ORGANISED CARE OF ACUTE STROKE AT GROOTE SCHUUR HOSPITAL — A CONTROLLED TRIAL

Nilesh-Kumar Patel

A thesis submitted to the Faculty of Health Sciences, University of Cape Town, in partial fulfillment of the requirements for the degree of Master of Philosophy in Epidemiology.

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DECLARATION

I, Nilesh-Kumar Patel declare that this thesis is my own work. It is being submitted in partial fulfilment for the degree of Master of Philosophy in the branch of Epidemiology to the University of Cape Town. This thesis has not been submitted before for any other degree or examination at this or any other university.

Signed by candidate _____ Date: 7/12/2000

TO MY PARENTS

PRESENTATIONS

The literature review, methods and results of this study have been presented, in part and as a whole, to the:

- The Stroke Symposium, Durban, South Africa, May 1999;
- The Stroke Consensus Working Party, Johannesburg, March 1997, and
- The Department of Medicine on their Research Day, University of Cape Town, October, 1997.

ABSTRACT

Background and purpose: Groote Schuur Hospital (GSH) admits about 570 stroke patients annually. These patients about occupy 10% of acute medical beds. Recent investigations have demonstrated that stroke services are poorly organised. Although "Organised stroke care" has been shown to improve outcomes, this has not been demonstrated locally. This study was undertaken to determine whether stroke unit care within a general medical ward improves outcomes.

Study design and sampling: The study was a prospective non-randomised controlled trial, with systematic allocation by admission day, of all acute stroke admissions to the Department of Medicine from 1 January to 15 May 1996.

Intervention: There were three comparison groups: in the *Stroke Intervention Ward*, the intervention was implemented by the author; in the *Guidelines Ward*, the manner in which the intervention can be set up and implemented was provided in the form of a Guidelines Booklet and in the *Control Ward*, stroke patients received routine care. The intervention consisted of (i) geographic/spatial unity and allocation of a designated nurse; (ii) use of a Stroke Clerking Pro forma and (iii) a multidisciplinary Team Care Plan and Post Intake Stroke Ward Round.

Results: 58 patients were admitted to the Stroke Intervention Ward, 40 patients were admitted to the Guidelines Ward and 91 were admitted to the 2 Control Wards. The groups had similar baseline characteristics, except for the percentage of patients continent on admission. There were no significant differences in the Modified Barthel

Index prior to admission, at discharge or at follow-up. There were no significant differences in the principal outcome measures (death, dependency, death or dependency, institutionalisation and death or institutionalisation) between the comparison groups. The median [inter-quartile range] length of hospital stay in days was significantly reduced in the Stroke Intervention Ward (6.5[5–9]) compared to the Guidelines Ward (9[7–14]) and the Control Wards (8[5–12]). The referral rates to Professionals Allied to Medicine were significantly increased in the Stroke Intervention Ward, except for referrals to the Community Liaison Sister. The referral rates to rehabilitation resources on discharge were significantly increased in the Stroke Intervention Ward, except for referrals to physiotherapy.

Conclusions: Organised Stroke Care is feasible in our setting and results in improved utilisation of resources without increasing length of stay. However, principle outcome measures were not significantly altered in this study.

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1. INTRODUCTION

Stroke or cerebrovascular disease is probably one of the most devastating illnesses in medicine. It is the source of considerable misery and suffering for patients and their families and is extremely costly for health services. These factors are complicated by the fact that lay and medical communities perceive stroke in a negative and nihilistic manner. Despite efforts by health professionals interested in the condition, stroke research has failed to attract the emotive appeal of cancer and coronary artery disease.

World wide there are approximately 4.6 million deaths from stroke each year, and three quarters of these occur in the economically developing world.[1] In Scotland stroke has been estimated to consume five percent of the National Health Service budget [2] and at Groote Schuur Hospital, stroke patients occupy about ten percent of medical bed-days at any one moment.[3] In economically developed countries, stroke is the most common cause of adult disability. The incidence of stroke is higher in economically developing countries (see below).

In the past decade there have been considerable efforts in many countries to change this negative perception, precipitated mainly by the realisation of the increasing cost of stroke care on the acute health care and long term care sectors. This has lead to much debate about the various approaches to stroke rehabilitation i.e. where should it occur,

which professionals should be involved, how to select patients who might benefit most and the type of programme that should be implemented.

South Africa has no clear policy at district, regional or national level on the appropriate planning, organisation, implementation and evaluation of services for stroke patients and their carers.[4] The services that are provided in hospital, primary care and the community seem to be haphazard, fragmented and poorly tailored to patients' needs.[5-11] Furthermore, there is also a striking lack of convincing data on the effectiveness of widely used medical, psychological and rehabilitative treatments.[12]

The ageing of our population and an increasing prevalence of cardiovascular risk factors associated with increasing urbanisation are likely to lead to a rapid increase in the incidence and prevalence of vascular disease, especially stroke. This associated with decreasing stroke mortality rates makes stroke a major public health priority.

1.1 Stroke epidemiology

The economic and social burden of stroke is determined by the incidence, mortality, prevalence, long-term outcome and cost of treating patients.

Stroke incidence data are most accurately derived from well designed studies which use standard diagnostic criteria and include prospective ascertainment of cases from a large, representative population using comprehensive case finding methods which identify non-fatal cases treated out of hospital as well as patients dying shortly after the acute event,

with a high percentage of cases confirmed by CT scanning or necropsy.[13-15] Such studies usually require considerable resources as well as rigorous methods as described. A 1987 review [13] of sixty-six studies of stroke incidence found only nine studies which met the criteria.

A considerable proportion of stroke patients may not be admitted to hospital and therefore hospital based studies do not reflect the full extent of the burden of stroke.[16-19] Hospital based studies underestimate the number of mild strokes, particularly cases of mild cerebral infarction that have most to gain from secondary prevention.[14] Rapid death following a stroke as a result of delay before being admitted to hospital also results in patients not being included.[14] Furthermore, factors influencing admission and case-mix vary unpredictably both within and between hospitals/countries resulting is varying degrees of case ascertainment. Thus not only do hospital-based studies underestimate the burden of stroke, but it is also difficult to compare them.

1.1.1. Incidence

The average crude annual incidence of first ever stroke ranges from 1.7 *(Rochester, USA)* to 3.6 *(Shibata, Japan)* per 1000 in the 55-64 year age group to 10.3 *(Rochester, USA)* to 37.7 *(Soderhamn, Sweden)* per 1000 in persons older than 85 years.[13]

Age standardised incidence rates (standardised to the European population) range from 2.0 *(Aukland, New Zealand)* to 3.2 *(Soderhamn, Sweden)* per 1000 in the 55-64 year age

group to 18 *(Rochester, USA)* to 40 *(Soderhamn, Sweden)* per 1000 in persons older than 85 years.[20]

There are no ideal studies of stroke incidence in Southern Africa. A number of hospital based studies have reported crude incidence rates ranging from 1.9 *(Harare, Zimbabwe [21])* to 2.8 *(Kalafong, South Africa [22])* per 1000 in the 55 to 64 age group and 4.7 *(Harare, Zimbabwe [21])* to 8.4 *(Kalafong, South Africa [22])* per 1000 in the age group 65 to 74 year age group.

The latter probably represent underestimation of the true incidence rates of stroke among black persons.[23] 'Racial' variation in the incidence of stroke has been shown in comparisons between white and Japanese as well as white and black persons. The incidence is higher in blacks, when standardised for the differences in the prevalence of risk factors.[24]

1.1.2. Mortality

Stroke is the third most common cause of death in the industrialised world [20], causing approximately 4.6 million deaths per annum [1] or 10 to 12% of all deaths. [20]

One-month case fatality rates range between 17 and 34% (average 24%) and 1 year case fatality rate is around 42%.[20] The case fatality rate in the Oxfordshire Community Stroke Project was 19% at 30 days and 31% at 1 year. [14] Age standardised mortality rates in the 40-69 year age group varies 10 fold between countries with high rates of 240 and 144 per

100 000 in Bulgarian men and women to those with low rates of 29 to 18 in Swiss men and women.[20] International mortality trends from stroke are showing a decline.[25] South African mortality rates from stroke have also fallen although they remain higher than most industrialised countries.[26]

The decline in mortality could be due to a decline in incidence or due to a decline in case fatality rates. This issue remains largely unresolved. Do morbidity trends mirror the declining mortality trends? This is difficult to establish with certainty. Morbidity patterns are influenced by a number of factors including changes in natural history, in admission policy and in the management of the acute phase of stroke. These trends are also influenced by the increasing availability of CT scanning and the improved case detection associated with increased awareness among clinicians.[20] A decline in stroke severity may be a possible explanation.[25]

Reducing the mortality from disease (and thus increasing disease prevalence) carries with it the responsibility of facilitating optimum quality of life for survivors. This is particularly important in stroke where a significant proportion of stroke survivors remain disabled. If first strokes are being prevented then the decline in stroke mortality represents a major public health achievement.[1]

If on the other hand the decline is a result of the improvements in survival of stroke patients then there are major public health implications. Tentative results from important community based cohort studies that have measured stroke incidence, notably in the

USA and in Japan, suggest that improvements in survival, rather than decline in incidence is the more likely explanation for the mortality decline.[1]

1.1.3. Prevalence and long-term outcome

Stroke is the most common cause of adult disability. Long-term outcome or disability after stroke can be measured in a number of ways, with varying degrees of accuracy.

The most commonly used measure of outcome is independence or dependence for self care tasks or the activities of daily living. About twenty percent of stroke patients die within a month and about a third of the survivors are dependent on others for activities of daily living at 6 months.[27] Of all cerebral infarction, which makes up about eighty percent of all strokes,[14] about thirty six percent of the seventy seven percent who are alive at one year are dependent on others for their activities of daily living.[28]

In addition to the decline in stroke mortality, several other factors contribute to the increasing prevalence of stroke. These include, firstly, the increasing prevalence and sub-optimal management of the chronic diseases of life style, of which stroke is a common end point; secondly, the effects of global ageing; and thirdly, sub-optimal secondary prevention of stroke.

1.1.4. Cost and hospital admissions

The cost of stroke care includes direct cost of providing health care as well as indirect costs related to premature death and morbidity, loss of potential earnings and productivity, the use of social services and unpaid carer time (family members or those employed by them) as well as other costs. Direct costs of stroke care (i.e. the cost of providing health care) is divided into the cost of acute hospital care and the cost of long-term care (e.g. nursing home care). National estimates of the total cost of stroke care are of limited value in an international perspective because of major variations in costs, available resources, organisation of stroke treatment and admissions policy.[29]

Stroke is a common cause of hospital admission and has been reported to result in four percent of all hospital admissions and fifty percent of neurology admissions in Africa.[30] In the (UK) National Health Service stroke accounts for eight to eleven percent of all acute medical ward admissions and stroke patients occupy thirteen percent of all general medical bed-days and twenty-five percent of all geriatric bed-days.[17] Stroke accounted for close to 10% of total inpatient bed-days in the general medical wards in a major South African teaching hospital[3] and accounts for 10% of the total number of bed days in Sweden.[29] In Harare, nearly all acute stroke patients are admitted to hospital;[21] in the United Kingdom, between forty and seventy percent of acute stroke patients are admitted to hospital.[18]

Of the direct cost of acute hospital treatment of stroke patients, hospital overheads and nurses' salaries account for ninety three percent.[31] Only the remaining five to seven

percent is accounted for by the salaries of physicians and therapists as well as the costs of investigations and drugs.[31] The direct cost of acute care can therefore be measured in terms of length of stay. Similarly the direct cost of long-term care includes mainly the care of dependent survivors of stroke in institutions.

In summary (firstly) a large proportion of stroke patients are admitted to acute hospitals where (secondly) they occupy a significant number of bed days in acute hospitals. Thirdly most of the direct cost of stroke care can be attributed to the number of days spent in hospital and or in an institution.

1.2. STROKE RESEARCH IN SOUTHERN AFRICA

The bulk of published research directly related to stroke in Southern Africa, as summarised in Table 1.1., has focussed on the quality of hospital and community services for stroke patients[7,8,9,10] with two studies[21,22] addressing the incidence of stroke and five studies addressing the case fatality rate.[7,8,21,22,31]

Table 1.1. Published research on stroke in Southern Africa

Author Year published	Study title	Study design	Study population and sample size	Principal outcomes measures	Results and Conclusions
Matenga [21] 1997	Stroke incidence rates among black residents of Harare— a prospective community based study	Prospective hospital based study	• Black residents (of six months or more) of Harare, Zimbabwe during the 12 months ending 31 December 1991	• Crude incidence rate of 30.7 per 100 000 • Std incidence rate of 68 per 100 000 • First week CFR of 35%	Stroke is an important cause of morbidity and mortality in the study population. The study is essentially a hospital-based study with added measures to maximise case ascertainment.
Whitelaw et al [7] 1994	Post-discharge follow up of stroke patients at Groote Schuur Hospital — a prospective study	Prospective hospital based community follow-up descriptive study with analytic component carried out 3 – 6 months after an intervention of 'a weekly stroke round'	• Completed strokes admitted to Groote Schuur Hospital, who graded 3 to 5 on the Rankin Scale, who were not institutionalised and who lived locally. • 59 patients selected by random sampling; period during which admitted not specified.	• rate of referral and use of hospital based rehabilitative services • disability status as scored by the Rankin grading • CFR • perceived needs of patients and carers	Referral rates to physiotherapy and occupational therapy were 68% and 58% respectively. CFR at 6 months was 34%. Older patients were referred less often and used less services than younger patients. More than 50% of patients/carers felt transport to hospitals was inadequate; 60% expressed a need for more help from social workers; 25% expressed a need for more education. Compared results with Putterill, 1984 and attributed improvement in outcomes to the intervention.
Joubert [31] 1991	The MEDUNSA stroke data bank. An analysis of 304 patients seen between 1986 and 1987.	Prospective descriptive study	• All patients over the age of 14 years that were admitted to Ga-Rankuwa Hospital with the presumptive diagnosis of either transient ischaemic attacks or stroke (including sub-arachnoid haemorrhage). • 304 patients admitted between 1986 and 1987.	• basic clinical and epidemiological aspects (including CFR) • pathological sub-types of stroke • risk factors	Similarities and differences with other population groups are highlighted. CFR at 1 month was 33%. Of the 82% of patients who had a CT scan: 71% had cerebral infarction and 26% intracerebral haemorrhages.

Author Year published	Study title	Study design	Study population and sample size	Principal outcomes measures	Results and Conclusions
Dewar [8] 1990	Stroke outcome in the absence of a structured rehabilitation program	Retrospective hospital case-note review and community based follow up study	• White patients admitted to a Durban hospital with a diagnosis of acute stroke as identified through a medical records retrieval system; • 210 patients admitted between January 1983 and December 1984. • Patients from the above group who had initial strokes, who lived in the Durban area and who survived to 12 months were followed up; N=35.	• CFR at 1week, 1 month and at 1 year • Degree of residual disability	CFR at 1 week–38%; CFR at 1 month–51%; CFR at 1 year–62%. 12-52% of stroke survivors were dependent in feeding, bed transfers, toileting, mobility, dressing, bathing, climbing stairs and shopping. Despite poor outcomes, stroke has failed to capture the emotive appeal of cancer and coronary artery disease.
Rosman [22] 1986	The epidemiology of stroke in an urban black population	Prospective hospital based descriptive study	• Urban blacks over the age of 20 who were admitted to the Kalafong Hospital with suspected acute stroke. • 116 patients admitted between May 1984 and April 1985.	• Incidence of stroke • Stroke sub-types • CFR at 1 month (CFR_1) • Prevalence of risk factors	Incidence of stroke is a minimum of 101 per 100 000 persons aged over 20. Stroke sub-types: 33%–haemorrhagic; 32%–thrombotic; 14%– embolic; 20%-lacunar. CFR_1=34%. Hypertension present in 70%, Atrial fibrillation in 7%.
Putterill et al [10] 1984	Coping with chronic illness: Part II. Cerebrovascular accidents	Prospective community based follow up descriptive study	• Acute stroke admissions who on discharge survived up to 5 weeks; did not return to work; and were not institutionalised. • 41 patients admitted between May and August 1983.	• Length of stay • Physical capacity • Out-patient therapy visits	Major deficiencies exist in the post discharge management of stroke survivors. 46-80% of patients were dependent in toileting, feeding, washing, dressing and mobility. 45% of patients visited the physiotherapist, 15% the speech therapist and 10% the occupational therapist.
Putterill et al [11] 1984	Coping with chronic illness: Part III. The carer	Prospective community based follow up descriptive study	• Acute stroke admissions who on discharge survived up to 5 weeks; did not return to work; and were not institutionalised. • 41 patients admitted between May and August 1983.	• The role of carers • Carer problems • Carer education in hospital	The responsibility for care fell almost totally on the principal carer, usually a spouse or a daughter. Two thirds of carers were not given or told where to obtain information on the implications of a stroke for the patient and/or the family nor had they been advised on where to obtain help in coping with problems.

Abbreviations: CFR = case fatality rate

None of the latter fulfils the criteria for a well-designed incidence study as described above (1.1). Five studies [7,8,21,22,31] describe similar case fatality rates and of these, two studies [21,22] describe significantly different incidence rates. Both of the latter studies [21,22] were essentially hospital based with only one [21] complementing hospital surveillance with other measures to ensure maximal case ascertainment.

Matenga [21] showed a crude incidence of 30.7 per 100 000 population whereas Rosman [22] describes an incidence of 101 per 100 000 population over 20 years. The first source of bias to consider in these studies is the accuracy of the denominator. Both authors obtained their denominators from recent population censuses. The quality of the denominator in both studies is probably similar and as accurate as can be expected with a census in this part of the world. A second source of bias to consider in these studies is case ascertainment.

Matenga [21] describes figures most comparable to community based studies as he ensured maximal case ascertainment by complementing daily hospital ward surveillance with monitoring emergency department and post mortem registers as well as monthly discharge summaries. Furthermore, his study was conducted in a city (Harare, Zimbabwe) where all stroke patients are admitted to one of four general hospitals.

Rosman [22] only included patients who were admitted to hospital, without accounting for patients who may have died prior to admission or those who may have presented to other hospitals. Matenga's study [21] probably represents the most accurate crude stroke

incidence figure in Southern Africa, although it probably represents an underestimate of the true incidence.[23]

The case fatality rates described in the five studies [7,8,21,22,31] reviewed are similar. Except for Matenga,[21] these studies were purely hospital based and this limits their generalisability and comparability. The case fatality rates range from 33% to 38% at one week to one month compared to 19% at 30 days reported in the Oxfordshire Community Stroke Project.[14] The difference is probably related to (i) case ascertainment: as many milder cases of cerebral infarction are probably not admitted (and/or do not present) to hospital in Southern Africa and (ii) the Oxfordshire Community Stroke Project had excellent case ascertainment compared to the essentially hospital based studies reviewed above.

A study by Wyndham [26] in 1982 suggested that mortality rates from stroke in South Africa have fallen, even though they remain higher than those in western countries.

Whitelaw,[7] Dewar [8] and Putterill [10,11] describe the lack of co-ordinated focussed rehabilitation services both within acute hospitals and after discharge. Measures used to describe this include referral rates to Professionals Allied to Medicine as well as reported use and satisfaction with services.

Whitelaw [7] demonstrated improvement in the quality of services for stroke patients (measured by referral rates to Professionals Allied to Medicine) by comparing his results

to those of Putterill.[10] There is a need for demonstrating that these improvements in process measures leads to improvements in health outcomes.

This series of studies reflects two interesting points about stroke in Southern Africa and mirrors international trends. Firstly, stroke is and will continue to be a major public health problem and secondly, services for stroke patients are haphazardly arranged and poorly co-ordinated despite evidence which suggests that services are better co-ordinated with simple re-organisation of existing resources.

Fritz [4] in 1995 conducted an extensive review on the available information on stroke in South Africa and called for a multi-disciplinary team to define the scope of the burden of stroke, co-ordinate available resources and formulate a comprehensive stroke program the future.

1.3. LITERATURE REVIEW PERTAINING TO STROKE UNITS

1.3.1. Introduction and history of stroke units

The role of "stroke unit care" or "organised care" in the management of stroke patients during the acute and rehabilitation phases has been controversial for a number of years. This is attributable to a number of factors including a negative attitude towards stroke, the lack of an effective pharmacological intervention for acute stroke, little evidence/consensus with regard to acute management, secondary prevention, and rehabilitation.

Even where consensus statements and guidelines have become available,[32,33] stroke services have remained poorly co-ordinated.[34-36] The medical establishment has been slow to develop and adopt guidelines and consensus statements on stroke management, until recently.

Admitting practices and policies for acute stroke patients have also generally been undefined and in fact sometimes irrational. For example, the mild stroke patient, who might benefit most from medical intervention was not admitted in favour of the considerably more disabled stroke patient.

Associated with the lack of appropriate medical management of stroke patients, are a number of unanswered questions relating to the rehabilitation of stroke patients. Is rehabilitation after stroke effective, where should it occur and who should be delivering such services? These questions remain largely unanswered and are, in fact, difficult to address.

The earliest available evidence as to what a stroke service should consist of was derived from commentaries.[37-40] While these stimulated some discussion around the value of stroke units, there was still an insufficient body of evidence to justify a change in management strategies.

1.3.2. Trials of organised inpatient care after stroke

Between 1962 and 1997 nineteen trials of organised inpatient care after stroke were conducted. Of these, only fourteen published trials [41-56] were available for review by the author via South African medical libraries.

These trials generally demonstrate good internal validity. However, external validity considerations are limited by two main factors. Firstly, the trials lack precision and do not demonstrate consistent improvements in the health outcome measures studied. Secondly, the heterogeneity of the intervention package makes generalisation difficult.

Although the trials reveal valuable information on the manner in which services should be organised to show improved outcomes, they have been unable to show any significant improvement in measurable outcomes such as mortality and residual disability. This lack of a clear improvement in most of the trials was probably due to the fact that the likely modest benefits (if any) could only be detected with large-scale, randomised trials or, alternatively, by means of a systematic overview and meta-analysis of the available small randomised trials. The first systematic overview of stroke unit trials was published in 1993 [57] and has been the most significant contribution to the improved interest and rapid development of stroke care this decade.

The methodology that is employed in the evaluation of stroke unit care, depends largely upon the manner in which the particular stroke services is organised. Unlike pharmacological interventions, the "package of care" or "intervention package"

consisted of a multitude of individual interventions. This heterogeneity of approaches made repeatability of the intervention difficult in subsequent trials and also in implementation of stroke unit care. Furthermore, the trials also used a variety of process and outcome measures.

1.3.2.1. Internal validity appraisal of trials of organised inpatient care after stroke

Although they were broadly similar in design, stroke unit trials employed slightly different methods. A systematic approach to critical appraisal of randomised controlled trials [58] has been used here to illustrate a detailed methodological appraisal of two representative trials (by Indredavik et al [46] and Strand et al [48]) of stroke unit care (Table 1.2.). An additional twelve trials were reviewed and their design characteristics and the most important methodological aspects have been summarised in Table 1.3.

A key feature of the critique is whether the trial design minimises the potential for systematic error or bias, as depicted in figure 1.1. Study entrants should be randomly allocated to the intervention independently of the decision about their entry into the trial *(selection bias)*. Participants, their relatives, those who deliver the intervention as well as those who measure the outcomes should not be aware of the intervention status of the patient *(performance and detection bias)*. Analysis must be by intention-to-treat (thus to minimise *selection bias*) and loss to follow-up *(attrition bias)* should avoided.

Table 1.2. Methodological characteristics of two stroke unit trials

City, year, author	Umeå, 1985, Strand et al [48]	Trondheim, 1991, Indredavik et al [46]
Was the assignment of patients to treatment randomised?	No, there was no formal randomisation. All eligible patients were admitted to the stroke unit (SU) provided a bed was available. If no bed was available, patients were admitted to the general medical ward (GMW).	Yes, patients were screened first and only if they met the entry criteria were they randomized.
Were all patients entered in the trial properly accounted for at it's conclusion? (Was follow-up complete? Were patients analyzed in the groups to which they were assigned?)	The study results clearly account for all patients up to the end of scheduled follow-up. All patients were analyzed in the group to which they were allocated.	Fourteen patients were found not to meet the entry criteria after the randomization process and were then returned to nursing homes, transferred to other hospitals or departments. Follow-up was complete with regard to the dichotomous outcomes monitored (proportion of patients who died, were living at home or in an institution). The primary analysis for these outcomes was an intention-to-treat analysis. A separate on-treatment-analysis was also performed and showed similar results. For the continuous outcomes monitored (the Barthel Index, the Neurological Score and the length of stay in institutions in the first year) only an on-treatment-analysis was possible, as the fourteen patients that were excluded after randomization, were not closely followed up.
Were patients, their clinicians and study personnel "blind" to treatment?	In a trial where the intervention consists of service delivery, all clinicians and patients/families are not blind. The follow-up at 3 months and at one year was conducted by a nurse, which was not affiliated to the SU. The study does not specifically mention that this nurse was blind to the intervention status of the patients.	The study specifically identified the open design as a potential source of bias in favor of the stroke unit. A single blind assessment of 100 patients was conducted by two physical therapists (who were not working in the hospital and were unaware of the patient's intervention status). There was good correlation for both scores on patients from both groups.

City, year, author	Umeå, 1985, Strand et al [48]	Trondheim, 1991, Indredavik et al [46]
Were the groups similar at the start of the trial?	The groups were comparable at baseline with regard to age, sex distribution, and various concomitant disorders, except for a history of heart disorder. Forty percent of SU patients had a history of heart disorder compared to eighteen percent of GMW patients. The groups were also similar with regard to prognostic indicators at baseline (level of consciousness, extent of neurologic deficits and ability to walk).	The groups were similar with regard to basic characteristics and prognostic, neurological and functional scores.
Aside from the experimental intervention, were the groups treated equally? (co-intervention)	Twenty one SU patients received Dextran 40 and venesection as part of a haemodilution trial. Patients from both groups were discharged to the only long-stay hospital in the district. The senior Physician of the long-stay hospital personally assessed patients from both groups using the same criteria. Patients eligible for discharge to the longstay hospital were then wait listed. By special arrangement, the interval to admission to the long-stay hospital was reduced for stroke unit patients. This is a potential source of bias, since patients at three month and/or one year follow-up could still have been in the acute hospital, while being on the waiting list for admission to the long-stay hospital.	There was no co-intervention.
Were all clinically important outcomes considered?	Morbidity, mortality and the need for institutional care were the main outcome measures. The proportion of patients deceased, living at home and in an institution was determined at discharge, three months and at one year. The proportion of patients that were independent, partially dependent or totally dependent with regard to ambulatory capacity, feeding, personal hygiene and dressing was determined at . No specific validated measure of functional ability was used.	Morbidity, mortality and the need for institutional care were the main outcome measures. The Neurological Score, Bathel Index were determined at baseline, twenty one days, forty two days, ninety days and at one year. The proportion of patients deceased, living at home and in an institution was determined at six weeks and at one year. In addition, the total length of stay in any institution in the fist year after stroke was determined.

Table 1.3. Summary of trials comparing "organised care" versus "conventional care" of stroke patients from published literature between 1962 and 1997

City	Year	First Author	Study population & sample	Intervention	Principal Outcome Measures	Conclusion and Comments
Perth	1997	Hankey et al [41]	First ever stroke of less than 7 days duration; Ni=29; Nc=30	DSU-CAR in NW versus GMW/GW	• Mortality • Rankin and Barthel Scores • Mortality or Disability at 6 months • Length of hospital stay • Institutionalization • Death or Institutionalization	Slightly more patients in the DSU with lacunar stroke with absent or mild weakness, although allocation was random. Lack of power and wide confidence levels due the small number of patients.
Helsinki	1995	Kaste et al [42]	Acute stroke patients aged 65 years and over Ni=113; Nc=119	MARU in NW versus GMW	• Mortality • Length of hospital stay • Quality of life at 3 months • Barthel and Rankin Scores at 1 year • Proportion discharged home	11 patients appropriately excluded before analysis due to incorrect diagnosis.
Orpington	1995	Kalra et al [43]	Acute stroke patients with a poor prognosis Ni=36; Nc=37	DSU-R in GW versus GMW	• Mortality • Functional Status • Length of stay • Discharge destination	2 patients LTF Stroke rehabilitation units improve outcome in severe stroke patients.
Orpington	1993	Kalra et al [44]	Acute stroke patients of less than 2 weeks duration Ni=124; Nc=121	DSU-R in GW versus MARU in GW/GMW	• Amount of therapy • Functional status • Discharge destination • Length of stay • Mortality	Stroke units improve outcome, reduce mortality without increasing length of stay.
Newcastle	1993	Aitken et al [45]	Conscious acute stroke patients within 3 days of the stroke Ni=34; Nc=33	DSU-R in GW versus GMW	• Type of therapy received • Mortality • Discharge destination • Functional status • Neurological deficits	Of 398 patients screened only 94 met the inclusion criteria and a further 27 were excluded due to no beds being available.
Trondeim	1991	Indredavik et al [46]	Hospital admissions Ni=110; Nc=110	DSU-CAR versus GMW	• Proportion at home/institution • Barthel ADL • Neurological deficit score • Mean institutional stay during first year Assessed up to 1 year	Functional state was significantly better for patients in the stroke unit. Stroke unit patients were also more likely to be at home one year after their stroke.

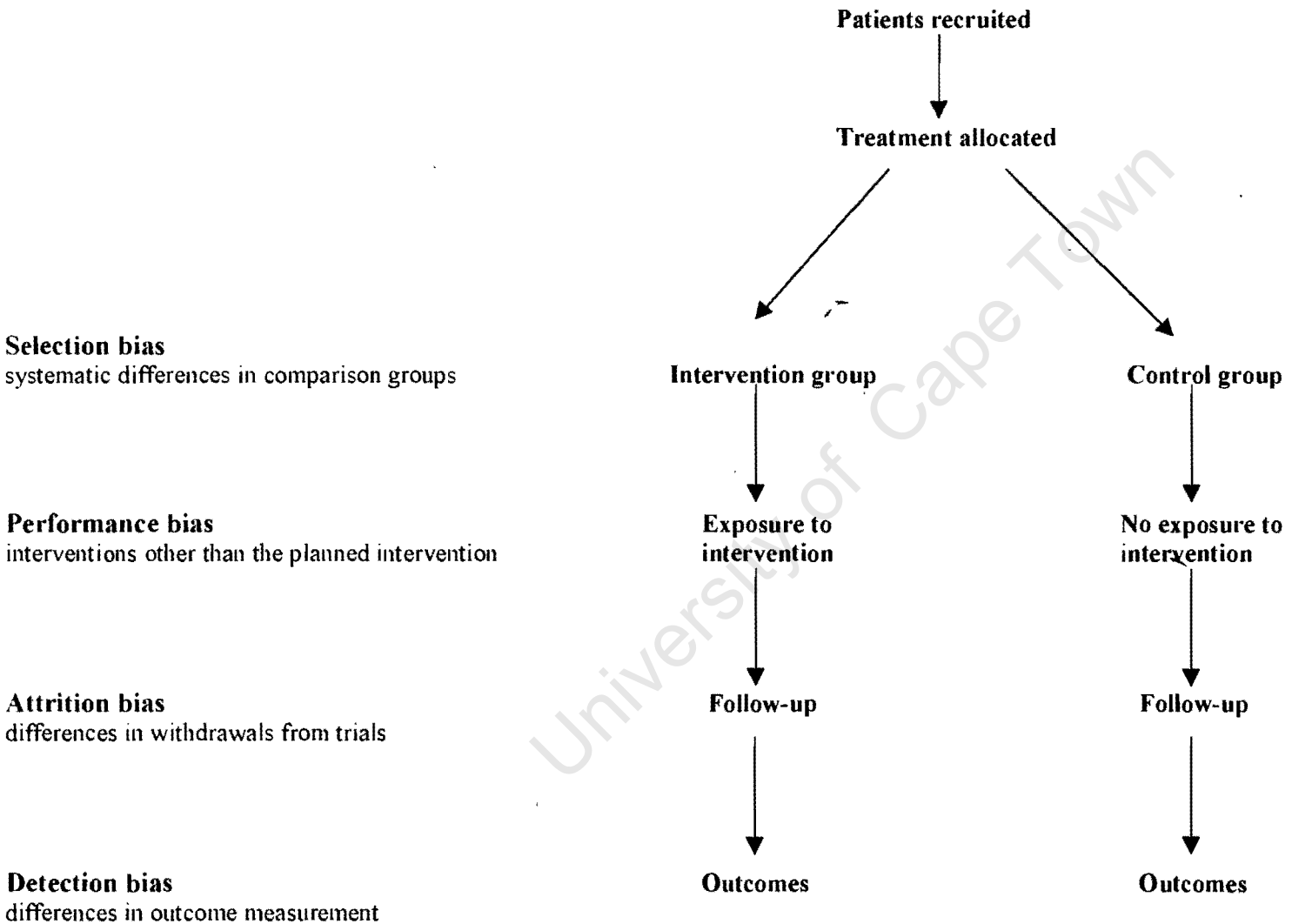
City	Year	First Author	Study population & sample	Intervention	Principle Outcome Measures	Conclusion and Comments
Kuopio	1985	Sivenius et al [47]	Community Stroke Register Ni=50; Nc=45	DSU in NW versus GMW	• ADL Scores • Neuromuscular deficits • Mortality • Place of care at 12 months Assessed up to 1 year	There was a difference in ADL and motor function up to one year after stroke.
Umea	1985	Strand et al [48]	Hospital admissions Ni=110; Nc=183	DSU-CAR versus GMW *(Quasi-experimental)*	• Place of stay • Mortality • ADL scores • Duration of stay Assessed up to one year	Patients in the stroke unit had significantly improved in some aspects of function at one year. Fewer stroke unit patients were in an institutional at one year. Quasi-randomised trial with treatment allocation according to bed availability. Subset analyses demonstrated that all stroke patients benefit from stroke unit treatment without selection.[49]
Dover	1984	Stevens et al [50]	Hospital admissions mostly within 3 weeks (85%); Ni=112; Nc=116	DSU-R versus MARU in GW/GMW	• Rankin disability scale • Mortality • Complications • Duration of stay • Follow-up appointment given • Place of care after discharge Assessed up to 1 year	At one year patients in the stroke had better outcome in terms of survival and proportion returning to the community. Despite randomisation , more patients in the control group had an initially decreased level of consciousness (drowsiness, coma) and scored lower on the Rankin Scale.
Montreal	1984	Wood-Dauphinee et al [51]	Hospital admissions Ni=64; Nc=62	DSU (mobile team) versus GMW	• Motor function • Barthel ADL scores • Assessed up to 5 weeks	Team and traditional care patients fared similarly in motor and functional outcomes
Uppsala	1982	Hamrin et al [52]	Hospital admissions Ni=60; Nc=52	Patients non-randomly allocated to MARU on GMW versus Conventional Care on GMW *(Quasi-experimental)*	• Activity Index (mental, motor function and ADL) • Mortality • Place of discharge	Although at 4 weeks there were improvements in activity in both groups, there was no significant difference between groups.
Edinburgh	1980	Garraway et al [53]	Conscious patients over 59 years old Ni=155; Nc=156	DSU-R versus GMW	• Proportion of patients independent at discharge and at 1 year • Case fatality rate • Referral rates to PAMs	Greater proportion of SU patients were independent at discharge, but this difference was not apparent at 1 year Greater proportion of SU patients were referred to PAMs. Improvement in functional outcome at the time of discharge had disappeared at one year.[54]

City	Year	First Author	Study population & sample	Intervention	Principle Outcome Measures	Conclusion and Comments
Illinois	1966	Gordan et al [55]	Stroke patients aged more than 55 years from a public roll of disabled persons. Ni=35; Nc=56	MARU versus GMW with special nursing input only (no therapist input)	• Length of stay • Functional status • Discharge Destination	Study population used severely limits any kind of generalisibility; 1:2 intervention:control; The study had too many exclusions (patients judged not to need physical rehabilitation, patients with intellectual deterioration, patients with more acute medical conditions and those whose neurological deficit was severe).
New York	1962	Feldman et al [56]	Stroke patients within 2 weeks Ni=42; Nc=40	Patients randomly allocated to formal rehabilitation unit care or functionally oriented medical care in medical or neurological wards	• Severity of impairment • Functional status • Intellectual function • Place of discharge Assessed up to one year	The great majority of patients can be rehabilitated adequately on medical and neurological wards without formal rehabilitation services if proper attention is given to ambulation and self care activities. No deaths reported.

Abbreviations:

DSU = Dedicated Stroke Unit
DSU-A = Acute Stroke Unit
DSU-R = Rehabilitation Stroke Unit
DSU-CAR = Combined Acute Care/Rehabilitation Stroke Unit
ADL = Activities of daily living
SU = stroke unit
MARU = Mixed Assessment/Rehabilitation Unit
GMW = General Medical Ward
NW = Neurology Ward
GW = Geriatric Ward
LTF = Lost to follow-up
PAMs = Professionals Allied to Medicine

Figure 1.1. Sources of bias in randomised controlled trials
(Reference: The Cochrane Collaboration Handbook)



Strand et al [48] randomised patients informally. Patients were admitted to the stroke unit when a bed was available, otherwise patients were allocated to the general medical wards. This form of informal randomisation is unlikely to result in any selection bias, as patients probably sustain strokes and present to hospital at random.

It is not possible to ensure that participants, their families and those who deliver the intervention are blinded as to the intervention status of the patient. This is a particular problem when testing interventions consisting of a delivery of a health service or a collection of services. Thus performance bias in stroke unit trials is unavoidable and should always be considered in the design phase of the study. The importance of a *blinded outcome assessment* is essential in these trials to minimise any detection bias.

In the trial by Strand et al,[48] a nurse who was not linked to the stroke unit in any way assessed the outcomes, after discharge. While it may be fair to assume that the nurse was blinded as to the intervention status of the patient, this is not specifically stated. Indredavik et al [46] on the other hand clearly identified the potential for detection bias. They undertook a single blind assessment of one hundred patients by two physical therapists and showed good correlation between the data collected by the blinded and unblinded personnel.

Strand et al [48] clearly accounted for all patients at the end of the trial. Indredavik et al [46] excluded fourteen patients, who after randomisation, were found not to meet the entry criteria. These fourteen patients were followed up less closely. Indredavik et al [46] thus

performed an *on-treatment* analysis for the Barthel index and the Neurological Score. However, for the more important dichotomous variables, death and the need for institutional care, both an *intention-to-treat* and an *on-treatment* analysis were performed. The results were similar in both cases.

Another source of bias to consider in randomised controlled trials is performance bias. Strand et al,[48] who considered the need for institutional care as well as the length of initial hospital stay as important outcomes, demonstrated an interesting source of performance bias. Patients from both intervention and control groups were, if required, admitted to the only long-stay hospital in the district. However, by special arrangement, the interval to transfer to the long-stay hospital was reduced for the stroke unit patients. This directly improves two of the outcomes in the stroke unit group, increasing the length of initial hospital stay for the control patients, as well as possibly increasing the proportion of control patients who are still hospitalised at follow-up. This could be seen as a source of performance bias, or , in fact, as part of the intervention. However, it was not described as the latter.

These trials demonstrate important potential sources of bias. In addition to bias associated with double blind randomised controlled trials, *selection bias* associated with informal randomisation as well as *performance and detection bias* associated with the open design are important sources of bias to consider in stroke unit trials. The importance of addressing these potential sources of bias in trial design and outcome assessment is highlighted. Overall the trials demonstrate good internal validity.

1.3.2.2. External validity considerations of the stroke unit trials

As discussed earlier, two main considerations with regard to generalisation of the stroke unit trials pertain to power and the heterogeneity of the intervention package.

1.3.2.2.1. Systematic overview and meta-analysis of organised inpatient care after stroke

In an influential book,[60] "Effectiveness and Efficiency – Random Reflections on Health Services" Dr. Archie Cochrane draws attention to our great collective ignorance about the effects of health care, and explains how evidence from randomised controlled trials can help us use resources more rationally.

In 1979,[61] he wrote: "It is surely a great criticism of our profession that we have not organised a critical summary, by speciality and sub-speciality, adapted periodically, of all relevant randomised controlled trials". The Cochrane Collaboration has evolved in response to this challenge.

The systematic overview and meta-analysis initially published by Langehorne et al,[57] was one of the first to be updated and included in the Cochrane Collaboration's database on systematic reviews.

Randomised controlled trials are usually not designed to examine effectiveness of an intervention. For the most part, however, randomised controlled trials do provide

evidence of efficacy, as one of the major advantages of randomised trials is internal validity. This is achieved in the study design and analysis as is discussed above (1.3.2.1).

Systematic overviews of randomised controlled trials are of greater scientific value for a number of reasons. The first is that individual trials are usually of insufficient statistical power [62] to detect modest effects on outcomes, which nonetheless may suggest a trend in the direction of a beneficial effect. Associated with improved power is increased precision of an effect.

The second is external validity (clinical effectiveness in contrast to biological efficacy).[63] Systematic overviews summarise the therapeutic effects of similar, related interventions that were tested in different populations and settings. The therapeutic effects (such as reduction in mortality) of individual trials are likely to be different, but the differences are most likely to be seen in the size of the effect rather than the direction of the effect. If a systematic overview produces a statistically significant effect on an outcome, such effect is likely to be valid as a generalisation to the less well defined range of patients in ordinary clinical practise (i.e. outside the tightly selected cases that are entered into trials).

Systematic error (bias) in systematic overviews is avoided by including only randomised controlled trials of good quality (internally valid). In order to avoid further bias, it is helpful to define an objective and unbiasedly ascertainable end-point, such as death. Measures such as dependence for self- care are susceptible to detection bias. An

important feature of systematic reviews is that every effort is made to include all research that meets the criteria for good quality, including unpublished, usually negative, trials.

The Stroke Unit Trialists' Collaboration's systematic overview of organised inpatient care after stroke [64] was of good quality. The methodological criteria [65] used to assess the quality of the overview are summarised in Table 1.4.

In addition to providing an overview of the effects of organised inpatient care after stroke, collaborators (Stroke Unit Trialists) provided detailed information which was not always published in the original trials.[64]

The overview [64] reported results for death, death or institutional care and death or dependency. A number of sensitivity analyses excluding certain trials or including only certain trials were also conducted and in general revealed no significant alteration of the results. The principal results reported in the overview [64] are summarised in Table 1.5.

Equally important was the fact that organised inpatient care after stroke did not systematically increase the length of hospital stay.[64]

Table 1.4. Methodological assessment of the systematic overview and meta- analysis of organised inpatient stroke care

Validity Criteria	The systematic overview of organised inpatient stroke care
Did the trial address a focussed clinical question?	Yes: 'To define the characteristics and determine the effectiveness of organised inpatient (stroke unit) care with conventional care in reducing death, dependency and the requirement for long-term institutional care after stroke'.
Were the criteria used to select articles for inclusion appropriate?	Trials were included if the treatment allocation was carried out on a strictly random basis or a quasi-experimental basis (such as by date of admission).
Is it unlikely that important relevant studies were missed?	Yes. Systematic hand searches of twenty-two core neurology journals, five Japanese journals, and systematic searches of Index Medicus, Medline and dissertation abstracts. Reference lists of trials, review articles and textbooks; Current Contents and the proceedings of forty-three recent conferences on neurology, geriatric medicine and rehabilitation were also searched. Furthermore, the network of trialists who collaborated in the review have extensive knowledge of published and unpublished randomised trials thus reducing the risk of publication bias.
Was the validity of the included trials appraised? Were assessments of studies reproducible?	This was specifically stated in the first edition of the overview*, but was not specifically mentioned in the most recent overview.

Table 1.5. Summary of results of the systematic overview of trials of organised inpatient stroke care

Outcome	Treatment observed/total	Control observed/total	Odds Ratio (95% CI)	NNT (range)
Death	340/1626	413/1623	0.82(0.69–0.98)	22 (10–∝)
Death or institutional care	640/1597	755/1600	0.75(0.65–0.87)	14 (8–30)
Death or dependency	843/1409	944/1421	0.71(0.61–0.84)	16 (10–25)

Abbreviations: NNT: numbers need to treat to prevent one event; CI: confidence intervals; ∝ : infinity.

Reference: Stroke Unit Trialists' Collaboration. A collaborative systematic review of the randomised trials of organised inpatient (stroke unit) care after stroke. *Br Med J* 1997;314:1151-9

In addition to the quantitative summary of outcomes, the collaborators provided detailed information on the various characteristics of the intervention in their own settings. The benefits of organised inpatient care after stroke as opposed to conventional care are, to a large extent, due to structure, departmental setting, the amount of medical, nursing and therapy input available. These components of the "black box of stroke unit care" are now considered in more detail.

1.3.2.2.2. The components of stroke unit care

The most distinctive components of stroke unit care are thought to be ***organization*** (co-ordinated multi-disciplinary team care; nursing integration with multi-disciplinary team care; involvement of relatives/carers in the rehabilitation process); ***specialization*** (medical and nursing interest and expertise in stroke and rehabilitation) and ***education*** (education and training programmes for staff, patients and families/carers).[64]

The first aspect to consider is the setting [64] within which stroke units are established. Stroke units are usually set within a Neurology, Geriatric Medicine, General Medicine or Rehabilitation Medicine Department and consist of a geographically discrete ward or a mobile team of professionals. The variety of settings reveals that stroke patients are not exclusively managed by a particular medical speciality, but rather by persons and departments with a keen interest in stroke.

In the systematic overview,[64] the intervention was defined according to the way services were organised. Services were defined according to whether they admitted only stroke

patients or all patients with disability, and further according to whether stroke patients were admitted early (acute care) or later (rehabilitation) or both (combined acute care and rehabilitation). The definition of stroke units is presented in Figure 1.2.

Other general principles or common denominators of "stroke unit care" have been employed in various ways and with varying intensity in the published trials of stroke unit care. These include staffing, admission and discharge policies, communication protocols, routine protocols, regular education and outcomes monitoring and have been summarised in Table 1.6. The reported components of stroke unit care in the two trials appraised [46,48] above have been summarised in Table 1.7.

Efforts should be made to identify more specifically and accurately the components of this "black box of care" in order to draw clear conclusions that may be generalised to other settings. This area (the specific components of rehabilitation therapy) is as yet poorly researched and currently the topic of intense debate. To date most trials have been confined to examining the effects of an "organised" deployment of the rehabilitation team versus less organised deployment.

1.3.3. Community-based stroke services

A number of recent studies [66-68] have examined the provision of orgainsed stroke care through community-based services. In our setting community-based services are likely to prove less expensive and probably equally effective in the developed parts of South Africa. However, such services are unlikely to be feasible in the vast majority of our

country, where community-based services depend upon hospital-based services for considerable structure and support. The kind of support required for community-based organised stroke care is generally unavailable where hospital-based services for stroke are generally poorly organised and there is an ever increasing shortage of posts for Professionals Allied to Medicine.

1.3.4. Summary of the literature review pertaining to stroke units

In summary, review of the literature pertaining to stroke units demonstrates a number of points. Firstly, the trials reviewed demonstrate good internal validity. Secondly, the limitation of generalisation of individual trials of inadequate power may be overcome by a powerful systematic overview and meta-analysis which demonstrates definite (statistically significant) benefit of important health outcomes. Thirdly, the specific component or components of stroke unit care to which the benefit can be attributed remains unclear.

Figure 1.2. Definition of stroke units

Dedicated stroke unit

This type of service consists of a discrete stroke ward or stroke team working exclusively in the care of stroke patients. This includes ***acute stroke units***, which accept patients acutely but discharge early; ***rehabilitation stroke units,*** which accept patients after a minimum delay and focus on rehabilitation for several weeks; and ***combined acute care/rehabilitation stroke units*** which accept patients acutely and also provide rehabilitation for several weeks.

Mixed assessment/rehabilitation unit

This type of service consists of a ward or team that has interest and expertise in the assessment and rehabilitation of all disabling illness and not exclusively stroke patients.

General medical wards

This service is provided in acute medical wards, which focus on the management of acutely ill general medical patients, without any specific focus on acute or post-acute rehabilitation.

Table 1.6. The components of stroke unit care

Staffing	Most of the stroke units were staffed by consultants with an interest in stroke or disability management as well as a multi-disciplinary team of physiotherapists, occupational therapists, speech therapists and social workers supported by trained nursing staff. Most stroke units did not have clinical psychology support. The nursing staff, who provide twenty-four hour per day care for stroke patients are less involved in mobile stroke teams. Most trials specifically state (or imply) improved referral rates to therapists, more therapy time as well as dedicated nursing input in the intervention limbs.
admission and discharge policies	There was usually a clear policy as to when admission should occur and what type of patients should be admitted. The timing of admission was either early (direct admission to the unit or within a few days of the stroke) or delayed admission (after a week). The units admitted either only stroke patients or all patients disabled patients. Most trials had clear discharge policies, based on improved ability to cope at home, social conditions and available support after discharge or a specified length of stay in the stroke unit.
communication	Regular formal communication occurred between members of the multi-disciplinary team and relatives.
routine protocols	There were usually routine assessment and management procedures as well as a proactive approach to managing potential complications, both acute medical management and for rehabilitation.
regular education	Most units conducted regular education and training of staff and family members.
outcomes monitoring	Death, dependency and the need for institutional care were the key outcomes measured in all the trials. In addition, length of hospital stay and process measures (such as referral rates to therapists and actual therapy input) were reported in a fair number of trials. For the purposes of the overview, independent was taken to mean that an individual did not require physical assistance with transfers, mobility, dressing, feeding, or toileting. Individuals who failed any of these criteria were considered dependent. The criteria were roughly equivalent to a Rankin score of 0-2 or a Barthel score of >18/20.

Table 1.7. Reported components of "Stroke Unit Care" in the trials appraised in Table 1.2.

City, year, first author of trial	Umeå, 1985, Strand et al [48]	Trondheim, 1991, Indredavik et al [46]
Setting	Department of Medicine	Section of Cardiology, Department of Medicine
Type of intervention ward	Six bed combined acute care and rehabilitation ward	Six bed combined acute care and rehabilitation ward
Type of control ward	Four general medical wards	Six general medical wards
Staffing	A part-time physician, a full-time nurse who also made contact with families and social institutions with occasional assistance of a social worker, a part-time physiotherapist, a part-time occupational therapist and trained nurses aids. The stroke team and family members usually treated aphasic patients, but the speech therapist was also occasionally consulted.	It is implied that therapists were routinely involved, although this is not specified.
Admission policy	All patients, regardless of age, who without preceding trauma to the head, presented with focal neurological dysfunction with a duration of less than one week or patients with TIA during the last week.	Acute stroke patients less than one week after onset. Patients with brain tumor, subarachnoid or subdural hemorrhages, unconscious patients, patients living in nursing homes or other districts and patients who presented when the stroke unit was full were excluded.
Discharge policy	Patients were discharged once they were able to return home, or depending upon social conditions and the degree of functional disability, were transferred to a long-stay hospital.	If patients had not returned home within forty-two days, they were transferred to one of the general medical wards, a rehabilitation clinic or a nursing home.
Communication	Team work lead by the stroke nurse as well as weekly rounds with specialists in Physical and Rehabilitation Medicine.	Not specified, but implied.
Routine protocols	Each patient was investigated in a standardized manner including repeated clinical assessments, computerised tomography of the brain and blood and spinal fluid tests. There was early detection and uniform management of deterioration and secondary complications. There was routine very early and determined rehabilitation.	A standardized program for diagnostic evaluation, acute treatment and rehabilitation was used. A team approach to diagnosis and functional evaluation followed by a systematic program for recovery of function was used. Rehabilitation was commenced within twenty-four hours of admission.
Family involvement	There was active participation of family members in rehabilitation efforts as well as education of patients and family members.	A specific nurse was designated to provide information to patients and relatives.
Regular education	There was a program of staff education to improve knowledge of stroke and to promote a dedicated attitude towards stroke care.	The staff were trained in the rehabilitation of stroke.

1.4. IMPLICATIONS FOR OUR SETTING

There are two important points to consider when assessing the generalisability of the findings of the systematic overview of organised inpatient care after stroke.

Firstly, only one [41] of the many trials reviewed in the systematic overview on organised inpatient care after stroke was carried out in the Southern Hemisphere (Hankey et al [41] reported a small trial from Perth in 1997). There have been no trials of organised inpatient care after stroke from any economically developing country.

Secondly, only one of the trials of organised inpatient care after stroke (by Ilmavirta et al, Finland, 1993) had an intervention that only consisted of acute care after stroke. The intervention in the reviewed trials was either combined assessment and rehabilitation or purely rehabilitation for either, stroke patients only or stroke patients combined with other disabled patients.[64]

A number of other factors are important to consider when considering implementing organised inpatient care after stroke in our setting. There is currently an enormous pressure on acute hospital beds. In fact during the design phase of this investigation, the number of Medical Firms in the Department of Medicine, at Groote Schuur Hospital was reduced from five to four.

This pressure also exists for rehabilitation beds in the community. Again, at the time of the design of this investigation, one of the three hospitals providing inpatient rehabilitation services for all patients was facing closure due to the limited resources.

The incidence and prevalence of stroke and vascular risk factors and the age of the population is increasing in the developing world. The burden of stroke in Southern Africa is significant and is increasing. Stroke and the risk factors for stroke are not adequately managed. Despite an expressed need, no programme to assess the burden of stroke, co-ordinate the available resources and formulate a comprehensive stroke programme exists.

Demonstrating that effective organised inpatient care after stroke is feasible in our setting is an important hurdle to cross. It would be important to monitor the impact of such a service on the cost of care for stroke, as resources continue to be limited and health planners in the economically developing world face the challenge of improving the health of the population despite limited resources.

Once the feasibility and cost implications of organised inpatient care after stroke have been demonstrated, health planners should be encouraged to employ an evidenced-based decision-making approach to implement interventions of proven effectiveness.

Figure 1.3. Advantages of stroke unit care

- development of medical, nursing and therapist expertise in the management of stroke patients
- improved prevention, detection and treatment of stroke complications (such as aspiration, chest infection, urinary tract infections, pressure sores, deep vein thrombosis and pulmonary thrombo-embolic disease)
- improved early management of stroke risk factors
- training of new and junior staff
- increased understanding among the team members of each others roles

Figure 1.4. Possible mechanisms by which stroke units improve outcomes

- improved diagnosis
- focused rehabilitation
- prevention and early proactive management of complications
- early secondary prevention
- improved staff expertise

2. METHODS

The overall purpose of the study was to improve the quality of acute stroke care in the general medical wards at Groote Schuur Hospital. This entailed reviewing the literature to establish the most effective interventions and establishing the feasibility of implementing these interventions in our setting.

2.1. AIMS

The aim of the study was to determine whether 'stroke unit care' or 'organised care' of acute stroke patients within a general medical ward improves outcomes.

2.2. OBJECTIVES

The study objectives were: —

(i) to implement organised stroke care (the intervention);

(ii) to measure stroke outcomes;

(iiia) to examine the effect of the intervention on stroke outcomes;

(iiib) to examine the effect of the intervention when provided as written guidelines;

(iv) to compare these with similar stroke patients who did not receive the intervention (the control group) and

(v) to examine the effectiveness and efficiency of the intervention.

Stroke/Health Outcomes included dependency (as measured by activities of daily living), mortality and institutionalisation at discharge and follow-up.

Efficiency of care refers to appropriate access to the correct health care professionals within as short a length of hospital stay as possible.

2.3. STUDY DESIGN

The study was a quasi-experimental controlled clinical trial with between-ward comparisons, in which the unit of allocation (ward) was systematically allocated to three arms:—

- Routine care (Control Ward);
- Guidelines Ward (ward staff provided with written guidelines, but no other input) and
- Stroke Intervention Ward.

2.3.1. Setting

The study was conducted within each of the four Medical Firms of the Department of Medicine at Groote Schuur Hospital, an academic tertiary referral hospital with a significant secondary level function. Each firm had three full-time consultants and three part-time consultants; two registrars and two to three interns. Each of the firms had approximately thirty-two beds.

2.3.2. Population and Sampling

The study population includes all acute stroke patients who 'drain to' the Groote Schuur Hospital. The study sample included all acute stroke patients who presented to the Emergency Unit and who were admitted to one of the four Medical Wards at Groote Schuur Hospital between 1 January and 15 May 1996.

Two variables were used to estimate sample size using EPI INFO's statcalc function for an unmatched cohort study. Using 95% confidence and 80% power, it was calculated that:—

- a sample size of 124 (93 exposed and 31 unexposed) was needed to show an improvement in the referral rate to occupational therapy from 45% to 75%;
- a sample size of 736 (184 exposed and 552 unexposed) was needed to show a decrease in the case fatality rate from 19% to 10%;
- a sample size of 928 (232 exposed and 696 unexposed) was needed to show a decrease in the case fatality rate from 34% to 24% and
- a sample size of 5856 (1464 exposed and 4392 unexposed) was needed to show a decrease in the case fatality rate from 34% to 30%.

For practical purposes, it was planned to included 200 patients over approximately five to six months.

2.3.3. Inclusion Criteria

The clinical diagnosis of an acute stroke, as well as a decision to admit the patient, by a Medical Officer in the Emergency Unit were the only entry criteria. Patients who presented with Transient Ischaemic Attacks (TIAs) were excluded. Patients with acute stroke who were discharged from the Medical Admissions Ward were also excluded from the study.

2.3.4. Intervention

The intervention, "organised stroke care" was applied by the author in the Stroke Intervention Ward and guidelines describing the implementation of the interventions were supplied to the Guidelines Ward. This made it possible to assess the impact of an intervention in the "real world" against an "ideal environment", where there is interest in and enthusiasm for organised stroke care.

The Stroke Intervention Ward medical staff consisted of the author and one of the supervisors (SJL) as the additional staff, who, with support from existing medical staff, assumed full responsibility for all stroke patients within one of the medical firms.

Professionals Allied to Medicine included social workers, community liaison sisters, occupational, speech and physiotherapists as well as a dietician. Each professional usually covered two medical wards (firms).

The Guidelines Ward was where the three individual interventions, as described in a booklet could have been implemented by regular staff in the medical ward. They had access to the author if advice was required at any stage.

2.3.4.1. Definition of the Intervention

The following three components make up the managerial intervention of organised stroke care:—

- organisational changes,
- Stroke Clerking Pro forma and
- Post-intake Stroke Ward Round and the Team Care Plan.

The arms of the study and the components of the intervention are summarised in Figure 2.1.

Figure 2.1. The arms of the study and components of the intervention

Stroke Intervention Ward
• Organisational changes
  • Spatial/Geographic unity
  • Designated Nurse
• Stroke Clerking Pro forma
• Post Intake Stroke Ward Round and Team Care Plan

Guidelines Ward • A written description of the intervention and how to implement the intervention
Control Wards • Routine general medical ward care

2.3.4.1. Organisational Changes

Spatial/Geographic Unity

All stroke patients (male and female) were nursed in a single side ward (a 4-bed cubicle). There were seldom more than four stroke patients admitted on one intake. When required one side of the larger eight bed components of the ward was used.

Designated Nurse (DN)

Designated nurses were responsible for most of the care of all stroke patients (with help, when needed). This approach to stroke care was preferred in comparison to (i) all nursing staff caring for most of the patients in ward and to (ii) purely task oriented care.

There was a two-tier system where the lower tier nurse was a designated nurse of any rank (staff nurse or enrolled nurse) and the higher tier/supervisory nurse was a designated sister (Registered Nurse).

The DN initiated (i.e. completed the registration of) the Team Care Plan (see below) on admission to the Medical Ward. In a similar manner, one of the sisters (Registered Nurses) was responsible for supervising the care of stroke patients.

Such dedication of staff was thought likely to facilitate continuity of care, co-ordination of rehabilitation and discharge planning with the Professionals Allied to Medicine and hence an improvement in interdisciplinary communication and team functioning. When

hand-over to the next day shift occurred, the DN was responsible for handing over to the next DN.

2.3.4.2. The Stroke Clerking Pro forma

The Stroke Clerking Pro forma [69] of the Royal College of Physicians (RCP) Research Unit and The Stroke Audit Group was developed after initial audits [34] of care highlighted the poor quality of acute stroke care in the United Kingdom. General guidelines were not specific enough and hence certain standards were set. The clerking sheet was developed according to these standards.

The clerking pro forma has been shown [69] to improve the completeness of the recording of the assessment of hospitalised stroke patients. It particularly highlights the neurological features that have been found to be of prognostic significance. These features have previously been shown to be poorly documented by general physicians in their assessments of stroke cases.[34] The RCP Stroke Clerking Pro forma (Appendix A) was adapted for use in our setting by the author. The admitting ward medical staff were encouraged to use the Stroke Clerking Pro forma when they clerked cases in the medical admission ward. **This replaced the existing general medical clerking pro forma.** The clerking pro forma guides one through the entire medical clerking process. It includes items that prompt a detailed general and neurological assessment, baseline investigations, referrals to Professionals Allied to Medicine, setting dicharge and rehabilitation goals/plans etc.

The usual discharge summary was modified to include arrangements for post discharge rehabilitation, and it was attached to the front of the clerking pro forma.

2.3.4.3. Post Intake Stroke Ward Round and Team Care Plan

The Post Intake Stroke Ward Round

This short multi-disciplinary, bedside ward round occurred on the day after each intake day. It was attended by all Professionals Allied to Medicine, including the community liaison sister, the social worker, the physio-, occupational and speech therapists as well as the designated nurse (DN), ward sister and medical staff. The functions of the round included case presentation and triage, goal setting and discharge planning as well as appropriate documentation. These are all described in detail in the guidelines supplied to the Guidelines Ward (Appendix B).

This process was easy to set up and involved a ten to thirty minute time commitment on the part of the treating staff who are usually in the ward on the post intake day.

The Team Care Plan

This crucial four-page document was developed in a pilot workshop involving the staff of the intervention ward. The Team Care Plan (TCP) (Appendix C) was developed jointly by a multi-disciplinary team with experience and interest in stroke management. The team felt that it had the potential to co-ordinate and guide the comprehensive and efficient management of acute stroke patients. It was perceived as being concise and yet

highly informative. It was placed in the nursing process file at the foot of the patient's bed and was therefore within easy access of all team members at all times.

The TCP had a number of perceived benefits. It was likely to:—

- improve the awareness and understanding of the input and functions of each team member, both in general and specifically for each patient;
- improve interdisciplinary communication;
- facilitate the setting and achievement of realistic goals in a coherent and co-ordinated manner;
- serve as a check list ensuring that every patient need had been addressed, thus highlighting `gaps' or deficiencies as well as `overlaps' in the service.

The various sections of the TCP included (i) patient registration details, (ii) functional evaluation, (iii) therapists' comments and (iv) a discharge and education check list. The notes on how and by whom each section of this document should have been completed was described in the Guidelines (Appendix B).

2.3.5. Assignment of Intervention

The intervention ward was systematically (non-randomly) assigned on the grounds that the Wednesday Firm had a work schedule that best suited the author. Thus, the intervention was allocated as follows:

Monday Firm Ward G16	Guidelines Ward
Tuesday Firm Ward G5	Control Ward
Wednesday Firm Ward G8	Stroke Intervention Ward
Thursday Firm Ward G7	Control Ward

Another feature that was considered was an attempt to minimise "contamination" (uncontrolled flow of information and change in behaviour*{performance bias}*) when allocating the Guidelines and Control Wards. The hospital is an H shape structure, as shown in Figure 2.2., with each side of the H being made up of two wards. Therefore, we allocated the Guidelines to the ward adjacent to the Intervention Ward, so that contamination would be reinforcement to the implementation of the Guidelines.

2.3.6. The Guidelines

The Stroke Clerking Pro forma and the Team Care Plan should have been used with the suggested Organisational Changes as described in "Guidelines for Management of Acute Stroke" (Appendix B). This booklet was handed to the Head Nurse in the Guidelines Ward for circulation to all members of the multi-disciplinary team working in the Guidelines Ward.

2.3.7. Contamination

The possibility of "contamination" by staff resulting in the intervention being implemented in other wards *(performance bias)* was considered. There could have been contamination from the stroke intervention ward to the guidelines ward or to the control ward or even from the guidelines ward to the control ward.

Figure 2.2 The layout of the Intervention, Guidelines and Control Wards

Other Ward		Other Ward
Common Reception Area	Common Corridor	Common Reception Area
Intervention		Ward G 4
Guidelines		**Control**
Common Reception Area	Common Corridor	Common Reception Area
Other Ward		**Control**

Contamination resulting from the use of the Guidelines and clerking pro forma in the control wards was minimised by physically ensuring that the forms were not available to the staff in these wards.

In a further attempt to reduce the likelihood to contamination, "out-liers", which are patients in wards other than that of their managing firm, were by agreement restricted to non-stroke patients.

A further source of contamination could have been staff changes (frequent within the Nursing Department) and cross-cover (Professionals Allied to Medicine usually have the responsibility to cover more than one ward). In this case we felt that that there was little doubt that the numerous elements of efficient team functioning produced the end result in unison. We therefore thought that this source of contamination was unlikely to be significant.

2.4. MEASUREMENT

2.4.1. Baseline patient characteristics (inputs)

In order to assess the comparability of patients entered, the following variables were measured at baseline (i.e. on admission):—

- the date of birth;
- the Modified Barthel Index [70] prior to admission;
- the level of consciousness at the time of first contact after admission;
- the state of urinary continence [71] during the first 48 hours and

- history of previous stroke.

2.4.2. System outcome measures (process measures)

An audit of the documentation of the medical clerking process was undertaken to derive the following measures of efficiency of care: —

- the inpatient referral rates to all the Professionals Allied to Medicine;
- the referral rates to all Professionals Allied to Medicine on discharge and
- the length of hospital stay.

2.4.3. Health outcome measures (outcomes)

The following health outcome measures were determined at discharge and at follow-up:—

- mortality as a case fatality rate;
- morbidity as measured by the Modified Barthel Index [70], a measure of the ability to perform the activities of daily living independently and
- institutionalisation.

2.4.4. Data Collection

2.4.4.1. In-patient data collection routine

A trained Research Nursing Sister collected the in-patient data. The Research Nurse collected data daily. She used the following validated instruments as part of a structured questionnaire:—

- the Modified Barthel Index [70] and

- our adaptation of the RCP Stroke Audit Pro Forma.[72]

The Modified Barthel Index was used to measure the morbidity in terms of the activities of daily living and has been shown to be reliable and valid [70] in Australia. It has been shown to be particularly sensitive measure of ADL in patients with stroke. The Stroke Audit Pro Forma had been validated in the United Kingdom and shown to have good inter-observer reliability.[73,74] The audit form was modified appropriately. Both instruments were used according to their published guidelines. [70,72]

Stroke patients were identified from the admissions register in the Medical Admissions Ward. The first contact with the patient occurred in this ward and the following were determined at this point:—

- the level of consciousness,
- history of stroke/transient ischaemic attack and
- the pre-admission Modified Barthel Index.

The level of consciousness was ascertained by direct observation at the time of first contact after admission and was graded as:—

- grade 1 = conscious,
- grade 2 = drowsy/confused or
- grade 3 = unconscious/comatosed.

The history of stroke was determined by asking the patient/carer or from the medical notes. The ADL score was determined by interviewing the patient or the carer. Where the carers were not present, the research nurse made telephonic contact with them and arranged to interview them at an agreed time.

The patients were then flagged until discharge, i.e. the research nurse made regular contact with patients and ward staff until discharge. Upon discharge, the research nurse would interview the patient/family to establish:—

- the discharge destination,
- the Modified Barthel Index and
- the correct address and telephone number.

Incontinence was assessed either by the research nurse, directly (at the point of first contact, where it was only recorded if the patient was catheterised) or by scrutinising the nursing records at the time of discharge. The frequency of wetting during the first 48 hours of admission was recorded as grades 1-4:—

- grade 1 = dry;
- grade 2 = one episode/24 hours;
- grade 3 = 2 or more episodes/24 hours or
- grade 4 = catheterised.[68]

Following the usual hospital procedure, once patients were discharged their records were collated and filed in the ward until a formal discharge summary was dictated. The

research nurse then audited the documentation of each patient's entire hospital stay. Where necessary, PAM (Professionals Allied to Medicine) and radiology department records were examined.

2.4.4.1.1. Sub-routine to examine bias

The Stroke Audit Pro Forma was originally developed using the Stroke Clerking Pro forma and they therefore resemble each other. This made auditing of the patient documentation in the intervention ward where the Stroke Clerking Pro forma was used, considerably easier than in the other wards where the usual medical clerking sheet was used.

In order to determine whether the use of the Stroke Clerking Sheet influenced the audit of the patients' hospital notes, the Research Nurse audited two sets of identical patient notes. One was the actual patient record in the original format (i.e. stroke clerking sheet versus routine medical clerking booklet), the other was the exact documentation written out in the other format. This exercise was done on a sample of patients and only on part of the clerking sheet.

2.4.4.2. Follow-up data collection routine

A second trained research assistant (in most cases) and an occupational therapist (in a few cases) followed up patients between 3-5 months after discharge. The second interviewer was trained by an occupational therapy lecturer and the author to assess the activities of daily living using the Modified Barthel Index. A Xhosa speaking occupational therapist

interviewed patients whose first language was Xhosa. Both research assistant and the occupational therapist were blinded as to the intervention status of patients.

All patients (or carers of patients) who were discharged alive were contacted by telephone (where available). If alive, their consent to be interviewed was obtained and their exact address and any preferred time of interview was confirmed. If deceased, their date of death was recorded. Patients for whom no telephone number had been documented were visited at their given addresses.

Ten patients were not interviewed in their homes by choice. These patients had a normal Modified Barthel Index at discharge and were therefore unlikely to require/utilise rehabilitation resources in the community. In order to ensure that this did not result in any bias, these patients were contacted by telephone (where available) to ascertain two of the main outcome measures (mortality and institutionalisation). Patients in this category with no documented telephone number were assumed to be lost to follow-up.

After all contactable patients had been interviewed, twenty five patients were still not interviewed. This was either because they lived outside of the Cape Town metropolitan area or because their address could not be found. In order to minimise the potential bias resulting from this large number of patients possibly lost to follow-up we contacted them by telephone (where available) to ascertain 2 of the main outcome measures (mortality

and institutionalisation). The remainder (those with no documented telephone number) were assumed to be lost to follow-up.

2.4.4.2.1. Inter observer reliability of the research assistant

Of those non-Xhosa speaking patients with telephones, 18 were randomly selected and components of the follow-up questionnaire were repeated telephonically by the author in order to assess reliability.

2.5. THE PILOT STUDY

The initial phase commenced in October 1995. The main objectives were :—

- to establish a routine procedure for implementation of the organisational changes in the intervention ward;
- to develop a suitable document for use by all team members caring for stroke patients, the Team Care Plan;
- to ensure that the flow of stroke patients from the emergency unit to the medical admissions ward to the medical wards was according to agreed criteria.

These objectives were achieved timeously. A number of meetings were held with representatives of the PAM Departments, Nursing Division and the Heads of the Medical Firms to familiarise these essential role players with the aims of the study. A series of presentations and workshops was then held with the staff of the Intervention Ward to familiarise them with the aims. In this time, the interventions were applied to varying degrees and data was not collected.

3. RESULTS

Figure 3.1. shows a breakdown of the patients entered. During the study period 257 possible stroke patients were entered from the Emergency Unit and Medical Admissions Ward registers. Of these, 62 patients were excluded due to incorrect diagnoses (including cerebral metastasis, epilepsy, drug overdose, and previous strokes). Ninety seven percent (189) of the remaining 195 patients with acute stroke were studied. Of these 58 patients (31%) were admitted to the Stroke Intervention Ward, 40 patients (21%) to the Guidelines Ward and 91 patients (48%) to the 2 Control Wards.

Thirty-eight patients (20%) had died in hospital and of the remaining 151 patients (80%), 132 patients (87%) were followed-up and 19 patients (13%) could not be traced and were lost to follow-up.

Of the 132 patients followed up, 23 had died after discharge and the total number of patients dead at follow-up was thus 61 (32%). One hundred and nine patients were interviewed at follow-up and 128 patients were assumed alive at follow-up.

Table 3.1. shows the baseline characteristics of the groups studied. There were no significant differences between the groups with regard to the mean age, the proportion of patients who were male, had a normal level of consciousness, whose first stroke it was, who had had previous transient ischaemic attacks or who were independent prior to the

current stroke. However, a considerably higher proportion of patients admitted to the Stroke Intervention Ward were continent of urine on admission. Table 3.2. shows the functional dependence of patients in the three comparison groups, as measured by the Modified Barthel Index, before admission, at discharge and at follow-up.

The length of hospital stay by comparison group, as seen in Table 3.3., shows a considerably reduced stay in the Stroke Intervention Ward.

Table 3.4. summarises the principal outcome measures. Death, dependency, death or dependency, institutionalisation and death or institutionalisation are shown as proportions with confidence intervals. As seen there are no differences between the comparison groups with regard to these measures.

Table 3.5. and 3.6. show key process measures. Table 3.5. summarises the proportion of patients referred to rehabilitation services in hospital and on discharge. The proportion of patients referred to the Professionals Allied to Medicine was higher in the stroke intervention group compared to the guidelines group and compared to the control group for occupational therapy, speech therapy and social work. Referrals to the community liaison sister were similarly high in all the comparison groups.

The proportion of patients referred for physiotherapy in hospital was similar in the Stroke Intervention and Guidelines Wards but significantly less in the Control Wards. Surprisingly, the proportion of patients referred for physiotherapy on discharge was

considerably less in the Stroke Intervention and Guidelines Wards compared to the Control Wards. Similar proportions of patients from each of the comparison groups were referred for admission to one of the rehabilitation hospitals.

The proportion of patients who were clerked and assessed using the Stroke Clerking Pro forma and the Team Care Plan in the Stroke Intervention and Guidelines Wards is shown in Table 3.6. The comparison groups had similar proportions of patients in whom a CT scan was performed and who had specific documentation of plans to manage fluid intake. Similar proportion of patients had documented plans for the management of urine incontinence in the Stroke Intervention and Guidelines Wards, however, considerably less patients had similar plans documented in the Control Wards.

A considerably higher proportion of patients in the Stroke Intervention Ward had documented evidence of consultant review, re-assessment of functional status and the results of multi-disciplinary meetings.

Table 3.7. shows the mean time to follow-up in the Stroke Intervention, Guidelines and the Control Wards.

Table 3.8. shows the agreement between the research nurse's folder audit of patient documentation using two formats of the same documentation. There was very good agreement between the research nurse's audit of patient documentation using the Stroke Clerking Pro forma and the routine medical clerking sheet.

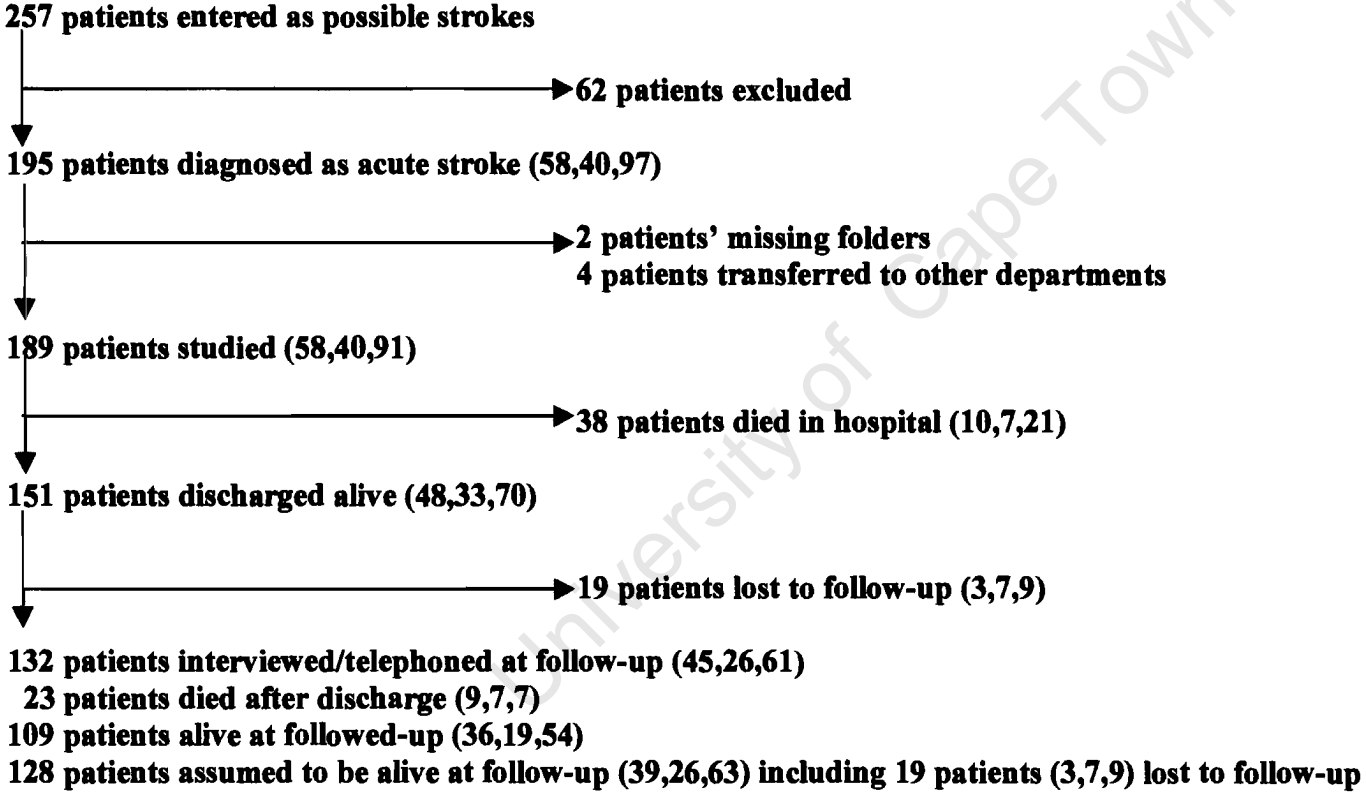
Table 3.9. shows the inter-observer agreement for mortality, institutionalisation and rehabilitation resource use at follow-up.

The characteristics of the patients lost to follow-up are shown in Table 3.10. There are no significant differences in the characteristics of these patients by intervention group.

Table 3.11. shows the principal outcome measures under two scenarios. The first scenario, as presented in Table 3.4., assumes that all patients (i.e. patients from all the comparison groups) lost to follow-up are alive. The second scenario assumes that all patients lost to follow-up in the Stroke Intervention Ward achieved negative outcomes and that all patients lost to follow-up in the Guidelines and Control Wards achieved a positive outcome. In the later scenario, therefore, only the numerators (event rates) change in the Stroke Intervention Group.

Figure 3.1. Breakdown of patients studied by intervention group

$N(n_{intervention}, n_{guidelines}, n_{control})$



132 patients interviewed/telephoned at follow-up (45,26,61)
23 patients died after discharge (9,7,7)
109 patients alive at followed-up (36,19,54)
128 patients assumed to be alive at follow-up (39,26,63) including 19 patients (3,7,9) lost to follow-up

Table 3.1. Baseline characteristics of patients studied by intervention group

	Intervention	Guidelines	Control
	58 (31%)	40 (21%)	91 (48%)
median age (years)*	62.2 (52.7–70.6)	65.8 (56.8–73.2)	60.7 (52.2–69.0)
male patients	24(0.41;0.34-0.48)	17 (0.43;0.35-0.50)	40 (0.44;0.37-0.51)
normal level on consciousness	34 (0.59;0.52-0.66)	20 (0.50;0.43-0.57)	52 (0.57;0.50-0.64)
continent of urine on admission	30† (0.52;0.45-0.59)	11 (0.28;0.21-0.34)	29 (0.32;0.25-0.39
first stroke	40 (0.69;0.62-0.76)	27 (0.68;0.61-0.74)	54 (0.59;0.52-0.66)
previous TIAs	2† (0.03;0.01-0.06)	3 (0.08;0.04-0.11)	11 (0.12;0.07-0.17)
patients independent prior to the stroke	42 (0.72;0.66-0.79)	31 (0.78;0.72-0.83)	59 (0.65;0.58-0.72)

Notes:

- Results are presented as N (proportion; 95% confidence intervals), except for age, which is presented as median (inter-quartile range);
- **Kruskal-Wallace Test:** $\chi^2 = 0.3.8196$, DF = 2; p = 0.1481;
- † denotes proportions that fall out of the confidence intervals of one of the comparison groups.

Table 3.2. Modified Barthel Index prior to admission, at discharge and follow-up

	Intervention	Guidelines	Control
pre-admission*			
median (IQR)	100 (99.5–100)	100 (100–100)	100 (95–100)
mean ± std deviation	91.1±21.7	91.8±21.4	93.2±17.5
range	86	100	100
	* **Kruskal-Wallace Test:** $\chi^2 = 0.9044$, DF = 2; p = 0.6362		
discharge†			
median (IQR)	59 (25–81)	40 (6–71)	63 (9–90)
mean ± std deviation	54.0±33.4	41.6±34.4	52.9±38.3
range	100	100	100
	† **Kruskal-Wallace Test:** $\chi^2 = 3.22$, DF = 2; p = 0.1999		
follow-up‡			
median (IQR)	97.5 (66–100)	89 (46–98)	85 (44–98)
mean ± std deviation	79.4±31.0	72.6±30.8	68.7±34.4
range	99	85	99
	‡ **Kruskal-Wallace Test:** $\chi^2 = 3.60$, DF = 2; p = 0.1654		

Abbreviations: IQR = inter-quartile range; std = standard

Table 3.3. Length of hospital stay (in days) by intervention group

	Intervention	Guidelines	Control
median (IQR)	6.5 (5–9)	9 (7–14)	8 (5–12)
mean ± std deviation	7.5±3.9	10.8±6.5	9.9±7.9
range	21	29	38

Notes:

- **Kruskal-Wallace Test:** $\chi^2 = 6.4517$, DF = 2; p = 0.0397;
- **Abbreviations**: IQR = interquartile range

Table 3.4. Principal outcome measures: death, dependency, death or dependency, institutionalisation and death or institutionalisation at discharge and at follow-up of stroke patients treated in the intervention, guidelines and control wards

	Discharge			Follow-up		
	Intervention (n=58)	Guidelines (n=40)	Control (n=91)	Intervention (n=58)	Guidelines (n=40)	Control (n=91)
Dead	10 (0.17;0.12–0.23)	7 (0.18;0.06–0.29)	21 (0.23; 0.14–0.32)	19 (0.33;0.26–0.39)	14 (0.35;0.28–0.42)	28 (0.31;0.24–0.37)
Dependent	43 (0.74;0.68–0.80)	32 (0.80;0.74–0.86)	59 (0.65;0.58–0.72)	21 (0.36;0.29–0.43)	17 (0.43;0.35–0.50)	34 (0.37;0.30–0.44)
Dead or dependent	53 (0.91;0.87–0.95)	39* (0.98;0.95–1.00)	80 (0.88;0.83–0.93)	40 (0.69;0.62–0.76)	31 (0.78;0.72–0.83)	62 (0.68;0.61–0.75)
Institutionalization	0	2 (0.05;0.02–0.08)	2 (0.02;0–.04)	3 (0.05;0.02–0.08)	2 (0.05;0.02–0.08)	6 (0.07;0.03–0.10)
Dead or institutionalized	10 (0.17;0.12–0.23)	9 (0.23;0.17–0.28)	23 (0.25; 0.19–0.31)	22 (0.38;0.31–0.45)	16 (0.4;0.33–0.47)	34 (0.37;0.30–0.44)

Notes:

- Results are presented as N (proportion; 95% confidence intervals);
- denotes proportions that fall out of one or both of the confidence intervals of the comparison groups.

Table 3.5. Referrals to rehabilitation services in hospital and on discharge for the intervention, guidelines and control wards

	In hospital			On discharge		
	Intervention	Guidelines	Control	Intervention	Guidelines	Control
Occupational therapist	41*	22	36	29*	7	26
	(0.95;0.91–0.99)	(0.73;0.66-0.80)	(0.53; 0.45–0.61)	(0.76;0.68–0.84)	(0.33;0.26–0.40)	(0.46;0.38–0.54)
physiotherapist	37	27	42*	3	1	10*
	(0.86;0.80–0.92)	(0.87;0.81-0.93)	(0.61;0.53–0.69)	(0.10;0.04–0.16)	(0.07;0.02–0.12)	(0.21;0.13–0.29)
speech therapist	28	20	26*	19*	2	8
	(0.78;0.71–0.85)	(0.71;0.63-0.79)	(0.40;0.32–0.48)	(0.58;0.49–0.67)	(0.11;0.05–0.17)	(0.14;0.07–0.21)
community liaison sister	39	27	64	–	–	–
	(0.70;0.63–0.77)	(0.69;0.62-0.76)	(0.72;0.66–0.78)			
social worker	17	7	8*	–	–	–
	(0.30;0.23–0.37)	(0.03;0.12-0.24)	(0.08; 0.04–0.12)			
rehabilitation hospital	–	–	–	21	13	26
				(0.44;0.36–0.52)	(0.39;0.31–0.47)	(0.37;0.29–0.45)

Notes:

- Results are presented as N (proportion; 95% confidence intervals);
- * denotes proportions that fall out of one or both of the confidence intervals of the comparison groups.

Table 3.6. Key process measures according to documentation for patients studied by intervention group

	Intervention	Guidelines	Control
	58 (31%)	40 (21%)	91 (48%)
Stroke Clerking Pro forma used	55* (0.95;0.91-0.99)	13 (0.33;0.24-0.41)	-
Team Care Plan used	51* (0.88;0.82–0.94)	10 (0.04;0.17–0.33)	–
CT scan performed	29 (0.50;0.43–0.57)	24 (0.60;0.53–0.67)	53 (0.58;0.51–0.65)
specific plans to manage hydration	34 (0.94;0.91–0.98)	34 (0.89;0.85–0.94)	76 (0.88;0.83–0.93)
specific plans to manage incontinence	23* (0.88;0.82–0.95)	20 (0.83;0.76–0.91)	37 (0.70;0.61–0.79)
consultant review	28* (0.52;0.45–0.59)	6 (0.15;0.10–0.20)	27 (0.31;0.25–0.38)
re-assessment of functional status	43* (0.90;0.85–0.94)	23 (0.74;0.67–0.81)	49 (0.69;0.62–0.76)
results of multi-disciplinary meetings	36* (0.72;0.65–0.79)	5 (0.16;0.10–0.22)	3 (0.04;0.01–0.08)

Notes:

- Results are presented as N (proportion; 95% confidence intervals).
- denotes proportions that fall out of the confidence intervals of one of the comparison groups.

Table 3.7. Time (in days) to follow-up after stroke and discharge

	Intervention	Guidelines	Control
Since discharge*			
median (IQR)	131 (90–180)	98 (82–137)	142.5 (95–176)
mean ± std deviation	144.2±72.9	119.0±59.7	158.1±84.8
range	278	237	366

* **Kruskal-Wallace Test:** $\chi^2 = 5.45$, DF = 2; p = 0.0655

Since admission†			
median (IQR)	139 (95–195)	112 (87–148)	155 (104–192)
mean± std deviation	151.6±75.0	129.6±61.9	167.3±84.8
range	285	237	359

† **Kruskal-Wallace Test:** $\chi^2 = 5.57$, DF = 2; p = 0.0617

Abbreviations: IQR = inter-quartile range; std = standard

Table 3.8. Agreement between research nurse's folder audit of patient documentation using two formats of the same documentation (the Stroke Clerking Pro Forma and routine medical clerking sheets)

N=8	Kappa	se	95% CI
Consultant review	0.7	0.31	0.09–0.88
review of neurological deficits	1	0.35	0.31–1.62
patient not for active management	1	0.35	0.31–1.62
referral to occupational therapy	0.71	0.34	0.04–0.80
referral to physiotherapy	0.81	0.25	0.32–1.44
referral to speech therapy	0.81	0.25	0.32–1.44
referral to community liaison sister	1	0.35	0.31–1.62

Abbreviations: se = the standard error of kappa; CI = confidence intervals

Table 3.9. Inter-observer agreement for mortality, institutionalisation and rehabilitation resource use at follow-up

N=18	Kappa	se	95% CI
Alive or not*	/	/	/
living arrangement*	/	/	/
admission to rehabilitation hospital	1	0.24	0.0.53–2.0
rehabilitation hospital admitted to	1	0.18	0.65–2.27
occupation therapist consulted	0.77	0.24	0.30–1.36
physiotherapist consulted	0.64	0.24	0.17–0.97

Notes:

- * unable to calculate due to more than 2 cells empty

Table 3.10. Characteristics of patients lost to follow-up by intervention group

	Intervention	Guidelines	Control
	3 (0.05;0.02–0.08)	7 (0.18;0.12–0.23)	9 (0.10;0.06–0.14)
median age (years)*	40.9 (37.8–66.3)	57.3 (51.2–62.1)	55.3 (43.5–62.6)
male patients	1 (0.33;0.12–0.55)	3 (0.43;0.21–0.65)	3 (0.33;0.12–0.55)
normal level of consciousness	2 (0.67;0.45–0.88)	4 (0.57;0.35–0.79)	7 (0.78;0.59–0.96)
continent of urine on admission	2 (0.67;0.45–0.88)	2 (0.29;0.08–0.49)	5 (0.56;0.33–0.78)
first stroke	2 (0.67;0.45–0.88)	2 (0.29;0.08–0.49)	9 (1)
previous TIAs	0†	2 (0.29;0.08–0.49)	0†
patients independent prior to the stroke	2 (0.67;0.45–0.88)	5 (0.71;0.51–0.92)	8 (0.89;0.75–1.03)
patients independent at discharge	0†	1 (0.14;-0.01–0.3)	2 (0.22;0.04–0.41)
Modified Barthel Index at admission*	100 (32–100)	100 (92–100)	100 (100–100)
Modified Barthel Index at discharge*	52 (0–92)	40 (11–98)	76.5 (69–92)
length of hospital stay*	8 (8–10)	8 (4–17)	9 (6–10)

Notes:

- * indicates results are presented as N (inter-quartile range) otherwise results are presented as N (proportion; 95% confidence intervals)
- † denotes proportions that fall out of one or both of the confidence intervals of the comparison groups.

Table 3.11. Comparison of summary outcome measures at follow-up by intervention group under two different scenarios

	Follow-up†			Follow-up‡		
	Intervention (n=58)	**Guidelines (n=40)**	**Control (n=91)**	**Intervention (n=58)**	**Guidelines (n=40)**	**Control (n=91)**
Dead or dependent	40	31	62	[redacted]	31	62
	(0.69;0.62–0.76)	(0.78;0.72–0.83)	(0.68;0.61–0.75)	(0.74;0.68–0.80)	(0.78;0.72–0.83)	(0.68;0.61–0.75)
Dead or institutionalized	22	16	34	[redacted]	16	34
	(0.38;0.31–0.45)	(0.4;0.33–0.47)	(0.37;0.30–0.44)	(0.43;0.36–0.50)	(0.4;0.33–0.47)	(0.37;0.30–0.44)

Notes:

- Results are presented as N (proportion; 95% confidence intervals) and * denotes proportions that fall out of one or both of the confidence intervals of the comparison groups.
- †Assumes all patients lost to follow-up were alive, independent, living at home.
- ‡Assumes all patients lost to follow-up in the Intervention Ward achieved were dead, dependent or institutionalised and all patients lost to follow-up in the Guidelines and Control Wards were alive, independent and living at home.

4. DISCUSSION

4.1. DISCUSSION AND JUSTIFICATION OF METHODS

The validity of any study can be separated into two components; ***Internal validity*** is the validity of inferences drawn as they pertain to the study sample. ***External validity*** on the other hand, refers to the validity of inferences as they pertain to the study population.

Internal validity is a prerequisite for external validity or generalisation, which is the fundamental goal of scientific research.

These types of trials are subject to various sources of bias such as selection bias, which includes attrition bias, and information bias, which includes performance and detection/observation bias. This approach is suggested by the Cochrane Collaboration in systematic reviews randomised-controlled trials.

The bias in an open, non-randomised, controlled clinical trial, such as this study, as depicted in Figure 1.1, includes bias associated with informal randomisation and exclusion of patients after randomisation (*selection bias*), bias associated with the unblindedness of clinical staff (performance bias), bias associated with losses to follow-up (attrition bias) and finally bias associated with assessing the outcome *(observation/detection bias).*

4.2. INTERNAL VALIDITY CONSIDERATIONS

In this section of the discussion, the methods employed in this study are appraised in order to ascertain internal validity. The approach published by Guyatt et al[58] in the series 'Users guide to the medical literature' is used as a framework to allow an internal validity judgement of this study.

4.2.1. Was the assignment of patients to treatment groups randomised?

Randomised controlled trials maximise internal validity, by minimising the potential for bias in the allocation of patients to the comparison groups. Strict randomisation procedures ensure that the comparison groups are similar and thus avoid or minimise selection bias.

Allocation to treatment based on a strict roster system, as used in this study, is unlikely to have influenced the pre-treatment comparability of the groups. There is no evidence to suggest that average stroke severity differs by day of week.

In this trial, each of the four Medical Firms had a fixed day of admitting new patients and the three weekend days were shared. In this way patients, by presenting to the Emergency Unit on a particular day, automatically randomise themselves to a particular group. Informal randomisation is thus unlikely to have introduced selection bias in this study.

4.2.2. Were all patients who entered the trial properly accounted for in the conclusion?

The breakdown and flow of patients studied is shown in Figure 3.1. There were many exclusions prior to entry into the study. However, six patients were excluded after entry into the study and were not followed. Two patients were excluded because of missing documentation and a further four were excluded because they were transferred to other departments.

These patients had been allocated to the control group and their exclusion represents a form of selection bias. They were 'excluded' from further analysis because of criteria that could not be determined before treatment allocation. In other words, their treatment group allocation resulted in their later exclusion from the analysis. This is a form of selection bias.

An intention to treat analysis was therefore performed on ninety seven percent (189/195) of the patients who were randomised. This could have influenced the findings in both directions as these patients could have been substantially different (in either direction) from other patients in the study.

However, all six patients were most likely not representative of the patients in the study. If they achieved a positive outcome in favour of the control group, the treatment effect would have shifted in the direction of the null hypothesis. If they achieved a negative outcome, any treatment effect would be magnified. However, as these six patients

represent only three percent of all patients randomised, the treatment effect is unlikely to be altered significantly and this source of selection bias is unlikely to be significant.

4.2.2.1. Was follow-up complete?

Ten percent (95% Confidence interval (CI): 6–14%) of patients were not traced at follow-up. They were unequally distributed among the comparison groups: 5 percent (95% CI: 2–8%) of patients from the Stroke Intervention Ward, 18 percent (95% CI: 12–23) from the Guidelines Ward and 10 percent (95% CI: 6–14%) from the Control Wards were lost to follow-up. This implies that there is a relationship between the treatment group to which the patients were allocated and whether they were lost to follow-up or not.

There was likely an element of performance bias related to the numbers of patients lost to follow-up in each of the comparison groups. This was not due to awareness of the patients' intervention status among follow-up research staff. It was most likely due to diligent record keeping in the intervention ward, where the patients' given address (as per the hospital documentation) was always confirmed by the clinical staff. This was in addition to this usual practice by the research nurse in all the treatment groups.

The possibility of loss to follow-up could have been related to the disease severity at baseline, the outcome or the treatment, or a combination of these factors. Attrition bias definitely raises questions about the internal validity of the study, as patients who disappeared are likely to have different prognosis from those who were followed. The

greater the number of patients not traced at follow-up, the more questionable the internal validity of the trial. This is of particular concern when the event rate for one of the outcomes in this study is low (institutionalisation).

Patients who were lost to follow-up in this study might have achieved adverse outcomes (either death or institutionalisation) and consequently been untraceable or they could have achieved favourable outcomes. The main reason for loss to follow-up in this study was that the addresses recorded in the patient documentation could not be found. This is a common occurrence in Cape Town and relates to the retrieval of information by hospital clerks as well as the difficult address system used in the local townships. Patients who were lost to follow-up lived in areas where the addresses were hard to find, the township developments where they lived were informal or where entry into such an area posed a safety risk for the research assistant.

A sensitivity analysis was performed to examine the effect of loss to follow-up on the health outcomes. This could only be performed on categorical variables. The summary outcome variables, dead or dependent and dead or institutionalised were used.

We made two assumptions to conduct the sensitivity analysis. Firstly, we assumed that all untraceable patients in the Stroke Intervention Ward achieved a negative outcome (i.e. these patients were dead, dependent or institutionalised). Secondly, we assumed, that all untraceable patients in the Guidelines and Control Wards achieved a positive outcome (i.e. they were alive, independent and living at home). We then recalculated the

proportions of patients who were 'dead or dependent' and those who were 'dead or institutionalised'. The result of this exercise is summarised in Table 3.12. As can be seen, only the numerators (event rate) and the proportions changed. The results remain unchanged and show no differences between the comparison groups.

The wide confidence intervals and the small sample size of the study limit the likelihood of the sensitivity analysis resulting in a significant different result. The impact of patients lost to follow-up is therefore likely to be minimal in the context of this study.

4.2.2.2. Was an intention-to-treat analysis performed?

All patients were analysed in the group to which they were randomised. The study design did not allow for movement of patients between groups and thus this does not represent a source of bias.

4.2.3. Were patients, clinical and research staff blind to the intervention status of the patient? Were the groups similar at baseline?

In experimental studies where the intervention includes a range of services as opposed to a drug, it is not possible for patients, clinical or research staff to be blind as to the intervention status of the patients. The awareness of the intervention among staff in all the comparison groups will always introduce some changed behaviour.

Patients, clinical and research staff will, by being aware of the intervention, have an opinion as to the efficacy of the intervention. This opinion, pessimistic or optimistic, can systematically introduce information bias among patients, clinical and research staff.

In this trial randomisation was informal, based on a strict roster system. Bias in such a situation arises due to awareness among 'unblinded' clinical staff. This awareness could potentially change behaviour, such as the admitting practice for acute stroke patients who present to the Emergency Unit on the day, allocated to the Stroke Intervention Ward.

The baseline comparability of the comparison groups as shown in Table 3.1 shows that thirty-one percent of acute stroke patients were admitted to the Stroke Intervention Ward. This figure should really be closer to twenty-five percent. The equivalent figure for the Guidelines Ward is twenty one percent. So it is quite likely that some patients who were admitted to the Stroke Intervention Ward, may not have been admitted to hospital, if Emergency Unit staff were not aware of the study.

There may be a tendency for patients, families and primary care medical staff to delay admission until a Monday. In the case of stroke, a delayed admission could result in increased severity and worse prognosis. This source of information bias is unlikely in this study. The Monday Firm was the Guidelines Ward, which as mentioned admitted 21% of all patients (compared to an expected 25% of patients) entered in the study. Furthermore there was no difference in the proportion of patients with a normal level of

consciousness. A measure of time from the onset of stroke to admission would have definitively assessed delay in admission as a potential source of bias.

Having considered selection and information bias, were the groups similar at baseline?

Before considering baseline comparability, let's consider if appropriate measures of baseline severity were used in the study. Stroke severity at baseline is the most important predictor of outcome in stroke and direct measures of stroke severity, such as a neurological impairment scale would have been preferable. However, the accurate measurement of stroke severity, using scales such as the Scandinavian Stroke Scale, was not practical in the context of this study. Level of consciousness and urinary continence were used as surrogate measures for stroke severity.

The proportions of patients who were male, had a normal level of consciousness, whose first stroke it was and who had a history of transient ischaemic attacks were generally similar in all three comparison groups. However, the proportion of patients who were continent was significantly higher in the Stroke Intervention Ward.

This could be due to differences in stroke severity, of which incontinence is an indicator, between the groups or due to the more proactive approach to managing incontinence in the intervention ward. As discussed earlier (section 2.4.4.1) incontinence was graded at admission only if the patient was catheterised. Patients not catheterised were assessed by

reviewing the recorded number of wet episodes during the first forty-eight hours of admission.

A more diligent timed voiding programme for patients in the Stroke Intervention Ward could well have accounted for this difference. In the light of these several factors that served to heighten the detection rate and recording of incontinence in the Stroke Intervention Ward, it seems possible that continence was not more common in this limb of the study, but more proactively managed.

Observation bias results from systematic differences in the way information was obtained in the comparison groups and could have occurred at various stages of the study. The first source of potential interviewer bias was the manner in which the research nurse collected information during the inpatient data collection phase of the study. The research nurse could possibly have been more diligent in collecting information on patients in the intervention group.

Furthermore, there could have been a systematic bias in the reporting of certain outcomes and or variables in favour of the intervention group. Variables susceptible to such bias include the Modified Barthel Index prior to the stroke and at discharge, the patient's level of consciousness as well as urinary continence. However, categorical variables like the latter are less likely to have been misclassified.

A more diligent effort in extraction of information from patient records in the intervention ward may have occurred, especially since there was a resemblance between the Stroke Clerking Pro Forma and the Stroke Audit Pro Forma, which made auditing of patient records easier in the intervention ward.

A comparison of the audit of two formats of the same patient documentation (the Stroke Clerking Pro Forma and the usual medical clerking sheets) was conducted on a sample of eight patients using part of the clerking sheet. This showed very good agreement between the results of the two sets of audits, as summarised in Table 3.9.

A further source of interviewer bias could have occurred at the time of follow-up. Although the research assistants used for the follow-up component of the study were blinded as to the intervention status of the patient, it is possible that the interviewer could have ascertained the intervention status from the patient (or their relatives), by direct questioning or by the patients (or their relatives) volunteering this information.

Some information on interviewer bias was also obtained by telephonic interview with a small sample (eighteen) of non-Xhosa speaking patients with telephones. This sub-study showed moderate to good agreement between information collected by the research assistants in person and by the author telephonically. This information is summarised in Table 3.10.

Recall bias arising from patients who had an awareness of the intervention at the time of first contact with the research nurse during the in-patient data collection phase of the study and also at the time of the follow-up interview, could have resulted in systematic differences in the accuracy of the information supplied. Families of patients with poor outcomes are likely to have had better recall than families of patients with better outcomes.

The follow-up interview took place between four and five months after admission and this could also have been associated with recall bias. Furthermore, there were considerable differences, although not statistically significant, in the time to follow-up between the three groups. However, this is unlikely to have a systematic influence on the outcomes measured. The differences observed are probably due to a geographical approach that was used during the follow-up phase of the study, rather than the preferable chronological approach.

4.2.4. Aside from the planned intervention, were the groups treated equally?

The management of patients by clinicians with a keen interest in acute stroke including a proactive approach to identifying and managing likely complications could be a form of performance bias. This is associated with an awareness that the patients have been allocated to the intervention ward, as apposed to the control wards. It is likely that it is precisely this approach which comprises the intervention in this study. The author was clinically responsible for the acute stroke patients admitted and treated in the intervention

ward along with a consultant who shared a similar interest in Stroke Medicine. This can thus be considered as part of the intervention.

It is likely that the approach to nursing care in the intervention ward was associated with a more positive attitude towards caring and mobilising stroke patients in this ward, as well as more integrated functioning with the rest of the multi-disciplinary team. This again, is clearly part of the intervention.

However, therapists usually covered more than one of the four medical wards, usually two wards at any one time, and could have spent more time, with more enthusiasm in the intervention ward. On the other hand, therapists could have spent the same amount of time in the intervention ward, but as per the intervention, their approach was more focused and integrated.

This again is likely part of the intervention, as the environment in which the therapists delivered care was more integrated, supportive and facilitating of improved and efficient care.

A further source of information bias is the flagging and regular monitoring of patients in all wards, especially the control wards. This will have heightened awareness of the study and could well have influenced the behaviour of the staff, especially nursing staff, as the research assistant was a nursing sister. This source of bias would have favoured

the control wards, as the behavioural changes induced are likely to have been towards the null.

Apart from the above factors, which were considered as potential sources of performance bias, there was no co-intervention in the comparison groups.

4.2.5. Was there any contamination?

The lack of blinding among clinical staff is an important methodological limitation in trials of organised stroke care. This increased awareness of the intervention, especially with regard to therapy, nursing or medical staff that may be working in both the intervention or control wards, may result in contamination. Staff rotations occur frequently between wards and staff often have responsibility for covering more than one ward at the time. As a result of this awareness of the processes in the Stroke Intervention Ward, the Control Ward may have implemented some or all components of the intervention, resulting in co-intervention in the Control Wards, or 'contamination' of the Control Wards by the intervention processes.

The overall effect of the intervention is likely to be considerably diluted if the processes were introduced in a piece-meal fashion, i.e. not as an overall team strategy. We justify this because it is unlikely that the treatment effect is achieved by implementing only components of the intervention. Furthermore, most of the therapy staff were responsible for at least two wards at a time.

In order to address the potential contamination of, or co-intervention in the control wards, we decided to create an intermediate intervention ward, namely the Guidelines Ward. Here we provided the full spectrum of the intervention in a written format to the senior nursing and medical staff of the ward with which our therapy staff was shared. The guidelines included suggestions on how to get started, how many meeting with the various staff should be planned etc. This added arm of the study also allowed us to test the potential benefit of the use of guidelines with regard to stroke unit management, and also, measure the extent to which contamination occurred.

This did not entirely remove the possibility of contamination in the other two control wards which we thought was considerably less, due the layout and proximity of the wards, but still existed.

It was our expectation that the Guidelines Ward would have consistently outperformed the Control Wards. However, this was not the case. There was a graded improvement between the Control, Guidelines and Stroke Intervention Wards, for certain variables. With regard to other variables, the Control Wards outperformed the Guidelines Ward. This performance was assessed based on the various process measures monitored, as we did not expect significant changes with regard to the health outcomes measures monitored.

This was most likely due to the lack of consultant level interest in stroke care and this lack of a managerial approach to facilitating an integrated approach to acute stroke management including rehabilitation triage and screening.

The Guidelines Ward outperformed the Control Ward with regard to in-hospital referral to the occupational, speech and physiotherapist, the documentation of the results of team meetings.

The Control Ward outperformed the Guidelines Ward with regard to reduced length of stay, referrals to physiotherapy on discharge and the documentation of consultant review.

In summary, organised inpatient care after stroke, when applied by means of written guidelines has the potential to work, but the extent to which the guidelines are adhered to is likely to be dependent on consultant interest.

While this has implications for generalisability of the guidelines in our setting, it also demonstrates that contamination as a source of performance bias in this study, was unlikely.

4.3. SUMMARY OF INTERNAL VALIDITY ASSESSMENT

The above appraisal of the study methods and consideration of the various sources of bias allow an internal validity judgement.

The assignment of patients was according to strict roster system and this is an acceptable means of informal randomisation. All patients in the trial were accounted for and although three percent of patients were not followed after randomisation and a further ten- percent of patients were lost to follow-up, this does not seem to have altered the results significantly. All patients were analysed on an intention-to-treat basis.

Although blinding was not possible, the extent of performance and observation bias seems limited. The groups were comparable at baseline and there was no co-intervention.

In summary, the trial is of fairly good internal validity and the results are thus likely to be valid.

4.4. EXTERNAL VALIDITY CONSIDERATIONS

The study shows improvement in the point estimates of some of the principal health outcome measures. However the confidence intervals are wide for each of the principal health outcome measures. The trial does not therefore clearly demonstrate effectiveness of the intervention. To do this by showing significant improvements in the principal health outcomes, the power of the study would have to have to been considerable, as discussed earlier (2.3.2.). A trial of such power would not have been practical or feasible in our setting.

These findings are consistent with other similar trials conducted in the developed world. The systematic overview and meta-analysis, by the Stroke Trialists' Collaboration, was able to demonstrate effectiveness by demonstrating significant improvement in the principal health outcomes as reviewed earlier (section 1.3.3) and summarised in Table 1.6. This did not, however, include studies conducted in economically developing countries, as no such studies have been reported..

An important result of this trial was the demonstration of the feasibility and efficiency of implementing stroke unit care in our setting. Efficiency has been demonstrated by improved processes as well as a significantly reduced length of stay in the Stroke Intervention Ward.

This study is the first report of organised stroke care in the developing world and provides important original information, which is consistent with scientific findings in the developed world.

Furthermore, as our study examined organised acute care for stroke and only one other trial in the systematic overview examined only acute care for stroke patients, our study provides further important corroborating findings.

Organised inpatient care after stroke would therefore be of benefit in Southern Africa, where stroke is a significant public health problem. In our setting there is increasing

pressure on acute hospital beds, as a result of competing diagnoses, heavy utilisation as well as increasing rationing within the health sector.

The generalisation of organised inpatient care after stroke in our setting (South Africa) can be made with confidence. The generalisation of the intervention to other settings in the developing world has to be made with consideration of the many factors, which make the South African setting atypical in comparison to the rest of the developing world.

South Africa has a relatively well developed and fairly sophisticated acute care infrastructure with relatively poorly developed, although improving, community-based and primary level care infrastructures. While this setting is less developed than the first world, the available infrastructure is still far better than that available in other developing countries.

As our study examined the effect of an *acute stroke unit,* the long-term needs of stroke survivors required special early attention. Where longer-term rehabilitation services are limited, as is likely in the developing world, the responsibility for rehabilitation screening and triage fall squarely on the acute care clinicians. This factor needs fair consideration when the findings in this study are generalised. In our trial, a key component of the package of stroke unit care was diligent screening and triage of disability among stroke survivors, as there is and will always be, a limited number of in- and out-patient rehabilitation services available in the public sector in South Africa. This

component of the intervention required detailed knowledge of the available community based rehabilitation services including those provided by the various health authorities, training and non-governmental organisations.

4.5. How do stroke units improve outcomes?

It is difficult to identify which components of the package of organised inpatient care after stroke result in improved outcomes. The outcomes included decreased case fatality rate, decreased dependency and decreased need for institutional care as well as improved efficiency of care.

In our trial the tangible and measurable components included the use of specifically designed documentation (The Stroke Clerking Pro Forma and the Team Care Plan), specifically designed and timed process and format of communication between the various role players (the multi-disciplinary team including the nursing and medical staff as well as patients and their relatives) and geographic/spatial unity of patients.

Except for geographic unity, which was always the case, the extent to which the above components were applied has been measured and demonstrates improved processes. These include use of the Stroke Clerking Pro Forma, the Team Care Plan, improved referral to the Professionals Allied to Medicine, improved documentation of the results of team meetings and functional reviews as well as consultant review.

An added component is that the process of organised care was 'managerially driven'. This includes special attention to factors that contribute towards good team integration and coherence. Factors such as professional and personal respect, communication, consultative decision making and regular 'debriefing' etc. are not tangible and are hard to measure, but played an important role in achieving improved processes.

In order to achieve the above, i.e. good team coherence, a 'team leader' or 'team manager' who fulfils this role in addition to their professional role has to be identified. In this study the author fulfilled this role. The key function of the team leader would be to change the functioning of the team from a traditional multi-disciplinary team to an inter-disciplinary team. In the latter scenario, the team members evaluate patients and synergise their individual assessments into one integrated and unified team assessment. This approach is considerably better than a summation of individual professional assessments, which is the case in multi-disciplinary team functioning.

Our experience in this trial demonstrates that improved processes can only be achieved by improved coherence and integration of the multi-disciplinary team, resulting in a well functioning inter-disciplinary team. This we feel is a key un-measurable component of organised inpatient care after stroke. Further research should aim to identify measurable components of improved team functioning.

4.6. EVALUATION OF THE STUDY AGAINST *A PRIORI* OBJECTIVES

The study was successfully conducted and each of the objectives was achieved. Organised stroke care was implemented successfully. Stroke outcomes were measured. The effect of the intervention on stroke outcomes has been assessed. The impact of the intervention when provided in the format of written guidelines was assessed. Stroke outcomes in the intervention and guidelines wards were compared to control wards and the efficiency of the intervention has been demonstrated. The study was not powered to demonstrate differences in stroke outcomes.

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APPENDIX A

The Stroke Clerking Pro Forma

STROKE SERVICE

GROOTE SCHUUR HOSPITAL
DISCHARGE SUMMARY

(PLEASE PRINT)

AFFIX PATIENT STICKER HERE

FIRM:	WARD:	DATE OF ADMISSION:
FIRM'S CONTACT PHONE NO:		DATE OF DISCHARGE:

NAME AND SIGNATURE:	PATIENT'S ADDRESS:
CONSULTANT:	
REGISTRAR:	
HOUSE OFFICER:	PHONE NO:
SUMMARY PREPARED BY:	PATIENT REFERRED TO:
PATIENT REFERRED BY: DR	**DR** Name
ADDRESS:	Date/Time
	Place
PHONE NO:	**PHYSIO**: Name
PROBLEM(S)/DIAGNOSIS(ES):	Date/Time
	Place
	OT: Name
	Date/Time
HISTORY:	Place
	SPEECH: Name
	Date/Time
	Place

EXAMINATION:

INVESTIGATIONS:

OUTSTANDING RESULTS/FURTHER INVESTIGATIONS:

COURSE AND MANAGEMENT:

FUTURE MANAGEMENT:	MEDICATION ON DISCHARGE:

LETTER TO REFERRING DOCTOR/HOSPITAL DETAILING REQUESTS REGARDING FUTURE TREATMENT AND FOLLOW-UP:
MEDICAL:
REHAB:
Functional Status at Discharge:
Goals of Rehabilitation:

GROOTE SCHUUR HOSPITAL: STROKE SERVICE

Hosp. No: M/F DOB: "Patient sticker" Name:	Date: / /19 Source of history: *(spouse, GP, etc.)* Time: : hours

Presenting history *(You must document the ONSET of symptoms to diagnose a stroke).*
(If patient is unable to give history, look hard for an alternative source, e.g. telephone relatives.)

Risk factors *(tick or leave blank if not known)*

	Yes	No	Details and other past history
Previous stroke			
TIAs			
Hypertension			
Ischaemic heart disease			
Other cardiac disease			
Peripheral vasc. disease			
Diabetes			
Known hyperlipidaemia			
Current smoker			
Ex smoker			
Other			

Alcohol _____ units/week

(1 unit = 1/2 pint beer/single glass of wine/single measure of spirits)

IF INFORMATION UNAVAILABLE, TELEPHONE GENERAL PRACTITIONER

Medical and Surgical history:	Current Drugs:
	Name: Dose/frequency:
Family History:	**Allergies:** **Reaction:**

Systemic enquiry:

CVS

RS

GI

GU

CNS

Locomotor

Social details *(tick and give details)*

Married	☐	Single	☐	Widowed	☐	Divorced	☐
Retired/On Pension	☐	In employment	☐				

Type of accommodation? *(e.g. house, flat, Part III/IV)*

Details:	Yes	No
Owner?	☐	☐
Stairs inside?	☐	☐
Toilet?	☐	☐
Living alone?	☐	☐
Any family support?	☐	☐
Any social services?	☐	☐
Driver?	☐	☐

Leisure activities?

Pre-stroke function *(tick whether independent or normal etc. and give details)*

	Independent or normal	Needs help or abnormal
Ambulation	☐	☐
Bathing	☐	☐
Continence	☐	☐
Dressing	☐	☐
Emotions *(cognition)*	☐	☐

General examination:

Temp. °C

	Yes	No
Is there neck stiffness?		
Is the patient continent?		

CVS:

Pulse /min. reg/irreg BP

JVP Apex beat Heart sounds

	Yes	No
Neck bruit?		
Oedema?		
Absent peripheral pulses?		

If any Yes, specify:

Chest:

Abdomen:

Locomotor:

Neurological assessment

Right handed ☐ Left handed ☐ Both ☐

Glasgow Coma Scale

Eye opening ☐	- Never	1
	- To pain	2
	- To sound	3
	- Spontaneous	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

Mental Test Score (Hodkinson) *(Tick correct answers)*

Age	☐
Time *(nearest hr)*	☐
42 West Street *(ask patient to recall at end)*	☐☐ ☐
Name of hospital	☐
Year	☐
Recognise two people *(e.g. Dr & Nurse)*	☐
Date of birth	☐
Date of First Democratic Election	☐☐ ☐
Present President	☐
Count down 20 - 1	☐
Total	☐

(N.B: If unable to complete, give reason)

Communication *(written if not verbal)*

Can the patient communicate normally? *(tick)* Yes ☐ No ☐

If not: Dysphasia? ☐ Dysarthria? ☐ Other? ☐ None? ☐

Details:

Cranial nerves (*If not possible to test, record reason*)

	R	L
I		
II (*Pupils/Acuity*)		
Horner's?		
Fundi		
III/IV/VI (*Eye movements*)		
V I II III		
VII (*Facial*)		
VIII (*Hearing*)		
IX/X (*Palate*)		
XI (*Sternomastoids*)		
XII (*Tongue*)		

	Yes	No
Are the visual fields normal?	☐	☐

(? Inattention)

If NO, then specify:

	Yes	No
Can the patient swallow safely?	☐	☐

Ask the speech therapist for formal swallowing assessment if:

Drowsy
Unable to cough
Loss of palatal sensation
Palate not moving properly
You suspect aspiration

If no put 'Nil by Mouth' and give fluids by alternative route.

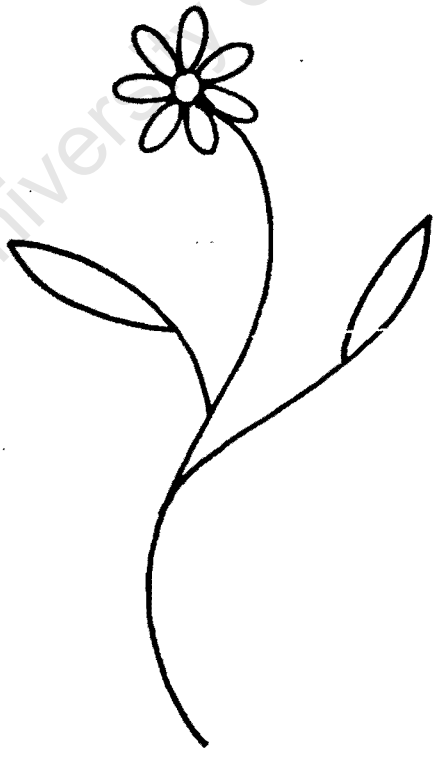
Visuospatial (*e.g. neglect, sensory or visual inattention, agnosias, etc.*)

Is there evidence of visuospatial dysfunction? **Yes** ☐ **No** ☐

Draw a clock face
(circle with numbers)

Copy this picture

Patient



(If not possible to test, record reason).
Sometimes NEGLECT is obvious from observing the patient.

Test the truncal control/gait			Yes	No	Details?
Can the patient:	1)	Sit?			
	2)	Stand?			
	3)	Walk?			

Limbs

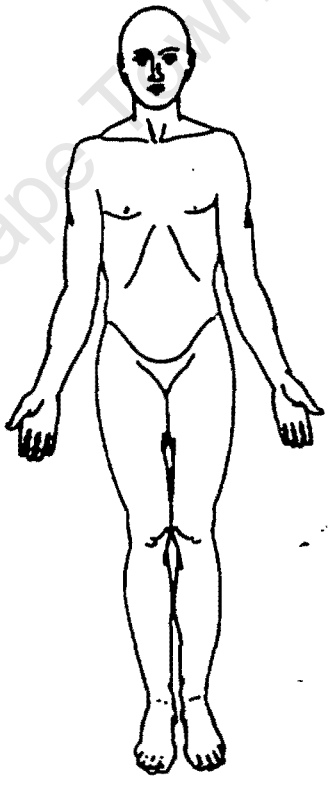
	R	L
Arms		
Drift		
Fine finger movement		
Tone		
Power		
Shoulder		
Elbow		
Wrist		
Hand		
Co-ordination		
(Finger/Nose)		
Legs		
Tone		
Power		
Hip		
Knee		
Ankle		
Co-ordination		
(Heel/Shin)		

Sensory Testing *(As a minimum test, PINPRICK or LIGHT TOUCH and JOINT POSITION SENSE. Look for sensory inattention).*
(If not possible to test, give reason).

	Yes	No
Is there any sensory loss? *(if Yes, record below)*		
Is there sensory inattention?		

Reflexes

	R	L
Jaw Jerk		
Triceps (C7,8)		
Biceps (C5,6)		
Sup (C5,6)		
KJ (L3,4)		
AJ (S1,2)		
Plantar		



Reflexes
0 = absent
+ = with potentiation
++ = normal
+++ = increased
C = with clonus

Joint Position Sense	R	L
Fingers		
Toes		

Assessment:

List neurological deficits:

Where is the brain lesion?
(Which side? Deep (lacunar) or cortical, carotid or vertebro basilar distribution?)

How certain is the diagnosis of stroke?	Definite stroke		probable		possible		other	

(If uncertain give differential)

List the risk factors and likely causes:

Essential investigations					**Other investigations** *(Are these indicated?)*		
	Requested		**Results**			**Requested**	**Results**
FBC		Hb		g/L	CT		
		WBC		10^9/L			
		Plat		10^9/L			
		MCV		fl			
ESR		ESR		mm/hr			
CEU		Na		mmol/L			
		K		mmol/L			
		Urea		mmol/L	Echocardiogram		
		Creat		mmol/L			
CHOLESTEROL		Chol		mmol/L			
BS		BS		mmol/L			
VDRL		VDRL					
ECG							
					Carotid Doppler		
CXR							
URINALYSIS		Blood					
		Protein					
		Sugar					
		Micro					

Management:	
Problem list *(Inputs, outputs, bloodsugar, BP)*	**Proposed action** *(advice to nurses, further investigations, referrals to therapists, initiate team care plan).*
1.	
2.	
3.	
4.	
5.	
6.	
Doctor's Name:	
Signature: *If you have been unable to complete parts of this form* ***FILL THEM IN LATER!***	

Date	Continuation Notes	Signature

Date	Continuation Sheet	Signature

PD 31

GROOTE SCHUUR HOSPITAL

PATIENT NOTES

COMPLETE BY HAND WHEN LABEL NOT AVAILABLE

Name .....

Folder No. ..... Birth Date ..... Race/ Sex .....

Dept .....

Ward/Clinic .....

Admis. Date .....

Problem .....

Date		Signature

Date	Continuation Sheet	Signature

APPENDIX B

The Guidelines for management of acute stroke

Introduction to
Guidelines for Management of Acute Stroke

Research Project

Organised Care of Stroke at Groote Schuur Hospital
A Controlled Trial

Project Coordinator

Dr Nilesh Patel (Bleep 1100)

Project Supervisor

Prof Stephen Louw (404 4259 or 406 6211)

These guidelines are accompanied by the Team Care Plan (TCP) and the Stroke Clerking Book. The guidelines are aimed at all health care workers who care for acute stroke patients during their hospital stay.

We suggest that the Head of Firm and the Nursing Head of Firm discuss this document with the entire firm (including nursing and medical staff as well as Professionals Allied to Medicine) at a meeting specifically convened for this purpose.

We recommend at least two of these meetings over a two week start-up period. Further meetings will depend on staff changes.

Introduction

There are few illnesses that are as devastating as stroke is to it's victims and their families. Groote Schuur Hospital admits approximately 570 stroke patients per annum.[1] At any one time these patients occupy 10 percent of our medical beds.[2] It is therefore a significant component of our clinical practice.

There are many pharmacological agents that are currently being studied in multicenter randomised trials. To date none of these have been shown to be effective in the treatment of all acute stroke patients, although low-molecular weight heparin may be of some benefit in ischaemic strokes.[3]

There have been a number of studies[4-7] that have shown our management of stroke to be deficient in a number of aspects.

The only effective intervention, however, that is generalisable to all acute stroke patients is "organised care". Organised care has been shown to decrease early mortality by 28% (odds ratio: 0.72; 95% CL: 0.56-0.92).[8] This reduction was maintained at 12 months (21% reduction; odds ratio 0.79; 95% CL 0.63-0.99).[8]

It is therefore imperative to organise the care of acute stroke patients in our hospital as effectively as possible. Once this has been achieved pharmacological interventions may be tested or implemented.

What does organised care consist of?

In our setting, it consists of coordinating currently available services, of which the following are essential components:

1) comprehensive medical assessment,
2) rehabilitation screen and plan and
3) discharge plan.

We believe that organised care and hence improved management of stroke patients can be achieved with existing resources and an interest in the management of stroke patients.

The intervention (ie. 'the package') that is needed to improve stroke care consists of:

1) Simple organisational changes

(the most crucial of which is having all stroke patients in the same cubicle/side ward),

2) the utilisation of the Stroke Clerking Sheet9-10

(to be used by the admitting doctor to ensure that all relevant data are collected in a systematic way).

3) Post Intake Stroke Ward Round and Team Care Plan

(to promote interdisciplinary communication and improve team functioning).

What is the aim of the research project?

The aim of the project is to improve the quality of acute stroke management at Groote Schuur Hospital by comparing two modified approaches to current management with regard to their ability to:

1) improve coordination
(by improving team functioning and interdisciplinary communication);

2) improve outcome
(morbidity) and

3) improve efficiency
(improving the referral rates to PAMs, both in hospital and post discharge).

What is the design of the research project?

We need to test the proposed intervention against existing care. Further, to increase the generalisability of the intervention we are also testing the intervention as Guidelines, ie. as if the package arrived via post and is implemented by resident staff.

Thus the 3 limbs of this nonrandomised control trial are:

1) The Intervention Firm (Seggie/Hift)
2) The Guidelines Firm (Maartens/Ress)
3) The Control Firms (Rayner/Ainslie & Swanepoel/Willcox).

To avoid contamination between the different limbs of the study ie. control, guidelines and intervention wards. we ask you to avoid admitting stroke patients to wards other than that of the managing firm. (see next paragraph)

The New System in the Medical Wards 1 February 1996

This system could have seriously threatened the integrity of the project. However, nursing management have been extremely helpful in deriving the following solution.

The stroke patients admitted by the Maartens/Ress and Swanepoel/Willcox Firms will be managed in Ward G17 from admission to discharge.

This has transformed a possible threat to our project into an excellent opportunity with the stroke patients of 2 firms being managed in one geographically discrete area.

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Guidelines for Management of Acute Stroke

1. Organisational Changes

1.1 Geographic Unity / Single Side Ward

All stroke patients (male and female) must be nursed in a single side ward (a 4 bed cubicle). This is crucial. It engenders the development of expertise in the nurses and it ensures that stroke patients are not competing with other more dramatically demanding acutely ill patients.

There are seldom more than 4 stroke patients admitted on one intake. If required one side of the larger 8 bed components of the ward may be used.

1.1.1 Will this be possible after the changes on 1 February 1996?

G17 will remain open as the overflow ward for each the medical firms. Stroke patients will be 'low care' patients unless they develop complications and require high care. In order to avoid contamination in this study all stroke patients admitted by the Maartens/Ress and Swanepoel/Willcox will be managed in ward G17 from admission to discharge. The stroke cubicle/s of these firms will be in Ward G17.

What about "outliers" (patients who cannot be accommodated in the intake ward)?

Since the organised management of acute stroke is a team effort, it is preferable that stroke patients are not outliers.

Where there are insufficient stroke patients to fill a side ward, other patients who would benefit from a holistic approach should be nursed with stroke patients (eg. geriatric patients).

1.2 Principal Nurse(PN)

One or two nurses should be responsible for most of the care on all stroke patients (with help, when needed). This approach to stroke patients is preferable to all nursing staff caring for most of the patients in ward and to purely task oriented care.

Stroke patients are often confused and feel extremely vulnerable - it is therefore in their interest to have contact with specific dedicated nurses.

The PN can be a dedicated nurse of any rank eg. staff nurse or enrolled nurse. The PN will initiate (ie complete the registration) the Team Care Plan (see below) on admission to the G floor ward.

In a similar manner one of the sisters should be responsible for supervising the care of stroke patients.

Such dedication of staff will facilitate continuity of care, co-ordination of rehabilitation and discharge planning and hence improved interdisciplinary communication and team functioning.

When handover to the next day shift occurs, the principal nurse will hand over to the next principal nurse.

2. The Stroke Clerking Sheet

The Stroke Clerking Pro Forma of the Royal College of Physicians (RCP) Research Unit and The Stroke Audit Group was developed after initial audits of care highlighted the poor quality of acute stroke care. General guidelines were not specific enough and hence certain standards were set. The clerking Pro Forma was developed according to these standards.

The Pro Forma has been shown to improve the completeness of the recording of the assessment of hospitalised stroke patients.

An adaptation of the RCP Stroke Clerking Pro Forma will be used by the admitting ward medical staff when they clerk cases from and in C17. **This replaces the existing clerking sheets.** The clerking sheet guides one through the entire medical clerk. It includes baseline essential investigations.

The usual discharge summary has been modified to include arrangements for post discharge rehabilitation. We recommend that the modified version be used for all stroke patients.

3. Post Intake Stroke Ward Round (PIWR) and Team Care Plan (TCP)

3.1 Who needs to attend this bedside Stroke Ward Round?

All the Professionals Allied to Medicine (PAMs) ie:
community liaison sister (CLS), physiotherapist (PT),
occupational therapist (OT), speech therapist (ST),
social worker (SW), principal nurse (PN), sister (RN) and the
doctor (Dr) from each side of the firm should attend this round.

Students (nursing, medical and PAM students) should also be encouraged to attend this round for exposure to formal interdisciplinary communication.

3.2.1 When should the round take place?

There are 2 options, of which the first is preferred.

Option 1:

The Stroke Ward Round should take place on the day following week-day intakes. The exact time of the ward round needs to negotiated with the PAMs. It is best to have it at 12h00 or at 14h00. This gives all the PAMs sufficient time to assess the patient before the round.

To deal with week-end intakes, is usually necessary to have a second ward round on Mondays.

Option 2:

Adding a further ward round on the post-intake day may clash with other post-intake ward rounds. The existing social round, if it does not occur later than the second post intake day, could begin with a bedside Stroke Ward Round.

NB

In view of the change that will occur on 1 February 1996, option 1 would be preferable. There will now one amalgamated social round between the 2 firms. Thus it may no longer be feasible to begin the social round with the bedside Stroke Ward Round. Furthermore for the purpose of this study, contamination is best avoided with option 1.

3.2.2 When should referrals take place?

The team may prefer that the admitting doctor refer patients early in the morning on day-one post-intake rather than referring on the scheduled round. This important organisational decision should be discussed with all the team members. The former is clearly more advantageous, especially if option 2 (see 3.2.1) is going to be used. Referring patients before the round allows the PAMs to assess each patient before the round. This clearly increases the value of their input and hence the usefulness of the Stroke Round.

3.3 Do all patients need to be referred to all PAMs?

Certainly blanket referral of all stroke patients to all PAMs is inappropriate. However it is important that all stroke patients and their families are referred to the Community Liaison Sister and to the Social Worker. It is important that the social worker counsels all patients and their families.

Patients with functional and speech/swallowing impairment should be referred to the occupational, speech and physiotherapist.

In summary here are some rules:

1) all patients must be referred to the community liaison sister;

2) all patients must be referred to the social worker;

3) all patients must be presented to all PAMs on the post intake ward round.

Item 3 allows those PAMs to whom a patient was not referred, the opportunity to advise on the assessment of patients and planning of rehabilitation. The PAM may volunteer that the patient should have been referred to him/her. With time inappropriate exclusion of some team members in the stroke team approach will happen less frequently.

Referrals to the dietician and the nutrition unit are only necessary when the patient/family require nutritional counselling/advice and education/support for the management of tube feeds at home.

3.4 How should the Post Intake Ward Round be conducted?

3.4.1 Case Presentation and Triage

The medical assessment is presented in brief from the clerking notes. The social history, pre-stroke function, risk factors, neurological deficits and exact diagnosis should be presented by the admitting doctor.

The CLS and principal nurse present relevant details of their contact with the family. The OT and PT present their findings as does the ST.

The aim of the above is to triage the patient into 1 of 4 categories viz:
{Each category has a different emphasis, but still requires some input from each PAM.}

1) severely dependent and/or terminal cases;
2) patients with a low baseline level of function ('non starters');

{In groups 1 and 2 the emphasis is on counselling family, educating family about catheter, nasogatric tube use, pressure/mouth care, chest secretions etc; each of which require dedicated teaching sessions with family; All of which should be documented in the Team Care Plan.}

3) moderately disabled patients, that will benefit most from ongoing rehabilitation;

{The emphasis here is on risk factor modification, setting of clear, coherent rehabilitation (short and long term) goals; these goals should be explicit and specific}

4) minimally disabled patients, who soon regain functional independence with little or no help.

{The emphasis in this category is secondary prevention.}

3.4.2 Setting Goals

Once the case has been presented, the team then plans inpatient rehabilitation, the number of education sessions with family, post discharge rehabilitation (in- or out-patient) and where appropriate long-term placement.

These goals, both short-term and long-term need to be as specific as possible and should be written in the Team Care Plan.

All team members should be encouraged to be as specific as possible in individualising the goal setting for each patient.
These goals are to be written in the Team Care Plan, so that the nursing staff can easily continue the rehabilitation process in the evenings and on weekends.

3.4.3. Implementation of goals

Having set the patient's specific goals, the team goes on to allocate the tasks. This should be done in two parts: inpatient plans and arrangements for continued post discharge rehabilitation. This may be outpatient therapy at GSH, the Day Hospitals or inpatient rehabilitation at Conradie, Lady Michaelis or Westlake Hospitals. The name of the team members who are to organise the post-discharge rehabilitation plan should be clearly documented in the notes or Team Care Plan.

3.4.4 Documentation of the Post Intake Ward Round
The Team Care Plan

In this respect the Team Care Plan is a crucial document. The format was jointly designed by experienced professionals involved in stroke care. It has the potential to coordinate and guide the comprehensive and management of acute stroke patients.

The Team Care Plan(TCP) has the following properties:

1) it was developed by a multidisciplinary team with an interest in stroke management;

2) it is concise yet highly informative;

3) it is available to all team members at all times and is kept in the nursing process file;

The TCP has the following advantages:

1) it will improve the awareness and understanding of, both in general and specifically for each patient, the input and functions of each team member;

2) it will improve interdisciplinary communication;

3) it will facilitate the setting of and achieving realistic goals in a coherent and coordinated manner;

4) it will serve as a check list ensuring that every patient need is addressed and

5) it highlights `gaps' or deficiencies as well as `overlaps' in the service.

3.4.4.1 What needs to be filled in on this Team Care Plan? Who needs to fill in each section?

Page 1 Registration

This page is filled in by the principal nurse. The information required includes basic patient details. the main carer and the medical assessment from the clerking book. There is some blank space for notes of contact with family and appointments with family for education, rehabilitation and counselling.

Page 2 Functional Evaluation

This page consists of graphs of functional status before admission, on admission and at discharge. The functional status is coded 1 to 5. The key will be available to all persons, although the task of completing the graphs is, at least initially, that of the occupational and physiotherapists.

These graphs will highlight the domains of function that need to be emphasised in the rehabilitation process. It will also increase the general awareness of specific aspects of function required for independent living, particularly for the medical and nursing staff.

Page 3 Pam Comments

This page has paragraphs for brief notes by each of the PAMs. The occupational and physiotherapist have been classed together because of the self-perceived overlap of their roles at GSH.

The goals of rehabilitation on this page have to be as specific as possible to allow the nursing staff to continue with rehabilitation in the evenings and on weekends. It is also useful for all activities to be focussed on specific, realistic goals that can be achieved during the admission.

Page 4 Education and Discharge Check List

This page consists of 2 tick lists. The education check list consists of the most important aspects of stroke and it's management that patients and their families need to be aware of. It should be perused regularly and ticked off day by day.

The discharge check list consists of aspects of discharge planning that need to be addressed from the first day of admission. This list should be completed by the day before discharge to facilitate an efficient discharge.

3.4.4.3 Is all this extra documentation necessary?

When you carefully consider the Team Care Plan, it becomes clear that each team member only has 5-10 extra lines of documentation. We believe that the enhanced communication between team members will well justify the extra effort; also the requirement to document goals and progress ensures that each patient's care is individualised and cost-effective.

3.4.5 But isn't all this meant to happen on the Social Round?

Although the social rounds function regularly, and are apparently well attended, they do not achieve what the PIWR is designed to achieve:

1) there is no documentation in patient notes on existing social rounds;
2) each patient is not always presented on the social round;
3) goal setting is often vague and designation of staff to carry out tasks often ambiguous.

The PIWR format described in these Guidelines aims to rectify the situation and to bring the management of acute stroke patients in line with current practice elsewhere.

APPENDIX C

The Team Care Plan

STROKE SERVICE : TEAM CARE PLAN

GROOTE SCHUUR HOSPITAL

REGISTRATION

"Patient sticker"

Nurse:	Ward:
Doctor:	Date of Admission:
Main Carer:	Date of Discharge:
Carer's Phone No:	

Risk Factors: (from doctor's notes)

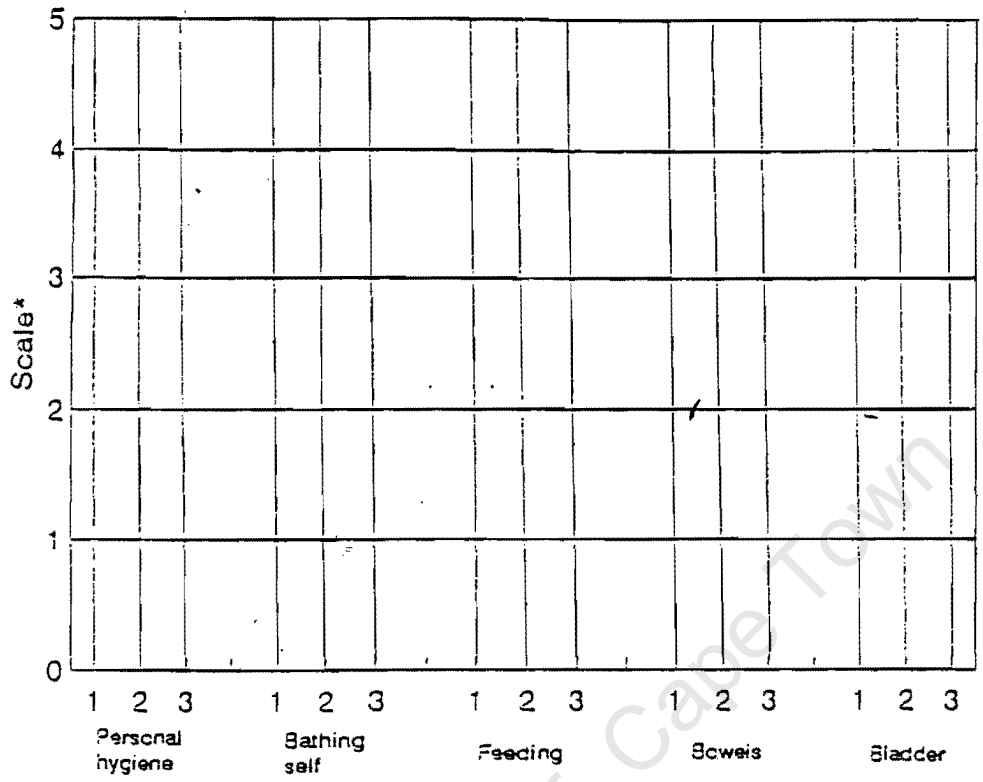
Deficits: (from doctor's notes)

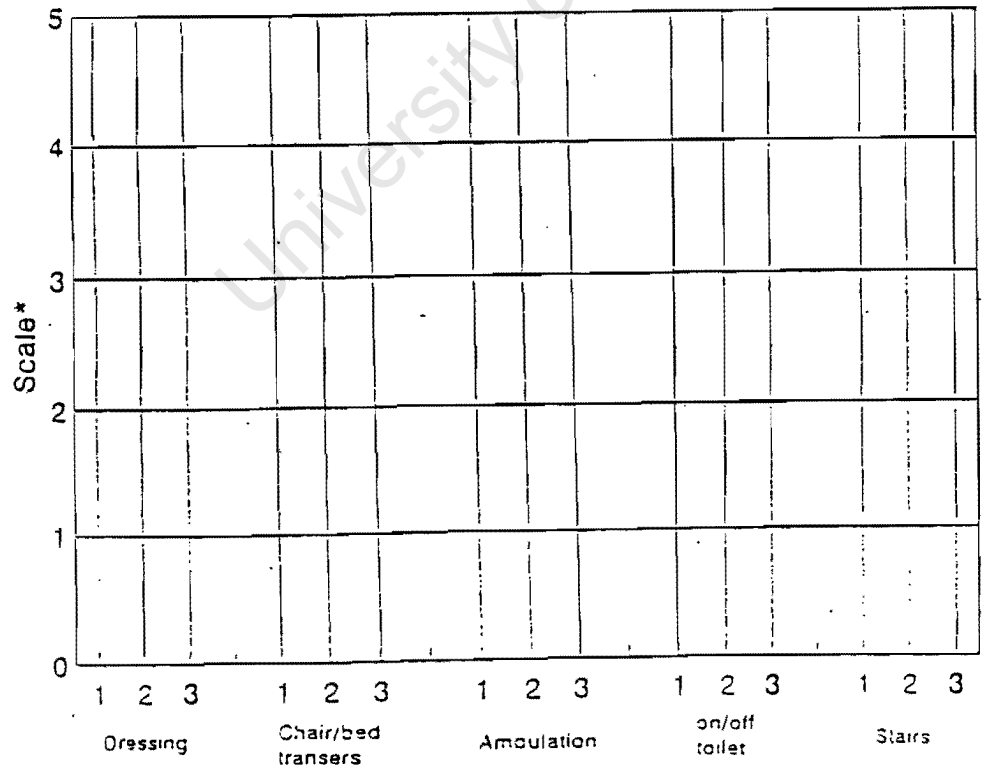
Diagnosis: (from doctor's notes)

NURSING COMMENTS: (information from family; PAM appointments with family)

FUNCTIONAL EVALUATION

"Patient sticker"





= Before Admission
= On day 1 of admission * Use "New Guidelines for Barthel Index functions"
= On discharge

PAM COMMENTS

"Patient sticker"

OCCUPATIONAL AND PHYSIOTHERAPY:

Deficits:

Goals during Admission:

Action Plan:

SPEECH AND SWALLOWING ASSESSMENT:

Findings:

Treatment Plan / Advice:

COMMUNITY LIAISON SISTER COMMENTS:

SOCIAL WORKER COMMENTS:

EDUCATION AND DISCHARGE CHECK LIST

Education Check list:	DATE & NAME
• **Nature of illness:**	
• **Home Care:** • NGT / diet	
• Feeding	
• Personal hygiene (Eye care, Mouth care, etc)	
• Positioning	
• Pressure Care	
• Other	
• **Home Activities:** • Activities of Daily Living	
• Exercises	
• Assistive Devices	
• Communication	
• Other	

Discharge Check list:	Checked by:
• Pension / Disability Grant	
• Home • Placement • Other:	
• **GSH FOLLOW UP:** 1. PT	
2. ST	
3. OT	
4. Home visit	
5. Medical	
• **Day Hospital/CHC:** 1. Medical follow up	
2. District Nursing Services	
3. OT	
4. PT	
• **Other Community Resources:** 1.	
2.	
3.	
4.	
ENTER DETAILS ON DISCHARGE SUMMARY. THIS IS ONLY A CHECK LIST	