit	☐	☐	☐	☐	☐
• The quality of regular multidisciplinary team meetings	☐	☐	☐	☐	☐
• The communication and interaction between different disciplines	☐	☐	☐	☐	☐

Do you think using the ICP on the ward has affected the following in any way?

	Higher		No Change		Lower
• The amount of time you spend treating stroke patients	☐	☐	☐	☐	☐
• The general morale of the staff working on the ward	☐	☐	☐	☐	☐
• Satisfaction of patients and relatives	☐	☐	☐	☐	☐
• The way others regard (i.e. the profile of) stroke care in the hospital	☐	☐	☐	☐	☐
• Your overall job satisfaction	☐	☐	☐	☐	☐

What do you think of the following aspects of the ICP?	Satisfactory				Unsatisfactory
• The way that you have been involved in the design process	☐	☐	☐	☐	☐
• The way that you have been explained the benefits of ICPs	☐	☐	☐	☐	☐
• The way that you have been taught how to fill in the forms	☐	☐	☐	☐	☐
• The way that you feedback comments regarding the forms	☐	☐	☐	☐	☐
• The way the ICP was implemented in general	☐	☐	☐	☐	☐
• The design of the form (e.g. layout, number of pages, wording, colour, etc)	☐	☐	☐	☐	☐
• The size (number of pages) of the documents	☐	☐	☐	☐	☐
• The number of questions to answer each day	☐	☐	☐	☐	☐
• The clinical relevance of the questions or checklists	☐	☐	☐	☐	☐
• The number of times you have to sign each day	☐	☐	☐	☐	☐
• The ease of getting used to the new system of documentation	☐	☐	☐	☐	☐
• The ease and speed of finding the information you need	☐	☐	☐	☐	☐

PLEASE TELL US MORE OF WHAT YOU THINK!

Feel free to write as much as you want and use a separate piece of paper if you need

THANK YOU!

Thank you very much for your time and attention!

Now, please put the completed questionnaire in the box marked "Completed ICP Questionnaires" in the Sister's Office on Ward 15.

Jo Kwan

Dr Joseph Kwan

Department of Clinical Neurosciences

Any queries please contact me on 32903 *or Dr Martin Dennis on* 31719