THE UNIVERSITY
of EDINBURGH

IMPROVING COMMUNICATION AND SHARED DECISION-MAKING AFTER MAJOR STROKE:

A mixed methods study

AKILA VISVANATHAN

Doctor of Philosophy

UNIVERSITY OF EDINBURGH

2020

Declaration

I confirm I composed this thesis and that it is my own original work. I have not submitted any part of the thesis for any other degree or professional qualification.

Parts of this work have been published in scientific journals, on which I am first author. This thesis contains extracts from the following:

- Shared decision making after severe stroke- how can we better involve patients and families? : published in International Journal of Stroke 2017. I was subsequently interviewed for a podcast published on the journal's website: https://ijspodcasts.podbean.com/e/shared-decision-making-after-severe-stroke-how-can-we-improve-patient-and-family-involvement-in-treatment-decisions/
- Reporting 'specific abilities' after major stroke to better describe prognosis: published in The Journal of Stroke and Cerebrovascular Diseases
- Maintaining hope after a disabling stroke: longitudinal qualitative study of patients' experiences, views, information needs and approaches towards making treatment decisions: published in PLoS ONE 2019
- The considerations, experiences and support needs of family members making treatment decisions for patients admitted with major stroke: a qualitative study: published in BMC Medical Informatics and Decision Making.

Parts of my work have also been submitted for consideration of publication in scientific journals. I have indicated this at the start of each chapter.

The awards and prizes I received relating to, and as a result of work contributing to this thesis are as follows:

- Clinical Academic Training Fellowship form the Chief Scientists' Office, Grant number CAF/16/01
- British Stroke Research Group prize: UK Stroke forum 2018 (poster)
- Runner up prize at the Clinical academics training conference 2018 (poster)
- Mansell Prize: The Medical Society of London 2020

My supervisors provided comments on versions of my work. Some of my chapters are published work or papers which have been submitted for consideration for publication. For other chapters, I made editorial changes for inclusion in this thesis. I have specified this at the start of each chapter. The publications can also be found in Appendix A.

Acknowledgements

I would like to express my gratitude to my team of supervisors: Professor Martin Dennis, Professor Julia Lawton, Dr William Whiteley, Professor Gillian Mead and Dr Fergus Doubal for their guidance and constructive critique throughout my fellowship. I feel very lucky to have had an immensely supportive group of supervisors who have created multiple opportunities for me to learn and develop my research skills. Their vast experience in different methodologies (quantitative and qualitative) has inspired me, and through their different backgrounds, I have grown to understand and appreciate how mixed methods research can be a robust way in influencing clinical practice. I particularly would like to thank Professor Martin Dennis and Professor Julia Lawton for their training in quantitative and qualitative methodologies respectively which has enabled me to gain invaluable insights into how these methods can be integrated. I would like to thank Catriona Graham, lead statistician at the Wellcome Clinical Trust facility, for her guidance and Aidan Hutchison for his support with IT.

I thank my parents, Shanthi and Visva, for their immense support and an upbringing that has taught me the importance of hard work, perseverance and self-discipline. I would like to thank my husband, Vishnu, for his support and my other close family and friends. The generosity of the patients and family members in giving up their time to participate in this study cannot be mentioned enough.

Finally, I would like to thank the Chief Scientist Office for funding my clinical academic fellowship to perform the research contained in this thesis.

Akila Visvanathan

Abbreviations

UK	United Kingdom
ICD 11	International Classification of Diseases 11
mRs	modified Rankin scale
OHS	Oxford Handicap Scale
GBD	Global Burden of Disease Study
IPC	Intermittent pneumatic compression
CLOTS 3	Clots in Legs or sTockings after Stroke Trial 3
FOOD	Feed Or Ordinary Diet trial
IST3	International Stroke 3 trial
NG	Nasogastric
PEG	Percutaneous gastrostomy
HRQoL	Health related quality of life
VAS	Visual analogue scale
BI	Barthel Index
WHO	World Health Organisation
SAH	Subarachnoid haemorrhage
6CIT	Six item cognitive impairment test
DNAR	Do not attempt resuscitation form
smRsq	Simplified modified Rankin scale questionnaire

NIHSS	National Institute of Health Stroke Scale
GP	General Practitioner
SD	Standard deviation
TIA	Transient ischaemic attack
TACS	Total anterior circulation stroke
PACS	Partial anterior circulation stroke
LACS	Lacunar stroke
POCS	Posterior circulation stroke
GCS	Glasgow Coma Scale
SSV	six simple variables
IQR	Inter quartile range
COREC	Consolidated criteria for reporting qualitative research
CPR	Cardio pulmonary resuscitation
PPV	positive predictive value
AUC	Area under the receiver operating curve
ROC	Receiver operating curve
CI	Confidence interval
OR	Odds ratio

Abstract

Introduction

Patients may be significantly disabled after a major stroke but two patients in the same disability level according to outcome scales such as the modified Rankin scale (mRs) can vary with respect to their specific abilities (e.g. ability to walk, talk and eat) and therefore may have different views on their quality of life. Treatment decisions after major stroke are often made based on predictions of survival and independence. Many treatments can prolong the survival of patients who may be significantly disabled. Knowledge of patient abilities and preferences for such treatments are needed to make treatment decisions in keeping with their wishes. However, shared decision-making after major stroke can be challenging.

Aims

First, to understand how patients may vary with regards to their specific abilities and reported quality of life after major stroke. Second, to understand the experiences, preferences, needs and involvement in decision-making regarding treatments by patients (who retained mental capacity) and family members (where the patient lacked capacity) in the early period after major stroke and their feelings six months later. Third, to develop ways to communicate diagnosis and prognosis after major stroke better.

Methods

I used a range of clinical research methodologies: i) A prospective cohort study (n=403) to investigate the progress and outcomes of patients admitted with a major stroke with respect to several domains (disability, quality of life and specific abilities e.g. walking, talking, eating.) ii) Qualitative interviews to explore the experiences, views, needs (information and support) and shared decision-making approaches of patients admitted with a major stroke who retained mental capacity (n=15) and family members where the patient

lacked capacity (n=24). iii) Questionnaires to evaluate communication between doctors (n=9) and participants (n=24). iv) Statistical modelling to develop (n=13,117) and externally validate (n=403) models predicting specific abilities after stroke.

Results

Patients varied with respect to their specific abilities even though they may be in the same disability level according to global outcome scales (e.g. mRs). In the early period after major stroke, patients looked for hope and were not ready to participate in shared decision-making. However, six months later they wished they had been better prepared for the impact of major stroke by having been given realistic information and psychological support. Family members who were involved in decision-making considered the patient's state of health and preferences before stroke. Some found communication of specific abilities after major stroke useful to decision-making. Based on our expert judgement, longitudinal cohort and qualitative interviews, we developed and externally validated prognostic models to predict six specific abilities after stroke. These models have limitations and need further evaluation. In the future, they may be useful for doctors as a sense check of their judgement of the patients' prognosis, and to provide hope or information to understand impact of major stroke and/or make treatment decisions. This thesis details the challenges of communicating prognosis and involving patients and families in shared decision-making after major stroke and will inform a future intervention to deliver tailored information.

Lay Summary

There are over 1.2 million stroke survivors in the UK. About a third are living with significant disability and may require help from others (e.g. family members or carers) to be able to carry out day-to-day activities (e.g. to walk or to wash and dress) but does not take quality of life components into account. Each person may vary with respect to their abilities (e.g. to walk, to talk or to eat normally) and therefore, may have different views of their individual quality of life.

Many treatments offered to people in the early period after major stroke may extend the person's life but increase the chance of the person being disabled. At present, we do not fully appreciate the impact of major stroke on people and their families or how patients and families are involved in making decisions to accept or decline treatments.

We need to find ways to understand how people progress after a major stroke and the impact of this diagnosis on them and their family. We also need to find ways to provide people with stroke and their families with the necessary information and support they may need to prepare for the consequences of major stroke and make treatment decisions that are in keeping with their wishes.

The research

By interviewing people who had capacity after major stroke and their family members, where the person with major stroke did not have capacity, I aimed to understand their experiences of major stroke and how doctors can support them better. I used their experiences and views and my observation of a group of 403 people with major stroke to develop ways that doctors may consider to communicate with people with major stroke and their family members.

Outcomes and expected benefits

I found that individual people who had had a major stroke varied with respect to their abilities (e.g. to walk, to talk). They were looking for hope that they would get better in the early period after major stroke. However, six months later, they wished they had been given information and psychological support to have helped them prepare for the impact of stroke. Family members (where the patient did not have capacity) who were involved in the decision-making process considered how the patient's health was like before the stroke and if the patient had expressed any wishes. They looked for information from doctors. Based on this, I have developed a method of predicting patient abilities after major stroke which, once further evaluated, may be able to be used to provide people with major stroke and their families with information on the likely impact of major stroke. Doctors may also find this useful to check their judgement on how a person may do after major stroke.

Thesis synopsis

I have compiled this thesis based on published manuscripts (which have formed some chapters), work that has been submitted for consideration for publication and original work that has not been submitted for publication but is relevant to informing my future intervention. I have indicated this at the start of each of my chapters.

My thesis is a result of a programme of mixed methods research which I conducted in the last three years (2017-2019).

In Chapter 1, I provide an overview; on which my work for this thesis is based on, and list my aims. In Chapter 2, I describe the recruitment and follow up of a longitudinal cohort of patients with major stroke, aiming to report patient progress and outcomes with respect to various domains including disability, quality of life and specific abilities (e.g. walking, talking and eating). These findings indicate how individual patients varied and informed my interviews with family members and the development of predictive models. Chapters 3 and 4 report the experiences, views, needs and involvement in shared decision-making regarding treatments by patients (with mental capacity) admitted with major stroke and family members (where the patient lacked capacity) respectively. These indicate varying information and support needs which informed the development of predictive models (Chapter 7), highlight implications for clinical practice and inform my future intervention. (Chapter 9) In Chapters 5 and 6, I describe feedback from doctors and family members regarding current communication between them and report the feedback received from family members with regards to various aspects of communicating diagnostic and prognostic information. These inform my approach towards developing predictive models (Chapter 7) and future intervention (Chapter 9). In Chapter 7, I describe the development and validation of new statistical models to predict specific abilities (e.g. walking, talking) after major stroke. This was based on my findings from Chapter 2 and Chapters 3-6. Chapter 8 provides an exploration of ways in which our

models may be improved. Chapter 9 brings together some of my findings which have implications for future interventions and clinical practice. I also detail the strengths and limitations of my research, further areas of research my work has highlighted and my next steps in pursuing my work further.

Keywords: Major stroke, hope, preferences, support, information, communication, prognostic models, shared decision-making

Contents

List of tables

List of figures

Chapter 1

1.1 Introduction: Shared decision-making after major stroke

Since there is no standardised definition of a major stroke, we have defined this as people with a modified Rankin scale score (mRs) of 3-5 after stroke and/or those who had two of their functional abilities (e.g. to walk, to talk, to eat normally) affected as a result of the stroke. I have detailed this in Chapter 2.

My work focuses on:

1) Observing the progress of patients admitted with a major stroke with respect to their specific abilities (e.g. to walk, to talk) and relating this to widely used outcome scales e.g. modified Rankin scale (mRs), BI (Barthel Index) and Health related quality of life (HRQoL).
2) Exploring the experiences, views, needs (information and support) and involvement in decision-making (focusing on life-extending treatments) of patients (with mental capacity) admitted with major stroke and family members (where the patient lacked capacity).
3) Obtaining feedback from patients/ family members on doctor-patient communication, thereby aiming to develop strategies to improve communication and shared decision-making between them in the context of major stroke.

In the sections that follow, I focus on aspects relevant to decision-making regarding life-extending treatments in the context of a major stroke. This chapter is only intended as a brief overview, as each chapter contains an introduction with literature relevant to that chapter.

1.2 Publication status and acknowledgement of contribution

This chapter contains extracts from my published manuscript in the International Journal of Stroke: 'Shared decision making after severe stroke- how can we better involve patients and families?' 2017 (Appendix A).

I wrote this chapter and publication and incorporated changes following comments from my supervisors.

1.3 The importance of stroke

1.3.1 The definition of stroke

In 1988, the World Health Organisation (WHO) defined stroke as a clinical syndrome consisting of rapidly developing clinical signs of focal (or global in case of coma) disturbance of cerebral function lasting more than 24 hours or leading to death with no apparent cause other than of vascular origin.(1)

Recently, the International Classification of Diseases- 11 (ICD-11) divided the term 'stroke' into four categories:

a) Cerebral ischaemic stroke; defined as acute focal neurological dysfunction caused by focal infarction at single or multiple sites of the brain or retina. The evidence of this acute infarction may come either from symptom duration lasting more than 24 hours or neuroimaging / other technique in the clinically relevant area.

b) Intracerebral haemorrhage; acute neurological dysfunction caused by haemorrhage within the brain parenchyma or in the ventricular system. This includes non-traumatic haemorrhage only.

c) Subarachnoid haemorrhage; acute neurological dysfunction caused by subarachnoid haemorrhage.

d) Stroke not known if ischaemic or haemorrhagic; acute focal neurological dysfunction lasting more than 24 hours (or leads to death in less than 24

hours), but subtype of stroke (ischaemic or haemorrhagic) has not been determined by neuroimaging or other techniques.

1.3.2 Burden of stroke

1.3.2.1 Incidence and prevalence

Each year, approximately 15 million people globally suffer a stroke. In their lifetime, 1 in 6 people worldwide will have a stroke. In 2016, there were greater rates of stroke in men between the ages of 55 and 75 years but women and men had similar incidences below the age of 55 and above the age of 75. (2) In the same year, the highest incidence of stroke was in East Asia. Latest figures from the global burden of disease (GBD) study report that there are more than 80 million stroke survivors worldwide. (3) Due to improved stroke survival and a growing and ageing population, the number of stroke survivors is only likely to rise. (3)

In the United Kingdom, approximately 150,000 people have an acute stroke each year and there are over 1.2 million stroke survivors.(4–6)

1.3.3 Impact

1.3.3.1 Death

There were around 5.5 million deaths globally due to stroke in 2016. (2) Stroke remains the second leading cause of death worldwide, though rates vary between developed and developing countries. (7) In the UK, stroke is the third highest cause of mortality and premature death; there were over 37,000 deaths due to stroke in 2016.(4)

1.3.3.2 Disability

Stroke is the third major cause of disability worldwide (8) and fifth major cause of death and disability in the UK. (9) In these contexts, disability refers to physical aspects of disability, measured by scales such as the modified Rankin scale (mRs), (10) the Oxford Handicap Scale (OHS) (11) or Barthel

Index (BI) (12) without consideration of quality of life components. These scales have been widely used in stroke trials for evaluating patient outcomes including recovery (10) and as an end point in randomised controlled trials of emerging stroke treatments. (13)

1.3.4 Burden of major stroke

After a major stroke, patients often face the reality of two likely outcomes: death or survival with significant disability. In this situation, the possibility of being independent is often small.

Over a third of stroke survivors in the UK are living with significant disability.(14) Stroke care accounts for approximately 3-5% of all healthcare expenditure. (9,15) In the UK, the cost to society is around £26 billion a year; £15.8 billion from the informal care sector (relatives and friends providing care) and the rest for NHS funded and formal social care. (16)

Furthermore, approximately 5-15% of patients who have had a major stroke and have significant disability are discharged from hospital to care homes. (17,18) Many of these patients have ongoing physical and psychological needs. (4)

1.3.5 Treatments after major stroke

There have been advances in stroke treatments. In comparison to 20 years ago, people have better access to treatments and care.(19,20)

Treatments after stroke can be broadly divided into categories according to the timing after stroke at which they are delivered and their likely effect on patients' outcomes. Where the healthcare team feel it is appropriate, each of these treatment categories may be considered for the patient admitted to hospital with a major stroke.

a) Hyperacute treatments e.g. thrombolysis, (21) mechanical thrombectomy (22): improve functional outcome but as yet, have not been shown to influence short term survival
b) Acute (and some ongoing) treatments e.g. decompressive hemicraniectomy, enteral tube feeding and intermittent pneumatic compression (IPC). These treatments are life-extending; i.e. they extend survival, predominantly in a disabled state but do not appear to improve functional recovery.(23–25)
c) Symptom management e.g. using morphine for pain and midazolam for agitation (26)
d) Multidisciplinary care in designated stroke units: improves both survival and functional recovery of stroke patients. (27)
e) Secondary prevention e.g. anti-platelets, statins: reduces risk of further strokes. (28)

In the early period after a major stroke, patients and/or their family members are often involved in discussing their preference for treatments such as those described in (a) and (b) above. As I mentioned above and will detail below, these categories of treatments have different impacts with respect to survival and functional outcome. It is important for patients and families to understand this when involved in making decisions which are in-keeping with their preferences. (29,30)

1.3.5.1 Hyperacute treatments

Intravenous thrombolysis refers to revascularisation of the blocked artery by using intravenous drugs e.g. alteplase which enhances breakdown of the occluding thrombus. A meta-analysis of pooled data from individual trials showed that earlier intravenous thrombolysis is associated with less patient disability at three months among patients with large vessel occlusion. Certainly, shorter door to needle times (time between patient arriving at the department to getting thrombolysis delivered) of less than 30 minutes had better functional outcomes. (21)

Endovascular thrombectomy refers to clot retrieval (by various techniques including large bore or flexible aspiration catheters and stent retrievers) to restore normal blood flow to the brain by removing the blood clot blocking the artery. A meta-analysis of pooled individual patient data from five randomised trials showed significant reduced disability at 90 days compared with control. However, mortality at 90 days, risk of parenchymal haematoma and symptomatic intracranial haemorrhage did not differ between populations.(22) This meta-analysis also reported significant favourable effects (on functional outcome) of endovascular thrombectomy in patients older than 80 years, those randomised more than 300 minutes after symptom onset, and in patients who did not receive thrombolysis with intravenous alteplase.

While meta-analyses of thrombolysis and mechanical thrombectomy have reported improvements in functional outcome (but not survival) of stroke survivors, a prospective cohort study of over 7,000 patients has shown that functional status six months after an ischaemic stroke is associated with long-term survival. Therefore, in the future, studies may be able to demonstrate positive effects on long-term survival of early interventions that reduce dependency. (31)

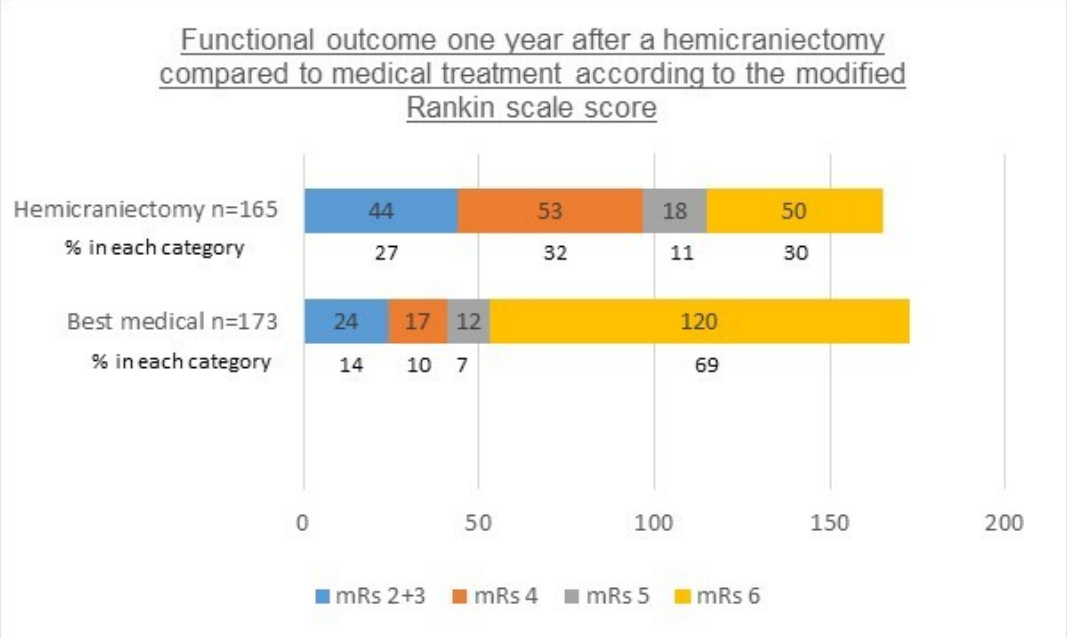
1.3.5.2 Acute and ongoing treatments

While the treatments above (i.e. thrombolysis and mechanical thrombectomy) have been shown to improve functional outcome of stroke survivors, other treatments such as decompressive hemicraniectomy, the use of enteral tube feeding and IPC in the early period post stroke are ‘life-extending’, i.e. they mainly increase the likelihood of survival of patients who are disabled after a stroke. Therefore, patients who are disabled after a major stroke are alive for longer with the net effect of a greater proportion of patients being alive with significant disability.

Decompressive hemicraniectomy is offered where there is cerebral oedema after a middle cerebral artery infarction, resulting in increased intracranial

pressure. This is a neurosurgical procedure where a part of the skull is removed and the dura is opened to allow a swelling brain to expand. A meta-analysis of seven randomised controlled trials (n=338) found that, at a year post procedure, while decompressive hemicraniectomy resulted in an absolute reduction in death by 39%, it increased the number of patients with disability by 39%. [i.e. all those who survived were disabled] There was an increase of 13% in those with slight to moderate disability (mRs 2-3), 22% increase in those with severe disability (mRs 4) and 4% increase in those with very severe disability (mRs 5). (32) These results are based on all patients aged 18 and above; with six trials reporting outcomes to 12 months and 1 trial to six months. [Of note, the results from five trials reporting outcome to six months were similar]. This is illustrated in Figure 1.1.

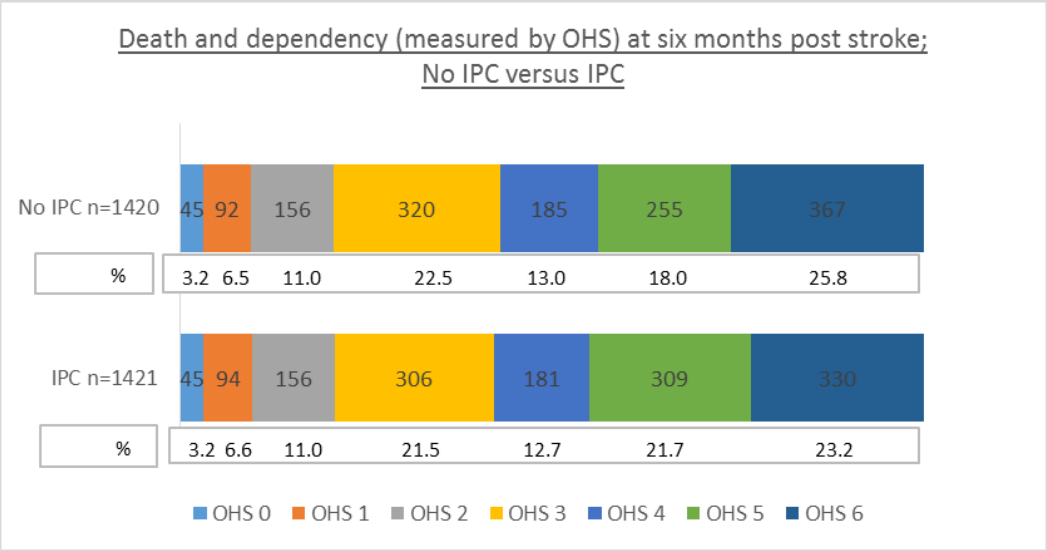
Figure 1.1 Functional outcome one year after a hemicraniectomy compared to medical treatment according to mRs [Based on all patients, aged 18 and above]



IPC devices use cuffs around the legs that fill with air and squeeze the legs to increase blood flow through the veins. In the Clots in Legs Or sTockings after Stroke 3 trial (CLOTS 3), IPCs reduced the likelihood of deep venous

thrombosis after a stroke. At six months, the use of IPC reduced deaths by 2.6% (25.8% in the no IPC group compared with 23.2% in the IPC group) but there was an increase in disability (measured by the OHS and defined as OHS 3-5) of 2.4% in the IPC group. [missing values excluded] (33–35) Figure 1.2 illustrates this.(35)

Figure 1.2 Death and dependency (measured by OHS) at six months post stroke; No IPC versus IPC



Enteral feeding refers to the intake of food via the gastrointestinal tract; either through the mouth or through a tube. This tube may be inserted via the nose into the stomach (nasogastric tube (NG)) or transcutaneously into the stomach (percutaneous gastrostomy (PEG)) or small intestine (jejunostomy). Enteral tube feeding is often used either to support or complement nutrition after a stroke. In the Feed Or Ordinary Diet 2 (FOOD 2) trial, early NG feeding (within the first week) after stroke reduced the likelihood of death by 5.7% but increased the likelihood of severe disability (mRs 4-5) by 4.7%

(36.6% in the NG fed group versus 31.9% in the non- NG fed group) at around six months post stroke. (36) Figure 1.3 illustrates this.

Figure 1.3 Outcomes six months after stroke; early NG feeding versus avoidance of NG feeding.

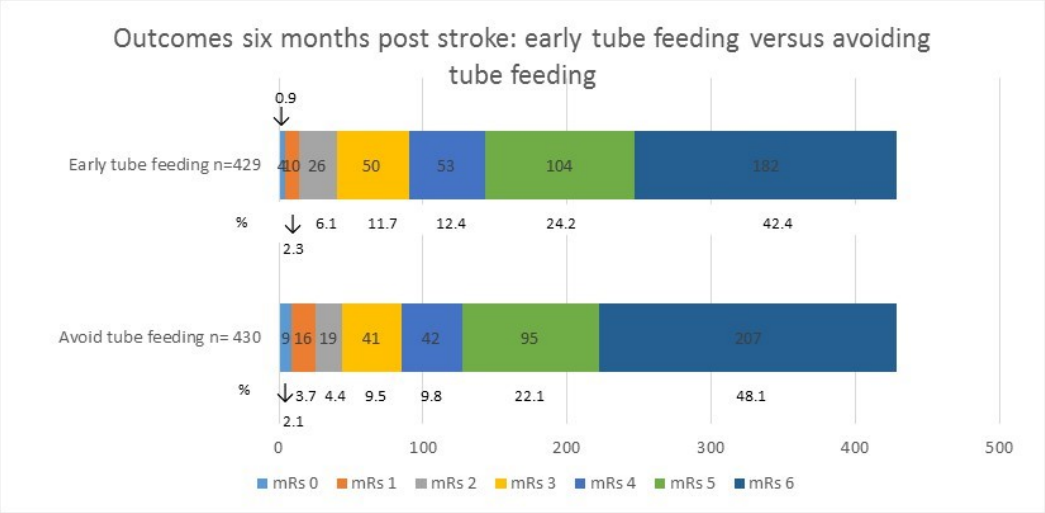


Table 1.1 summarises the absolute risk differences (between death and disability*) of life-extending treatments (decompressive hemicraniectomy, IPC and early enteral tube feeding) on survival and functional outcome. (23,32,36)

Table 1.1 Effects of life-extending treatments on disability* in stroke patients: absolute risk differences (between death and disability*)

Intervention	Time to follow up (months)	Dependent survivors (%)	Death (%)	Absolute risk difference (%)
Hemi-craniectomy >65 year	12	+39	-39	0
Intermittent Pneumatic Compression	6	+2.4	-2.6	-0.2
Early tube feeding	6	+4.7	-5.7	-1.0

*where disability is defined using the modified Rankin Scale (0-2 as 'independent' and 3-5 as 'dependent')

The effects these treatments have on survival and functional outcome may influence patients' decisions on accepting or declining these treatments. This may depend on what each individual patient regards as an 'acceptable' outcome. For example, some may consider survival at all costs to be acceptable and hence accept all treatments. However, others may decide that any disability would be a suboptimal quality of life for them, and hence, decline all treatments.

1.3.6 Health related quality of life (HRQoL) after major stroke

Health related quality of life (HRQoL) reflects the impact of a health state (in this case, stroke) on a person's ability to lead a fulfilling life. It covers an individual's perception of and satisfaction with their physical health, mental/ emotional health, family and social functioning.(37) An accepted method of reporting patient-centred outcome measure or HRQoL is the utility, which is a value derived based on values assigned to healthy individuals in the UK. This value indicates the desirability of a specific health outcome to the patient.

Using the EQ5D questionnaire where participants (patients or proxies) indicate their responses on five dimensions (mobility, self-care, ability to perform usual activities, pain/discomfort and anxiety/depression), each with the option of five levels, a combined score is obtained. This is used to derive a utility value. A utility value can be between -1 and 1, where values less than 0 indicate a health state which is worse than being dead. The other component of the HRQoL assessment is the visual analogue scale (VAS) which is a scale from 0 to 100 where participants indicate their health state from 'worse health state imaginable' (score 0) to 'best health state imaginable' (score of 100). (38,39)

To relate physical disability to HRQoL in the stroke setting, several attempts have been made to assign utility scores to mRs levels. (40–43) These

indicate a general trend where patients with higher mRs after stroke tend to have lower utilities.

However, when considering treatments on an individual patient basis, we would need to ascertain how the individual patient perceives his or her quality of life.

A ‘shared decision-making’ approach would be appropriate when considering life-extending treatments after major stroke.

1.4 Shared decision-making in the context of major stroke

The treatments patients with major stroke accept or decline may increase the chance of the patient surviving with significant disability, or dying. (Section 1.3.5) Even if ‘disabled’ (generally based on widely used outcome scales such as the mRs), each patient may rate their quality of life differently. It is therefore important to explore patient’s views about their physical state and HRQoL when deciding on treatment options, and offer treatments that are more likely to achieve the outcome they would prefer.

To facilitate informed decision-making, healthcare professionals should be able to communicate the patient’s diagnosis, likely prognosis and effects of different treatments on the patient’s prognosis. Patients, and/or their family members, should be able to express their preferences for treatments based on likely outcomes. Subsequently, patients and their family members, along with their healthcare professionals, should weigh up the pros and cons of treatments and collaboratively, arrive at a decision. This process, ‘shared decision-making’ is regarded the gold standard of care. (30,44–46) Specific to treatments that are life-extending, for the use of IPCs, revised national guidelines have recommended the use of this treatment (with caveats of shared decision-making). (47,48)

However, in the context of major stroke, implementing effective shared decision-making may be difficult. (49)

For instance, patients may lack capacity or not be well enough to participate in decision-making. Families may also not know patients' views on survival and disability (50,51) and even if they did, they may struggle to voice preferences which may result in decisions that are not life-extending.(52) Healthcare professionals find it difficult to confidently predict likely outcomes for individual patients after a major stroke (53) and there is further uncertainty about the specific abilities of patients who do survive (e.g. their ability to walk, eat normally or live at home). Communicating this uncertainty may be difficult for health professionals. (53)

Exploring the views, experiences and challenges faced by patients and their family members with respect to decision-making regarding treatments in the context of major stroke goes to the heart of the issues considered in this thesis. Here, I briefly detail the areas which I will explore in my chapters. I will revisit these areas in my conclusions chapter. (Chapter 9)

1.4.1 Patient management in keeping with their preferences

Healthcare professionals are encouraged to discuss patient needs, priorities and preferences at every stage of care. (30,44,46) However, there are five considerations:

First, people may have varying health beliefs and may therefore value outcomes differently. (54,55) For example, some patients may value survival at all costs, whereas others may regard surviving with any disability to be unacceptable.

Second, judgements made by patients regarding their preferences result from cognition, experience and reflection on potential outcomes.(56) Therefore, an individual needs to be able to project to a situation (e.g. being significantly disabled), when they may never have been faced with this situation before. (57) (A process called affective forecasting)

Third, the concept of ‘participation preference’- the willingness to get involved in the decision-making process: i.e. does a patient want to decide alone, or should the physician decide, or both. While literature suggest that most patients wish to participate (58–60) and are more likely to have higher treatment adherence and satisfaction with outcomes if treatments are matched to their preferences, (61–63) most of this evidence is from studies involving patients in outpatient settings who are generally less unwell (in comparison to inpatients with a major stroke). Evidence from the intensive care setting also suggests that patients who are critically unwell are less likely to be able to participate as they are in shock by their diagnosis (64) and therefore, often wish doctors to make treatment decisions on their behalf. (65)

Fourth, the concept of ‘treatment preference’; i.e. a preference for one or another treatment or a preference for no treatment at all. Treatment preferences can contain preferences for different settings (outpatient or inpatient), preference for specific medication, or a treatment goal. (66) Ascertaining this requires the patient to be able to understand their illness and implications of treatments.

Fifth, people may change their preferences over time; this is because they may change their self-assessment of quality of life. (A concept called ‘response shift’) (67) For example, when healthy adults are asked about living with significant disability, they would view this prospect as ‘worse than death’ (68–70) and many may say that they would refuse life-extending treatment if they were faced with a situation where they would be left significantly disabled. (68,71) However, literature has shown that those who had a decompressive hemicraniectomy after a severe stroke, and survived, reported a satisfactory level of psychological well-being in spite of their severe physical deficits. (72)

In the context of a major stroke where it is highly likely that the patient who had survived the stroke may be significantly disabled, and some treatments

are life-extending, the knowledge of patient preference would be important to guide treatment decisions.

However, eliciting patient preferences in the context of a major stroke may be challenging.

First, similar to other acutely unwell patients (e.g. those in intensive care), patients who have suffered a major stroke may be in shock and distress; therefore, due to their emotional state, they may not be ready to discuss their wishes or to weigh up the potential benefits or risks of available treatments. (64,65,73)

Second, some patients may have dysphasia or cognitive impairments as a result of stroke, preventing them from either communicating, or considering (or both) their preferences. (49)

Third, even if they are able to voice their preferences, it is possible that they may change their preferences regarding acceptable treatments over time.

I explore some of these challenges by engaging patients who retained mental capacity after a major stroke in qualitative interviews. (Chapter 3)

1.4.2 Legal aspects of proxy decision-making

Where patients are unable to be involved in shared decision-making due to lack of capacity (either due to mental illness, learning disability, dementia or a related condition, or an inability to communicate), the Adults with Incapacity Act is often consulted. This provides a framework for safeguarding the welfare and managing the finances of adults who lack capacity. As I describe below, the legislation differs between Scotland and England and Wales.

In Scotland, the Adults with Incapacity Scotland Act 2000 aims to protect people who lack capacity to make particular decisions, but also to support their involvement in making decisions about their own lives as far as they are able to do so. The individual with capacity (known as the ‘granter’) may also have appointed a power of attorney to deal with aspects of the granter’s

affairs e.g. financial/ property matters and/or personal welfare. In the context of immediate life-saving treatments, staff will act based on what would be considered best for the person. Where a welfare attorney or guardian with the power to give, or refuse, consent to treatment is available, doctors should consult them before treatment is administered. If they refuse consent, the doctor can ask the welfare commission to appoint an independent doctor to give an opinion. In the absence of a legally appointed attorney, proxies (often family members or others close to the patient) are consulted on what they think the person's likely wishes and preferences might be, but in this situation, ultimately, decisions that seem to be of greatest benefit to the person at that time have to be made by the professional team. (74)

In England and Wales, the Mental Capacity Act 2005 provides a legal framework for decision-making on behalf of people aged 16 and over who cannot make decisions for themselves. Where a person has made a valid and applicable advance decision to refuse treatment which applies in the person's clinical situation, this must be respected and no best interest decision by the professional team applies. Also, where the person has made a lasting power of attorney with the power to consent or refuse treatment, the attorney is the lawful decision-maker. (75)

1.4.3 Proxy decision-making in major stroke

As described above, in the circumstance where it is not possible to elicit patient preferences, doctors often ask the patient's family member(s) what the patient's preferences may be with regards to potential outcomes (i.e. survival and disability) and therefore, life-extending treatments.

There are several reasons to justify the involvement of proxies (usually family members) in decision-making after major stroke. (76)

First, this allows healthcare professionals to extend patient autonomy by incorporating their values and previously expressed treatment preferences to guide their medical care at a time when the patient themselves are unable to express their preferences and wishes. (77,78) Certainly, evidence has shown

that proxies are able to predict patients' preferences accurately in the majority of cases (79) in different settings including dementia (80), stroke (81) and in the context of using or withholding life extending treatments. (82,83)

Second, involving family members in decision-making manifests respect for the family unit and most proxies also wish to be involved in decision-making. (84–86)

Third, many patients do want their families to be involved in their treatment decisions. (87)

However, family members may find shared decision-making challenging, and potentially distressing, especially when decisions may result in life or death. (52)

First, where patients' preferences are unknown, they would need to consider what the patient would have wanted if s/he were able to make decisions. [A process called substituted judgement] (50) This can be difficult as they would need to ensure that they are making decisions based on the patient's wishes rather than their own. (50,51)

Second, they may find it emotionally difficult to voice preferences for treatments that are potentially not life extending even if these may be consistent with what the patient may have expressed in the past. (52)

Third, family members may be overwhelmed, in shock and feel unprepared for a potentially life-changing diagnosis. Therefore, they may wish to receive information and support from health professionals to be guided on what treatments may be appropriate for the patient. (88–90).

To explore the experiences and needs of family members involved in shared decision-making where the patient lacked mental capacity, I will report results from qualitative interviews with family members. (Chapter 4)

1.4.4 Prediction of outcomes after major stroke

The knowledge of likely outcomes after major stroke may be useful to patients and their families. This may help them prepare for potential consequences of stroke (e.g. the need for extra care at home, or adaptations to enable patients to live at home) and may even help them make treatment decisions. (91)

Many prognostic models exist in stroke (92) and generally predict survival or independence. Few are of any use due to their limited generalisability and lack of external validation.(92,93) There are prognostic models predicting specific abilities after stroke e.g. mobility, recovery of arm function and depression, but many also have limited use due to lack external validation. (94–97)

However, the six simple variables (SSV) models developed from the Oxford Community Stroke project (OCSP) have been widely studied and used in audit (98) and in clinical trials. (99) The models consist of six easily collected variables (age, living alone pre-stroke, being independent pre-stroke, normal verbal score of the Glasgow coma scale (GCS) post stroke, being able to lift arms post stroke and walk post stroke) and predict survival, independent survival and ability to live at home. (100) The model predicting independent survival at six months is validated for use in the acute (100) and hyperacute (101) stroke settings (for clinical trials). I detail this further in Chapter 7.

Communicating prognosis to patients and their family members by using terms such as dependence or disabled may have varied meanings to them. Also, the communication of poorer outcomes (i.e. dependence rather than independence) may also have an impact on any hope of recovery which they may be holding onto. Therefore, it is possible that describing prognosis by specific abilities (e.g. to walk, talk, live at home) may be more easily understood.

How ‘correct’ predictions are determine their use in clinical practice. Different terms have been used to define how ‘correct’ predictions from a statistical

model would need to be to guide patient management; e.g. accuracy and precision. This is often related to the sensitivity and specificity of the model, with a trade-off between the two. While predictions from models would ideally be 'very correct or very accurate' to guide patient management, (102) this is unlikely to be possible. Furthermore, different individuals (either patients or their family members) may decide to accept or refuse life-extending treatments based on different accuracies of information. Therefore, it may be more useful to provide prognostic information to individuals at the level of accuracy they may wish for. I will explore this in Chapter 6.

1.4.5 Presentation of prognostic information to patients and families

Existing literature has recommended that health professionals provide information to patients in a variety of formats based on the patient's stroke specific impairment and preference. (103) Graphical risk displays (104) (of various types) e.g. bar charts, grouped icon displays (dot or face diagrams) and flow diagrams have been suggested as best ways to communicate prognosis to patients. (105–108)

However, relatively few studies have explored the use of different graphic formats for presenting prognostic information for the purpose of shared decision-making. (109–112) Limited data has suggested that different types of charts e.g. bar charts and icon displays are more effective than simple numeric statements for decision-making, (113,114) and are well understood by patients over 75 years old. (115)

However, these formats have been evaluated in outpatient settings where patients are less medically unwell and patients and their family members may be less distressed. The transferability of these findings to the major stroke setting has not been studied.

Because of varying individual preferences and stroke specific impairments, health professionals may need to present multiple formats of prognostic

information to patients and families in the major stroke setting. (104,107) I will explore this in Chapter 6.

1.4.6 The influence of doctors on treatment decisions made for the patient with major stroke

Doctors may have different preferences when accepting treatments for themselves when compared to patients. (116) It is also possible that differing communication styles of doctors may influence information that is perceived by patients.

However, it is unclear if doctors' preferences and behaviours influence the treatment(s) received by the patient admitted with major stroke. I will explore this in Chapter 5 using a brief questionnaire study.

1.5 Summary of literature

From my review of existing literature, I have found that there are several areas relevant to shared decision-making regarding treatments in the context of a major stroke where further work is required.

Specifically,

- Patient outcomes are defined by levels of physical disability based on outcome scales such as mRs, rather than their specific abilities (e.g. to talk, walk) and quality of life.
- The experiences of patients admitted with a major stroke and their family members are under-reported though integral to understanding how, and why, certain treatment decisions are made.
- The most effective method of presenting information (especially that of prognosis) to patients and their family members is unclear.
- We do not know if doctor's views and communication influences decisions made regarding treatments in the context of major stroke.
- Many prognostic models have limited use in practice due to their lack of generalisability and external validity.

While shared decision-making in stroke is a team approach, where various members of the multidisciplinary team (e.g. doctors, nurses, physiotherapists, occupational therapists, speech and language therapists and dieticians) have input into patient management, the focus of my thesis is on decision-making regarding treatments that are life-extending. These discussions are primarily conducted between the patient/ their family and the hospital doctor. Therefore, in the rest of my thesis, I have used the term 'doctor' rather than a more general term such as 'health professionals' which could include other members of the multidisciplinary team.

1.6 Aims of thesis

a. To report how patients admitted with a major stroke progress over time with respect to several specific abilities (e.g. to walk, to be continent, to eat normally) and relate these to outcomes on scales such as mRs, BI and EQ5D (HRQoL).
b. To understand the experiences, views regarding survival and significant disability, needs (information and support) and approaches towards shared decision-making of patients admitted with major stroke who had retained their mental capacity; and how and why any of these views may have changed over time
c. To explore the experiences, views and needs (information and support) of family members who are involved in decision-making regarding treatments after major stroke where the patient lacked capacity; and their ongoing thoughts and feelings at six months on reflection of their time in hospital
d. To evaluate current communication of patient diagnosis and prognosis between doctors and patients/family members and determine if the doctors' views regarding appropriateness of treatments for an individual patient influences decisions taken about those treatments.

e. To determine the best way of presenting information (specifically that of prognosis) to patients and families to help their understanding and/or decision-making regarding life-extending treatments
f. To develop and externally validate new prognostic models which predict specific abilities after a major stroke at accuracies defined useful by individuals.
g. To explore how our models, and any future prognostic models may be improved.

I performed a mixed-methods study to address my aims.

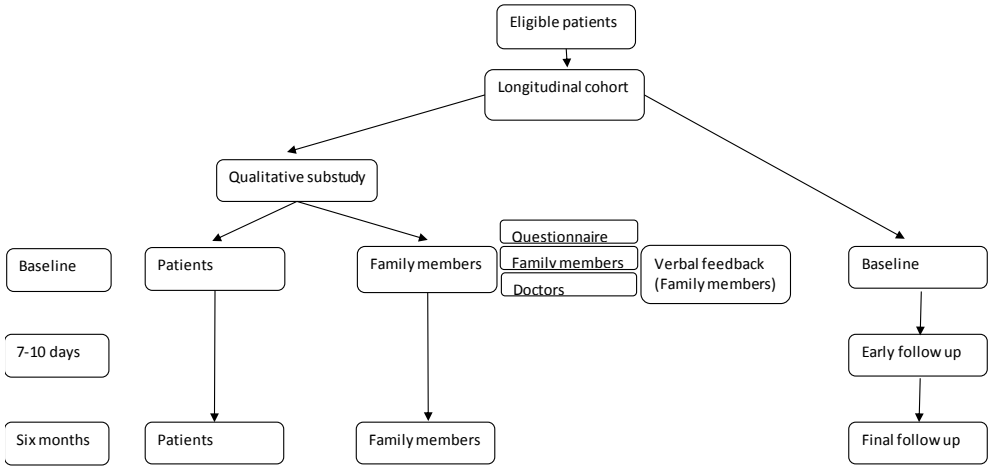
Specifically,

1. I recruited a longitudinal cohort of patients admitted with major stroke and followed them up for six months to address aim (a). I detail this in Chapter 2.
2. By performing qualitative interviews at two time points (early period after stroke and at six months), I explored the experiences, views and needs of patients with major stroke (aim (b)). I detail this in Chapter 3.
3. By performing qualitative interviews at two time points (early period after stroke and at six months), I explored the experiences, views and needs of family members involved in decision-making where the patient lacked capacity (aim (c)). I detail this in Chapter 4.
4. I used questionnaires to evaluate current communication between doctors and family members of patients admitted with major stroke and to ascertain if the doctor's views on treatment influenced treatment decisions (aim (d)). I detail this in Chapter 5.
5. By using a combination of an informal feedback exercise and questionnaires, I attempted to determine the views of family members on the presentation of information (specifically that of prognosis) (aim (e)). I detail this in Chapter 6.

6. By using data from large trials, we developed prognostic models predicting six specific abilities after major stroke which I externally validated in the cohort I recruited. (aim (f)) I detail this in Chapter 7.
7. I tested if our developed models, and any new models may be improved by using data from my cohort. (aim (g)) I detail this in Chapter 8.
8. In Chapter 9, I discuss my conclusions, detail the implications of my findings to clinical practice, strengths and limitations of my study and future plan.

Below is a flow diagram of my study. In each chapter, I will use this diagram to indicate which part of the study the chapter relates to.

Figure 1.4 Study schematic



While this thesis is written as a narrative based on my aims listed above, initially, the study was planned differently. My work began with analysis of available, large trial datasets to develop prognostic models to predict specific abilities at six months after stroke. (Chapter 7) This led to the recruitment of a prospective cohort of people with major stroke and collection of variables similar to those identified in our large trial datasets to externally validate these models and observe patient progress. (Chapter 2) We then identified samples of patients with

capacity and family members where the patient lacked capacity for participation in qualitative interviews (Chapters 3 and 4) and doctors and family members to participate in a small questionnaire study to explore communication and shared decision-making. (Chapters 5 and 6)

Chapter 2 Outcomes after major stroke: a longitudinal cohort study

2.1 Publication status and acknowledgement of contribution

A paper from this chapter has been accepted by the 'Journal of Stroke and Cerebrovascular Diseases'. This can be found in Appendix A. I wrote this chapter and publication following comments from my supervisors.

2.2 Introduction

The World Health Organisation (WHO) defines disability as an umbrella term covering impairments, activity limitation and participation restrictions. (117) Dependency is where a person requires support from others to be able to manage their day to day activities. As I described in Chapter 1, a large proportion of patients who have a major stroke may die. Those who survive with significant disability may be largely dependent on others for their daily activities (e.g. showering and dressing). In practice, these two terms (dependency and disability) are often used interchangeably, and may have varied meanings to patients and families.

Patient outcome in clinical trials is often expressed using scales such as the mRs and BI to describe dependency or disability. The mRs is one of the most widely used outcome scales which stratifies patient outcome into levels of disability from 0 (no disability) to 6 (dead). (118)

Patients who may be considered dependent or disabled may differ with respect to their specific abilities e.g. to walk, to talk. Therefore, it may be more appropriate to describe patient prognosis in terms of specific abilities. Patient and family members may also engage better with communication of positive information i.e. 'abilities' rather than 'disabilities' as this may offer them hope of recovery. (119)

As I described in Chapter 1, different individuals may regard their quality of life differently and therefore, even within a single disability level (e.g. based

on mRs), HRQoL may vary greatly. This may be due to variation in the patient's specific abilities.

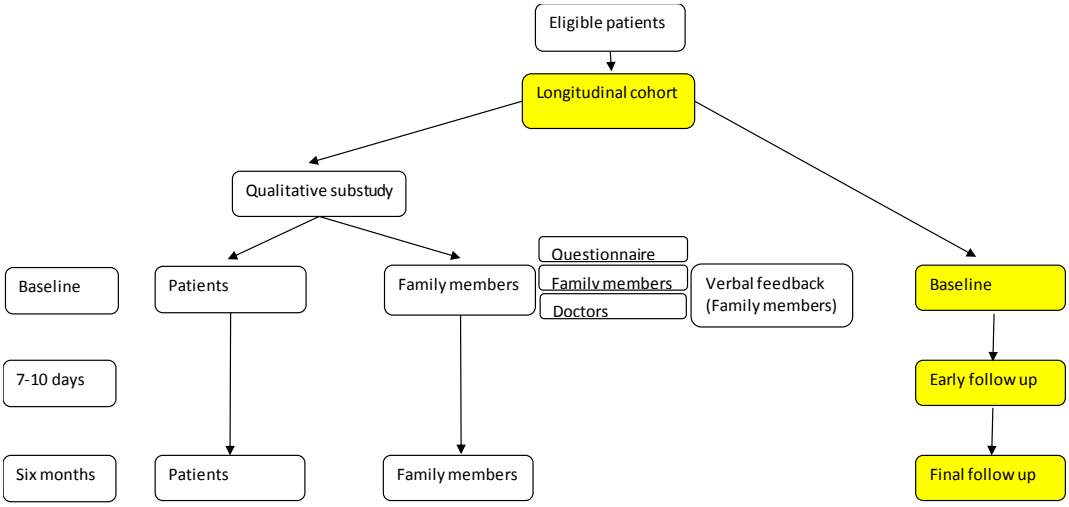
To understand the relationships between disability, HRQoL and specific abilities of patients with a major stroke, I recruited a longitudinal cohort of patients who had been admitted to hospital with major stroke. I followed them up 7-10 days after their stroke to determine their early progress and treatment, and at around six months. I recorded their function by using global scales (mRs and BI), their HRQoL (using EQ5D-5L) and derived their specific abilities either from single items from these scales (e.g. continence from BI) or by asking specific questions (e.g. no dysphasia, mild dysphasia, etc.) about their abilities. This longitudinal cohort was also recruited for the purpose of external validation of prognostic models (which I describe in Chapter 7) and therefore, the decision to collect certain variables and/or use certain outcome scales was based on already available data that was used to develop these models. I will indicate this in the sections that follow.

The specific abilities I determined were: to be independent, to walk, to be continent of urine and/or bowels, to talk without major problems, to eat normally, to live without severe pain, to live without major anxiety or depression, without major cognitive problems and to live at home. I chose to document these specific abilities based on expert opinion of stroke professionals in the hospital where recruitment took place and that was already available to us for the purpose of development of new prognostic models (Chapter 7). The dichotomies we chose to report whether patients had the specific ability (or not) was also based on expert opinion. I will detail this below. The final follow up time of six months was chosen to allow enough time for data analysis based on the length of my fellowship.

In this chapter, I describe our longitudinal cohort of patients with a major stroke. I report my methodology and results as per the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for cohort studies.(120)

The flow diagram below (boxes coloured in yellow) indicates the part of my study this chapter relates to.

Figure 2.1 Study schematic: Chapter 2



2.3 Aims

1) To describe the baseline characteristics of a cohort of patients admitted with major stroke
2) To describe patient progress after major stroke at three time points (baseline, 7-10 days and at around six months)
3) To relate patients' BI, HRQoL and specific abilities to their mRs at six months.

2.4 Approvals

The Scotland A research ethics committee which has responsibility for studies involving adults with incapacity provided ethical approval. (Reference: 17/SS/0029).

The NHS Lothian Research and Development Office also provided their approval. (Project number: 2017/0116)

2.5 Methods

2.5.1 Study design

I prospectively recruited patients with major stroke into a longitudinal cohort study with follow up at 7-10 days (early follow up) and at around six months (final follow up).

2.5.2 Setting

I recruited patients from the medical admissions unit, the acute stroke unit, and other wards in the New Royal Infirmary of Edinburgh, NHS Lothian between 10th May 2017 and 25th May 2018.

2.5.3 Participants

2.5.3.1 Inclusion criteria

Patient were eligible if they were over 18 years old, and had had a stroke (as defined by the WHO (121) and described in Chapter 1).

I only recruited patients with major stroke, which, as described in Chapter 1, I defined as having an mRs of at least three or mRs 0-2 but being unable to carry out or maintain at least two specific abilities as a result of their stroke: walking, talking, eating, continence. Recruitment criteria for these specific abilities was based on a simple 'yes' for affected and 'no' if not affected. If the patient already had an mRs of 3 or were unable to maintain two specific abilities before their current admission, I included them if there had been a further deterioration in their functional abilities as a result of the stroke (and therefore, they were not at their pre-stroke level of function).

2.5.3.2 Exclusion criteria

I excluded:

- Patients with subarachnoid haemorrhage (SAH) due to its different aetiology. Also, in the city where recruitment took place, patients with

SAH were looked after by the neurosurgical team at a different hospital site.

- Diagnosis was uncertain and stroke was not considered as the most likely diagnosis
- Patients where they did not have capacity, and no close family, friends or legal representative (proxies) were available to provide consent.
- Patients or proxies who were unable to understand English or communicate in English. This is because I could not be certain that translated information would sufficiently explain the processes involved in the study.

2.5.3.3 Screening

I made efforts to ascertain all patients, as soon after their admission into hospital as possible. I identified patients by screening admissions electronically twice a day. I discussed with medical staff seeing these patients and liaised with nurses and doctors on the relevant wards. Since I single-handedly recruited patients into this study, screening (and recruitment) ceased when I was on annual leave and at weekends.

2.5.3.4 Recruitment

Medical staff responsible for patients' care mentioned the study to eligible patients (if they had capacity) or their proxy (for those patients without capacity) and invited them to take part. If they were agreeable to be approached by me to receive more information about the study, I provided the patient or proxy with an information sheet and answered any questions about the study. Where they were amenable, I then obtained informed written consent. At the time of consent, I collected baseline data (first data collection) and this was also the time of recruitment into the study. To maintain consistency in the rest of this chapter, I will use the term 'baseline' to describe the time of recruitment/ consent / of first data collection.

I tried to recruit all patients as soon as possible, aiming days 0- 6 after the patient's stroke. Where the date of stroke was not known, I made a

judgement of the date based on the last time the patient was seen to be well. The date of stroke was day 0, and all subsequent follow up times were based on this. However, within the first two weeks into the study, I found that in some cases, patients presented late, some were very unwell in the first few days in hospital, I was unable to find the relevant proxy or some patients and families needed time to think about participation and consult relevant others. Therefore, on discussion and agreement with my supervisors, I extended the recruitment window to days 0 to 10 after stroke. However, this meant that there may be potential overlap between collection of baseline data and early follow up data of patients. To account for this, I ensured that there was at least one day (minimum of 24 hour) difference between collection of baseline and early follow up data.

2.5.4 Data collection

I assessed patients at three time points. As described above, these time points were relative to the date of stroke. I aimed for first data collection (i.e. baseline) between days 0 and 10 after stroke, second data collection to be between days 7 and 10 (i.e. early follow up) and at least 24 hours after the baseline data collection and third data collection (i.e. final follow up) at about six months after stroke. All baseline assessments and early follow ups were done in person. I checked patient electronic records to check if the patient was alive before carrying out six month assessments over the telephone.

I collected variables that described the cohort (e.g. demographics and other baseline characteristics), that which described patient early progress, their outcomes at six months and variables which might be useful in predicting some of these outcomes. Based on one of my aims which was to externally validate prognostic models, I tried to collect variables that were similar to those collected in large trials which was used to develop new prognostic models. (Described in Chapter 7)

2.5.4.1 Baseline

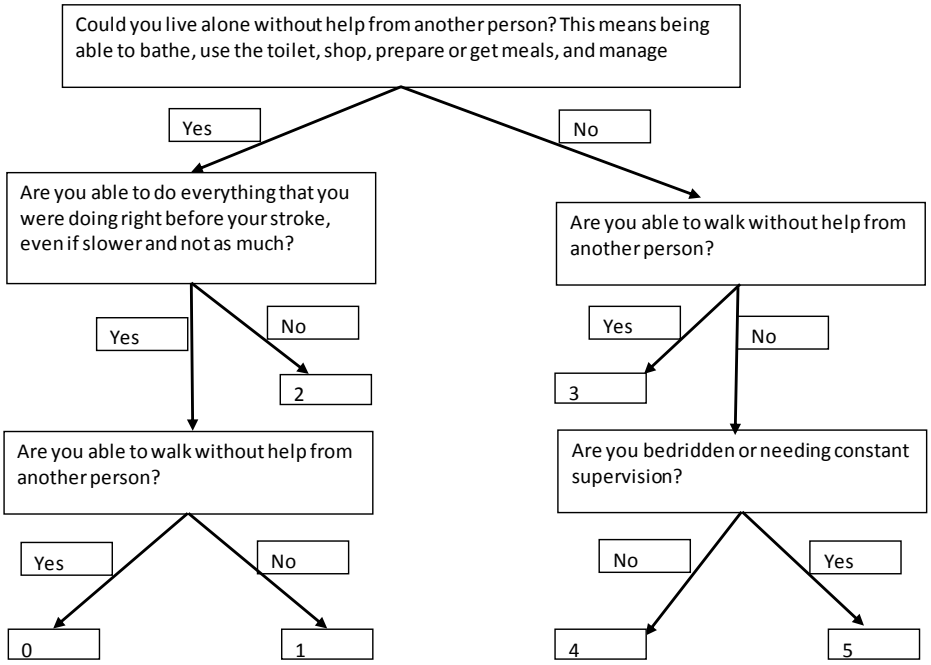
I recorded:

- Basic demographics (e.g. age, sex), recruitment details, date of stroke and consent details. These variables were collected to describe my cohort. Sex was also collected as a potential predictor variable- being male has been associated with increased odds of depression after stroke, while being female has been associated with increased odds of anxiety after stroke. (122)
- The patient's marital status, pet ownership, smoking and alcohol status and the highest level of education achieved. Marital status was collected to describe my cohort, but also as a potential predictor variable- being married has been reported to be associated with lower odds of depression after stroke.(123,124) 'Pet ownership' was collected as a potential predictor variable based on evidence that this improved psychological well-being. (125,126) The other variables were collected to describe my cohort.
- Charlson co-morbidity index (127): This includes 18 specific domains with a maximum score of 33. A score of 0 indicates no pre-existing comorbidity, 1-2: mild, 3-4: moderate and 5 or more: severe. I confirmed patient reports by inspecting their medical records (where available) at initial assessment. This was collected to describe my cohort and also because it has been described as a potential predictor variable of mortality and functional outcome six months after stroke. (127)
- Bamford or Oxford Community Stroke Project (OCSP) classification for ischaemic strokes (as recorded by medical staff): Total anterior circulation stroke (TACS), Partial anterior circulation stroke (PACS), Lacunar stroke (LACS) and Posterior circulation stroke (POCS). (128) This was collected to describe my cohort.
- Glasgow Coma Scale (GCS) (129,130): This is a general measure of neurological state and level of alertness determined by three areas: eye opening (scored 1-3), motor function (scored 1-6) and verbal response (scored 1-5). Therefore, the highest GCS is 15/15 and

lowest 3/15. This was collected to describe the baseline characteristics of my cohort.

- Six simple variables (SSV) (91): These six easily collected variables have been widely used in research (91,131) and audit (98) and predict survival at 30 days after stroke, survival and independence at six months and being able to live at home at six months and a year after stroke. The variables are: age, being independent before stroke, living alone before stroke, being able to walk unaided after stroke, being able to lift arms off the bed after stroke and normal verbal component of the GCS after stroke. I will describe the use of these variables in prognostic modelling in Chapter 7. The SSVs were collected as predictor variables as they were available in our large trial datasets for modelling and validation purposes.
- Barthel Index (BI)(12): This a scale measuring functional ability of the patient. This includes the patients' ability to self-care, mobilise, feed and be continent. I calculated a total score between 0 (fully dependent) and 100 (fully independent) from the individual components. Where information was not recorded in the patients' records, I asked nursing staff looking after the patient. I recorded the BI to describe the specific functional abilities of patients in my cohort. Urinary incontinence has also been reported to be associated with higher rate of institutionalisation two years after stroke. (132)
- Simplified modified Rankin questionnaire (smRsq): This questionnaire enables a rapid determination of the mRs score both in person and over the phone. (133) Since my follow ups were to be done over the telephone at six months, I used this questionnaire at all my follow up points to be consistent with data collection. (Figure 2.2)

Figure 2.2 smRsq for determination of mRs



- HRQoL using EQ5D: this questionnaire consists of two parts: a visual analogue scale (VAS) and a descriptive system (EQ5D-5L) covering five dimensions (mobility, self-care, ability to perform usual activities, pain/ discomfort and anxiety/depression), each with the option of five levels. Wherever possible, I encouraged patients to complete this questionnaire. However, if they were unable to do so (e.g. due to lack of capacity, medically unwell), proxies were invited to complete this on the patient's behalf. I decided to use the EQ5D-5L rather than the EQ5D 3L (which has been widely used and tested in multiple clinical trials) because the 3L version is not sensitive to the important quality of life impacts of all conditions (134,135) and may not be sensitive to smaller changes in health as it only has three response levels in each dimension. (136) In contrast, the 5L version offers more levels of options for participants to choose from. Also, the 5L version has better discriminatory power for the reported measure of anxiety/ depression. (137) I decided to use the EQ5D rather than other patient reported outcome scales because this scale was used in the large trial datasets that we used to develop our prognostic models (Chapter 7).

- Six item cognitive impairment scale (6CIT): In the absence of a validated brief cognitive assessment tool for use in the hyperacute stroke phase, (138) I chose the 6CIT due to its brevity and simplicity. (139) The test (assesses temporal orientation, attention and short term memory) has been used in a broad range of settings including primary care (140), acute care (141) and Alzheimers disease. (142) I performed this test with the patient at the follow-up times where possible (I.e. patient had capacity and did not have severe stroke related deficits e.g. severe dysphasia). Scores ranged from 0 to a maximum of 28 with higher scores indicating worse cognition. This was performed to describe my cohort.

2.5.4.2 Early follow-up

I recorded:

- Treatments and complications: if the patient had used intermittent pneumatic compression (IPC) for at least 24 hours, received at least 24 hours of parenteral fluids, had been treated with a course (at least 48 hours) of antibiotics, had been escalated to the high dependency or intensive care area for extra care, monitoring or circulatory support, had received (at least for 24 hours or had two or more trials of) enteral tube feeding via nasogastric tube (NG) or percutaneous gastrostomy (PEG), had a urethral catheter inserted (either for urinary incontinence or retention) or had a hemicraniectomy. I recorded if they had any form of infection (e.g. chest, urine, skin) which was diagnosed clinically. This diagnosis may or may not have been confirmed radiologically or from blood tests or cultures, and may or may not have been treated. I also recorded if they had another stroke between their initial stroke and follow up. I recorded these treatments and complications as each may influence patient progress and outcome.
- Do not attempt resuscitation (DNAR) decision: if patients had a DNAR form in their notes and if this was from the community or placed in hospital by day 10 of the patient's stroke.

- Assessments to determine progress: smRsq, BI, EQ5D-5L and 6CIT.

2.5.4.3 Six months after major stroke

I recorded:

- mRs using the smRsq
- BI
- EQ5D-5L and VAS
- 6CIT
- Ability to talk: By providing options (i.e. using our specific questions- no dysphasia, mild to moderate dysphasia, severe dysphasia or mute), I asked the patient/family member or GP about the patients' ability to talk. I took account of any speech and language therapy assessments in the patient's hospital electronic records, and/or my assessment when speaking to the patient. I recorded the responses, based on language assessments only, into no dysphasia/ mild to moderate dysphasia/ severe dysphasia and mute. This was similar to the 'best language' assessment on the National Institutes of Health Stroke Scale (NIHSS). (143)
- Ability to eat normally: By asking specific questions, I recorded responses of normal diet/ oral modified diet/ Nasogastric (NG) fed, percutaneous gastrostomy (PEG) or Radiologically inserted gastrostomy (RIG) fed.
- Ability to live at home: By asking specific questions, I recorded the place of residence of the patient at six months by either speaking to the patient or their proxy (usually family member), checking their records on the hospital electronic system or clarifying with their General Practitioner (GP).

Table 2.1 summarises the data I collected over the three time points:

Table 2.1 Summary table of assessments at three time points after major stroke

Assessment	Screening	Baseline	Early follow up	Six months
Demographics	+			
Eligibility criteria	+			
Age		+		
Date of birth		+		
Gender		+		
Medical history		+		
Social history		+		
Stroke classification		+		
Six simple variables		+		
Glasgow Coma Scale		+		
Early treatment			+	
Complications			+	
smRsq (mRs)	+	+	+	+
Barthel index (BI)		+	+	+
EQ5D-5L + VAS		+	+	+
Cognition (6CIT)		+	+	+
Talking	+			+
Eat normally	+			+
Capacity		+	+	+
Place of residence		+		+

2.6 Definitions of specific abilities at six months

To maintain consistency of reporting results, I defined ‘good’ and ‘poor’ outcomes as shown in Table 2.2. This is used as a convenient short hand throughout this thesis, and the dichotomies I have used are either based on conventional reporting in large trials (e.g. for mRs) or based on opinions of stroke professionals working in the hospital where recruitment took place. I acknowledge that different people would have different judgements on ‘good’ and ‘poor’ outcomes; for example, for some people, survival at all costs would be a ‘good’ outcome, whereas for some, any problem with a specific ability (e.g. to walk) may be a ‘poor’ outcome. Furthermore, for some specific abilities, different measures/ scales may be used to define the same outcome. For example, for ‘to walk’, specific question on walking from smRsq (‘Can you able to walk from one room to another without help from another person?’), single item measure from BI (mobility on a level surface) or single dimension (mobility) from EQ5D-5L may be used.

Table 2.2 Scales used to measure, and dichotomies of specific abilities at six months

Specific abilities at six months	Scale/ measure	Good outcome	Poor outcome
To be independent	mRs (via smRsq)	0-2	3-6
To walk	smRsq	Yes	No
To walk	BI	With the help of another person over 50 yards Independent over 50 yards	Wheelchair independent over 50 yards Immobile or less than 50 yards
To walk	EQ5D 5L	No problems Slight problems Moderate problems	Severe problems Unable or Dead
To be continent of urine	BI	Occasional accident Continent	Incontinent Catheter or Dead
To be continent of bowels	BI	Occasional accident Continent	Incontinent Catheter or Dead
To talk without major problems	Specific question*	No dysphasia Mild to moderate dysphasia	Severe dysphasia, Mute or Dead
To eat normally	Specific question*	Normal Oral modified	Nasogastric tube Percutaneous gastrostomy

			Radiologically inserted gastrostomy or Dead
To live without severe pain	EQ5D-5L	No pain Slight pain Moderate pain	Severe pain Extreme pain or Dead
To live without major anxiety or depression	EQ5D 5L	Not anxious/ depressed Slightly anxious/ depressed Moderately anxious/depressed	Severely anxious/ depressed Extremely anxious/depressed or Dead
To live without major cognitive problems	6CIT	No/mild CI Moderate CI	Severe CI Or Dead
To live at home	specific question*	Own home Families home	Residential home Care home Hospital or Dead

*Specific question: options given and dichotomised to ‘good’ or ‘poor’ outcome

Note: I decided to report urinary and bowel continence separately as some individuals may regard a problem with one to have a worse impact on their quality of life than the other.

2.7 Data management

I designed a Microsoft Access 2013 database to facilitate data entry, storage and to coordinate follow up. I created individual tables and forms for each

category of assessments. I linked variables to a unique identifier code and exported this into the statistical software package (Stata 15) for analysis.

I labelled each table and form separately to show what data the form had (e.g. social history, smRsq etc.) and at which time point. (i.e. baseline, early follow up, six months)

The database was stored on the central server in the Division of Clinical neurosciences and access was granted only to me and my primary supervisor via password entry. This allowed secure access. This server had automatic regular backup to the central server of the University. I consulted the data security officer of the University to ensure that all required security measures were adhered to.

2.8 Data checking

I employed a number of methods to ensure data consistency:

- I piloted the data collection forms with several patients on the stroke unit and made modifications. This ensured that the form was easy to use when I started recruitment.
- I designed my Microsoft Access database to be similar to the data collection form and for data items to be verified on entry. This was to reduce transcription errors and alert me to any data that were not in range and hence needed to be checked.
- Where possible, I used categorical answers to force yes/no decisions for each variable.
- Where possible, I used scales (e.g. smRsq, BI) where a numerical value could be calculated. This ensured consistency when making comparisons over time.
- I entered data into the database immediately after collecting it. This ensured that I was able to check for any missing data immediately and could collect these when the patient/ family and/or their medical records were still available.

- At several points of recruitment (e.g. patient number 100, 200, 300, 400), I checked the whole dataset for missing and incomplete records. If any were found, I went back to the medical notes to obtain this information.
- I performed a number of internal consistency checks using Stata 15 (statistical software) prior to analysis. This was to ensure that there were no obvious errors in my data- e.g. I would not anticipate a patient with mRs score of 5 to have a high BI, or a patient being recorded as having no capacity to have performed the 6CIT.

2.9 Sample size

I based my sample size on the NHS Lothian audit data for the Royal Infirmary of Edinburgh (RIE) in the year 2015 (the year prior to which I applied for funding for this study). This audit collected SSVs at patient admission. In this year, 620 (out of 861) admitted stroke patients had two of the following: prior dependency (i.e. not independent pre-stroke), immobility (unable to walk after stroke) and had an abnormal verbal GCS score response (i.e. unable to communicate normally) after stroke. Of these patients, 472 out of 861 patients survived to six months.

I aimed to recruit as many patients as possible as a larger cohort would mean a tighter 95% confidence interval around any estimates made of the proportion of patients with specific characteristics at the specified time points. I expected personally to be able to recruit 270 patients during the working week per year. Over 1.5 years of recruitment, about 400 patients might therefore be recruited into the study.

2.10 Analysis

2.10.1 Categorisation of variables

For the following variables, having collected the total score, I categorised the scores either to allow comparisons to be made between two scales (e.g. BI and mRs) or for reporting to be consistent with what is used in clinical practice (e.g. 6CIT). I detail this below:

- **To compare mRs and BI:**

The optimum cut offs for BI to make a comparison with mRs levels are varied. (12,13,144,145) Based on review of available literature, I categorised patients' BI score to reflect levels of disability (Mild 75-100, moderate 50-70, severe 0-45). (145) As I anticipated many of my patients to be at the functionally dependent (i.e. severely disabled) end of the BI spectrum, I further subcategorised 0-45 into 0-20 (severe) and 25-45 (moderately severe). I anticipated that having this extra category would provide a more detailed picture of our cohort of patients. I compared the numbers of patients in each category of disability as defined by BI and mRs; i.e. Comparing BI 75-100 with mRs 0-2, BI 50-70 with mRs 3, BI 25-45 with mRs 4 and BI 0-20 with mRs 5.

- 6CIT: as described above, scores ranged from 0 to 28. I categorised the scores based on how they are used in clinical practice (i.e. 0-7= no or mild cognitive impairment (CI), 8-9= moderate CI and 10-28= severe CI). (146)

2.10.2 Statistical methods

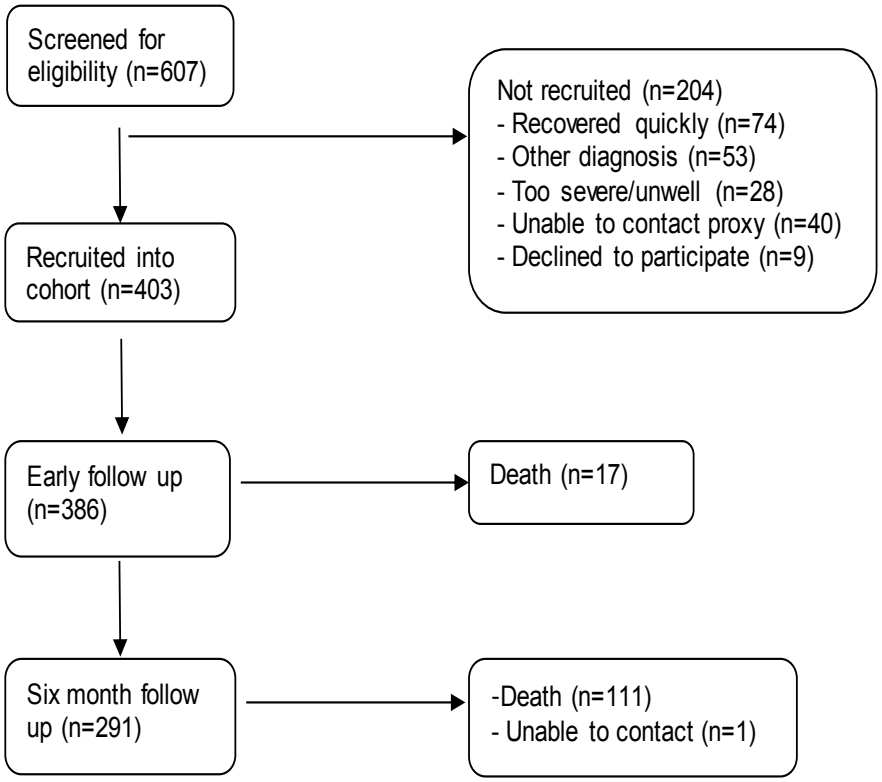
I carried out all statistical analysis using Stata 15 (Timberlake Consultants, 2017). I used descriptive statistics to summarise data and reported 95% confidence intervals for proportions. I performed cross tabulations to compare baseline and six month outcomes where appropriate. I took $P<0.05$ to be statistically significant. I derived utilities from EQ5D dimensions using the crosswalk calculator published on the EuroQol website.(147) This allowed me to compare individuals in our cohort's health states to those of healthy individuals in the UK population.

2.11 Results

I recruited 403 patients between 10th May 2017 and 25th May 2018. Of these patients, 386/403 (95.8%) completed early follow up (17/ 403, 4.2% had died) and 291/402 (72.2%) completed six month follow up (111/402, 27.5% had

died). I was unable to contact one patient for follow up at six months. This patient had moved abroad and was uncontactable. (Figure 2.3)

Figure 2.3 Flow diagram of recruitment and follow up of cohort of patients with major stroke



2.11.1 Recruitment details

Most patients were recruited from the acute stroke unit (384/403, 95.3%) and 248/403, 61.5% of these patients had mental capacity to be able to provide written consent themselves. (Table 2.3)

Table 2.3 Place of recruitment and consent details of recruited patients with major stroke

Details		N=403	%
Recruitment place	Acute stroke unit	384	95.3
	Medical assessment unit	13	3.2
	Other wards	6	1.5
Consent	Patient	248	61.5
	Proxy	155	38.5

2.11.2 Timings from stroke to baseline assessment and follow-up

The intervals from stroke to baseline assessment are shown in Figure 2.4.

The mean time from stroke to baseline assessment was 2.73 (SD 2.38) days.

Two patients were recruited out with the stated period (one on day 11 and one on day 32). These patients had provided verbal consent within the recruitment window (days 0-10 after stroke) but due to medical illness, they were unable to complete certain assessments till later. I gained permission from the patient and retrospectively reviewed the patient's notes to ensure that certain parts of the data (e.g. physical function) were collected from the early period after stroke.

Mean time to early follow up was 8.2 (SD 2.63) days [range 4-32] and to final follow up, 184.4 (SD 14.17) [range: 164- 291] (Table 2.4)

Figure 2.4 Number of patients recruited versus days from stroke to recruitment into study

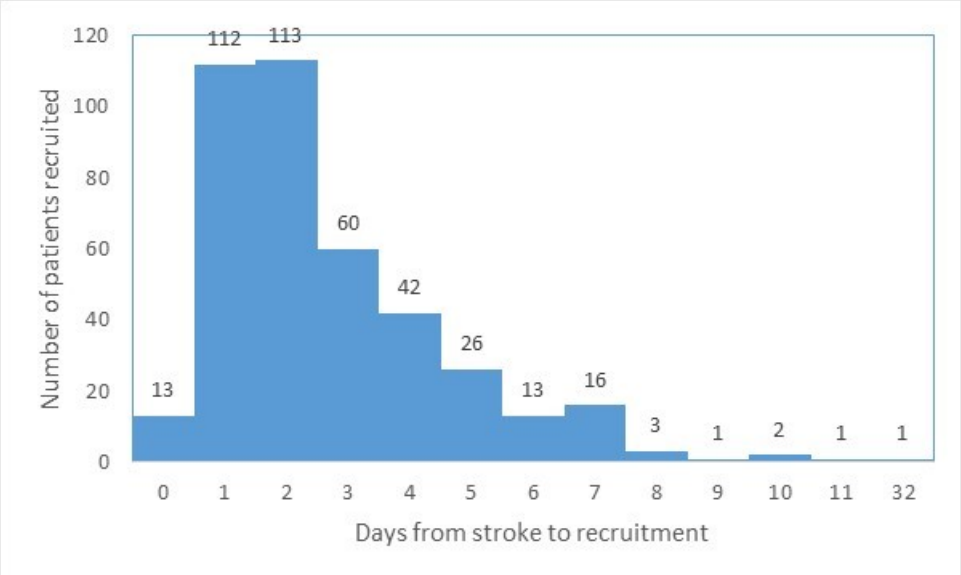


Table 2.4 Timing between stroke and assessments

Timing	n=	Mean (SD), days	Range, days
Baseline	403	2.85 (2.54)	0 to 32
Early follow up	386	8.2 (2.63)	4 to 32
6 month follow up	291	184.4 (14.17)	164 to 291

2.11.3 Baseline characteristics of recruited patients

2.11.3.1 Demographics

The mean age of the cohort was 77.5 years, standard deviation (SD) 11.8, range 36-101. Over a third of recruited patients were between the ages of 80 and 89. (150/403, 37.2%)

I recruited 179 males and 224 females into the study. The mean age of males was 74.5 (12.5) [36-101]. The mean age of females was 79.9 (10.6) [36-97]. (Table 2.5)

Table 2.5 Distribution of recruited patients by age group and gender

Age group	Male	Female	Total	Total
	n	n	n	%
30-39	1	1	2	0.5
40-49	3	2	5	1.2
50-59	22	9	31	7.7
60-69	38	21	59	14.6
70-79	40	57	97	24.1
80-89	57	93	150	37.2
90-99	17	41	58	14.4
100-109	1	0	1	0.3
Totals	179	224	403	100

2.11.3.2 Ethnicity

Most patients were White Scottish (343/403, 85.1%). (Table 2.6)

Table 2.6 Ethnicity of recruited patients

		N=403	%
Ethnicity	White other British	42	10.4
	White Scottish	343	85.1
	White Irish	5	1.2
	White Other	12	3.0
	Chinese	1	0.3
	Unknown	0	0.0

2.11.3.3 Social circumstances

Table 2.7 summarises the social circumstances of the cohort of patients.

Table 2.7 Social circumstances of cohort of patients admitted with major stroke

Variable	Categories	Total n=403	%
Living circumstances pre-stroke	Own home- alone	158	39.2
	Own home- with family	170	42.2
	Own home- with carers	57	14.1
	Sheltered home	2	0.5
	Care home	14	3.5
	Prison	2	0.5
	Unknown	0	0.0
Highest level of education achieved	School	318	78.9
	University	29	7.2
	Postgraduate	4	1.0
	College/diploma	52	12.9
	Unknown	0	0.0
Occupation	Retired	348	86.4
	Employed	32	7.9
	Self-employed	10	2.5
	Housewife/husband	2	0.5
	Permanently sick	10	2.5
	Student	1	0.3
	Unknown	0	0.0
Religion	No religion	128	31.8
	Christian (all denominations)	271	67.3

	Jewish	2	0.5
	Other	2	0.5
	Unknown	0	0.0
Smoking status	Current	69	17.1
	Never	162	40.2
	Ex >12 months	166	41.2
	Ex<12 months	5	1.2
	Unknown	0	0.0
Alcohol consumption	No	157	39.0
	Yes	245	60.8
	Unknown	1	0.3
Pet ownership	Never	273	67.7
	Current	66	16.4
	Yes in the last 12 months but not currently	64	15.9

2.11.3.4 Medical history

Some patients (23/403, 5.7%) had severe comorbidities before their hospital admission with major stroke as defined by the Charlson comorbidity index score. Around a third, (123/403, 30.5%) had a previous stroke or transient ischaemic attack (TIA). (Table 2.8)

Table 2.8 Medical characteristics

Variable		Total n= 403	%
Charlson Co-morbidity Index Score	Scores:		
	0	124	30.8
	1-2	180	44.7
	3-4	76	18.9
	</=5	23	5.7
Pre-existing dementia	Yes	49	12.2
	No	354	87.8
History of Atrial Fibrillation	Current	47	11.7
	Past	89	22.1
	None	267	66.3
Past history of Stroke or TIA	Yes	123	30.5
	None	280	69.5

2.11.3.5 Stroke related characteristics

The majority, (340/403, 84.4%) of recruited patients had an ischaemic stroke. (Table 2.9)

Table 2.9 Stroke related characteristics

Variable		Total n =403	%
Stroke Subtype	Haemorrhagic	63	15.6
	All ischaemic	340	84.4
Stroke Classification (ischaemic only)	Total Anterior Circulation (TACS)	122	35.9
	Partial Anterior Circulation (PACS)	146	42.9
	Lacunar (LACS)		
	Posterior Circulation (POCS)	45	13.2
		27	7.9

2.11.3.6 Six simple variables (SSV) (91)

Around three quarters of patients (308/403, 76.4%) in the cohort were independent before stroke. Few (28/403, 6.9%) were able to walk after their stroke (i.e. at baseline assessment). (Table 2.10)

Table 2.10 Six Simple Variables at baseline

Variable	N= 403	%
Independent before stroke	308	76.4
Living alone before stroke	158	39.2
Able to walk after stroke	28	6.9
Able to lift arms after stroke	152	37.8
Orientated speech after stroke	248	61.5
Age (mean, years (SD))	77.5 (11.8)	

2.11.3.7 Baseline mRs measured using smRsq

Over half of the patients I recruited had a mRs of 5 (209/403, 51.9%). Few (6/403, 1.5%) had a mRs of 1 or 2 at time of recruitment, but as per my inclusion criteria, these patients had two or more specific abilities affected as a result of their stroke and were therefore eligible. Of the patients with mRs 1 and 2 (six in total), all had been thrombolysed. Five of these patients had problems with their ability to talk and to eat normally at baseline. The two patients with mRs 1 had high level difficulties in their ability to talk and mild impairment in their ability to eat normally. Hence although they had symptoms, they were able to perform all their usual activities. Four patients with mRs 2 had problems with their ability to talk and eat normally and required assistance from nursing staff but they were able to walk and self-care independently. One patient (with mRs 2) had problems with talking and continence (urinary only). Though he/she was able to manage daily activities, he/she was unable to perform all previous activities e.g. reading. (Table 2.11)

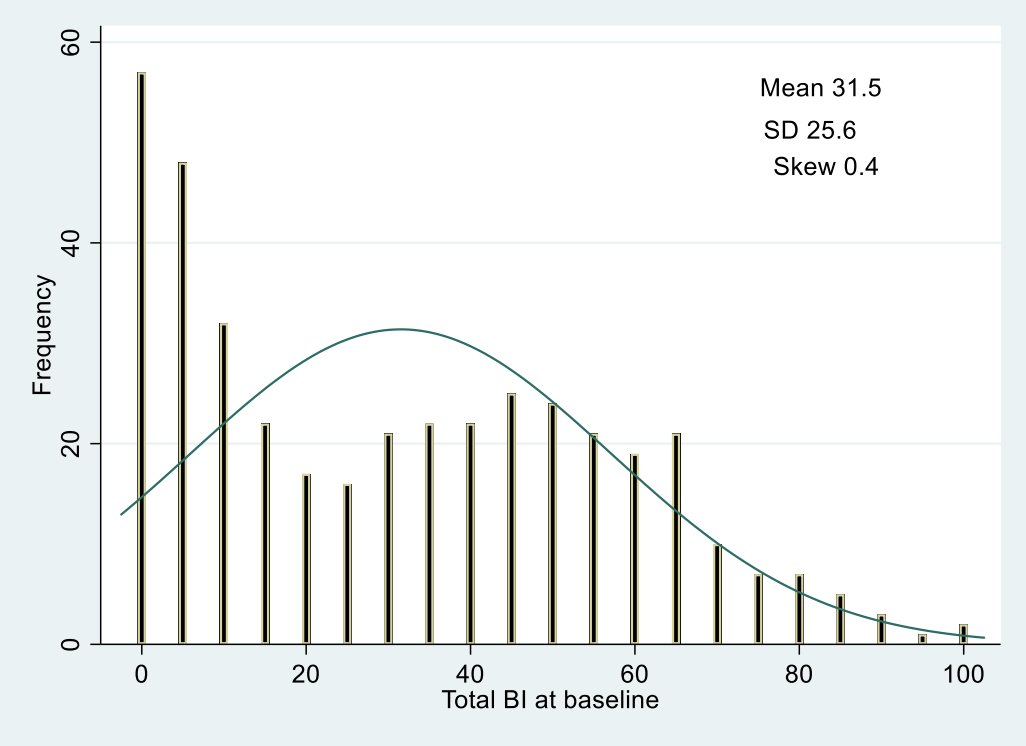
Table 2.11 Baseline mRs of cohort of patients with major stroke

mRs	n	%
0	0	0
1	2	0.5
2	4	1
3	17	4.2
4	171	42.4
5	209	51.9
6	0	0
Missing	0	0
Total	403	100

2.11.3.8 Baseline BI (score 0 to a maximum of 100)

The distribution of BI scores at baseline is shown in Figure 2.5. BI scores at baseline were normally distributed (mean 31.6, SD 25.6). Median score was 30, (5-50) [95%CI].

Figure 2.5 Distribution of BI at baseline



When I categorised BI (as described above), most patients were severely functionally dependent, with a BI score of less than 20. (Table 2.12)

Table 2.12 Categorised BI score at baseline

BI	n	%
0-20	176	43.7
25-45	106	26.3
50-70	96	23.8
75-100	25	6.2
Dead	0	0
Missing	0	0
Totals	403	100

Each individual component (single item) of the BI provided more detailed information on the ability of the patients. For example,

2.11.3.8.1 Mobility from BI

At baseline, 17/403 (4.2%) were classed as being independent over 50 yards, 83/403 (20.7%) were able to mobilise with the help of another person over 50 yards and 303/403 (75.2%) of patients were either immobile, or mobile less than 50 yards.

2.11.3.8.2 Continence from BI

At baseline, specific to urinary continence, 165/403 (40.8%) were continent of urine, 43/403 (10.7%) had ‘occasional accidents’ and 195/403 (48.5%) were incontinent or had a urethral catheter.

Specific to bowel continence, 250/403 (62.0%) were continent, 9/403 (2.2%) had occasional accidents and 144/403 (35.7%) were incontinent.

2.11.3.9 Talking (language assessments only)

At baseline, 273/403, 67.7% of patients had a problem with their ability to talk.

2.11.3.10 Eating

At baseline, 175/403, 43.4% of patients had a problem with being able to eat (i.e. they had a problem with their swallow).

2.11.3.11 HRQoL (EQ5D-5L and VAS)

A comparison between patients and proxies was not possible as proxies only completed these assessments when patients were unable to do so. In the absence of an alternative way of obtaining patients responses, I assumed proxies were completing the assessments based on what the patient may have answered.

Of the total number of assessments, 245/403 (60.8%) were completed by patients and 158/403 (39.2%) were completed by proxies at baseline. Three patients who were able to consent (Table 2.3) delegated the completion of EQ5D to their proxy due to fatigue (n=2) and did not have their reading glasses (n=1).

I assessed if the mRs of the patient had any bearing on who completed the HRQoL assessments. (Table 2.13) I found that proxies completed most of the HRQoL assessments in patients who had mRs 5. (127/403, 31.5%)

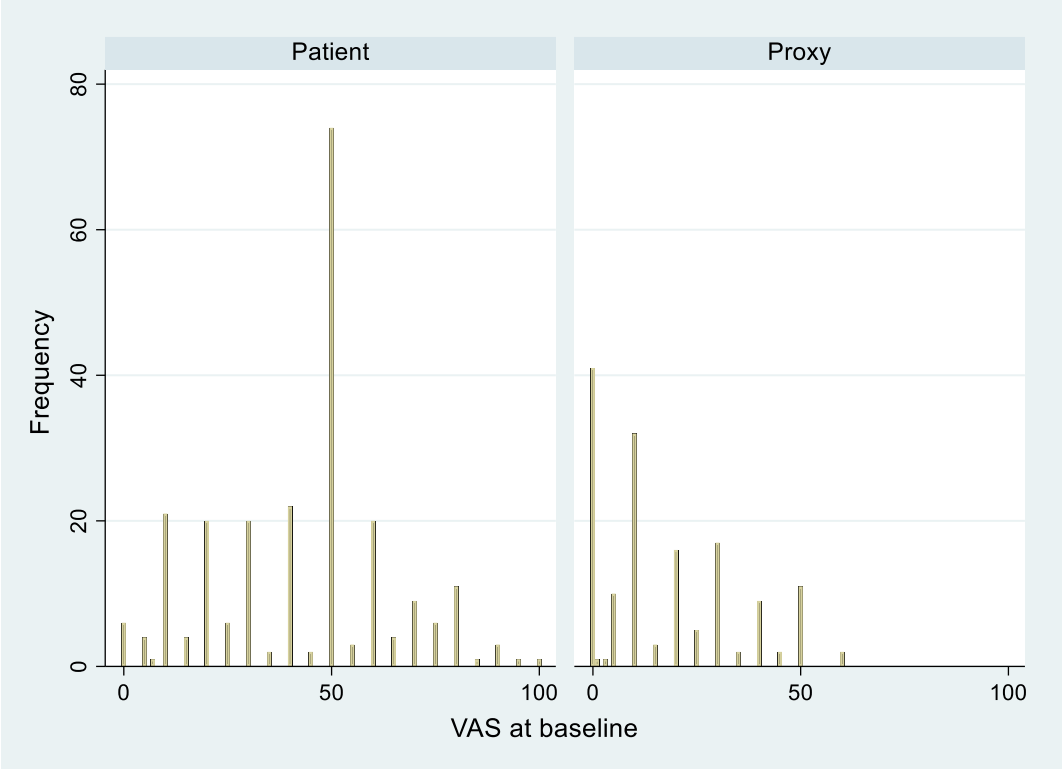
Table 2.13 Completion of HRQoL assessments based on patient mRs at baseline

	mRs at baseline						Totals
Completed by	0	1	2	3	4	5	
Patient	0	2	4	14	143	82	245
Proxy	0	0	0	3	28	127	158
Totals	0	2	4	17	171	209	403

Eight participants (4 patients and 4 proxies) (2.0%) did not complete the VAS at baseline.

The distribution of VAS scores (n=395), by patient (n=241) versus proxy (n=154) is shown in Figure 2.6. Patients tended to report a wider range of scores on the VAS, with most reporting a score of 50. Proxies tended to indicate lower scores. This is likely because proxies completed the HRQoL assessment where the patient had had a more severe stroke (as categorised by mRs and shown in Table 2.13). It is also possible that proxies may be more pessimistic of the patient's abilities.

Figure 2.6 VAS at baseline, patient and proxy



However, as I reported above, a direct comparison of patient versus proxy is not possible. Therefore, unless specified, for the rest of my analysis, I combined EQ5D-5L and VAS responses provided by patients and proxies (i.e. participants).

Figure 2.7 shows the distribution of all completed VAS at baseline (n=395) with corresponding summary statistics. The distribution of VAS at baseline was normally distributed: Mean 32.8 SD 23.6. Median was 30 (10-50) [95%CI].

Figure 2.7 Distribution of VAS (all) at baseline, n=395

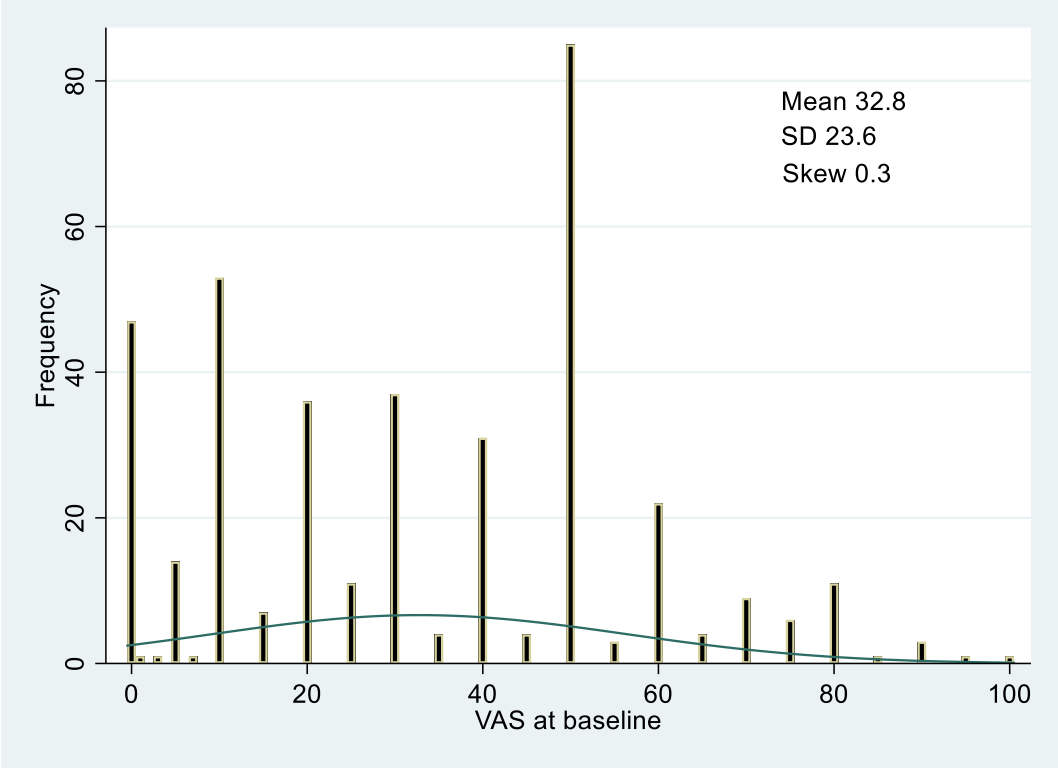


Table 2.14 shows the responses of participants in all five dimensions. When looking at each individual level within each dimension, the highest number of participants had indicated 'unable to perform' for the first three dimensions (i.e. mobility, self-care and usual activities) and 'none' for pain and anxiety/depression.

Table 2.14 Responses to each EQ5D-5L dimension at baseline

Dimension	Levels	n	%
Mobility	No problems	27	6.7
	Slight problems	58	14.4
	Moderate problems	63	15.6
	Severe problems	64	15.9
	Unable to perform	190	47.2

	Missing	1	0.3
Self-care	No problems	43	10.7
	Slight problems	72	17.9
	Moderate problems	80	19.9
	Severe problems	43	10.7
	Unable	164	40.7
	Missing	1	0.3
Usual activities	No problems	13	3.2
	Slight problems	41	10.2
	Moderate problems	54	13.4
	Severe problems	28	7.0
	Unable	267	66.3
	Missing	0	0.0
Pain	None	257	63.8
	Slight	69	17.1
	Moderate	52	12.9
	Severe	20	5.0
	Extreme	3	0.7
	Missing	2	0.5
Anxiety/depression	None	133	33.0
	Slight	111	27.5
	Moderate	99	24.6
	Severe	52	12.9
	Extreme	7	1.7
	Missing	1	0.3

The mean utility of patients at baseline was 0.23, SD 0.36.

2.11.3.12 Cognition at baseline

The distribution of cognitive scores of patients who were able to participate at baseline (232/403, 57.6%) was skewed. The median score was 6 (2-12) [95%CI]. Mean 7.2, SD 6.2. (Figure 2.8)

Figure 2.8 Cognitive scores at baseline, n=232

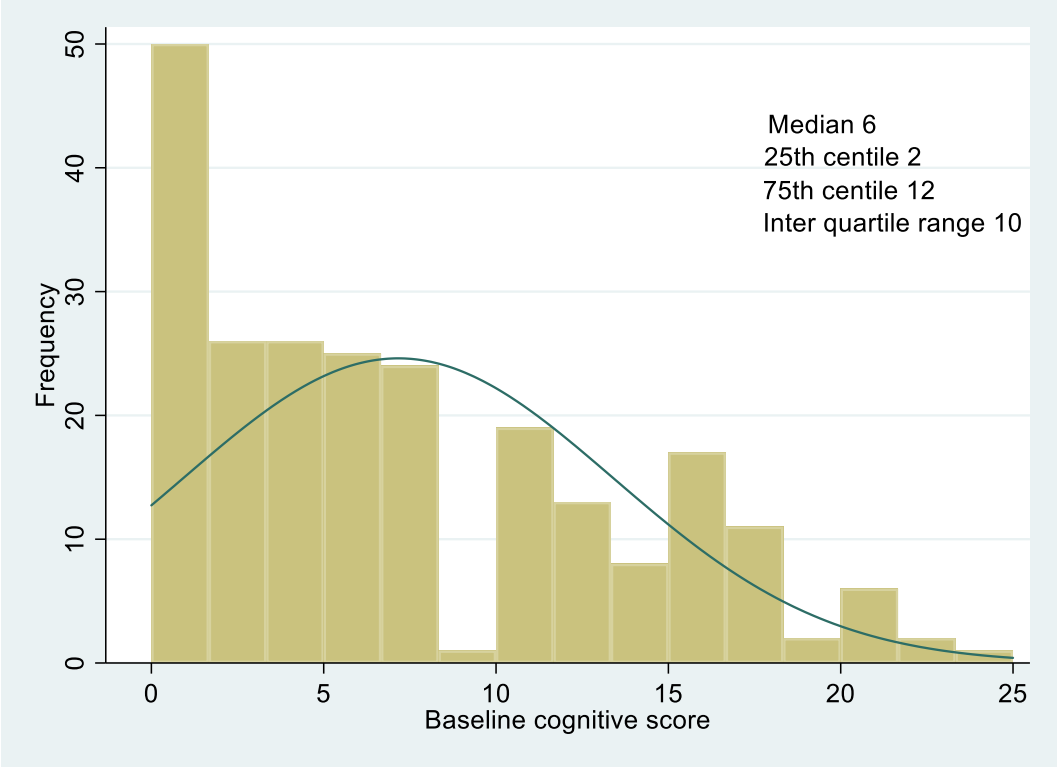


Table 2.15 shows the 6CIT scores of our cohort at baseline, categorised as reported in clinical practice. (146)

Table 2.15 6CIT scores at baseline, categorised

Scores	Definition	n	%
0 to 7	No or mild CI	129	32.0
8 to 9	Moderate CI	23	5.7
10 to 28	Severe CI	80	19.9
Missing	Could not perform (e.g. Lack of capacity)	171	42.5
Total		403	100

2.11.4 Progression of cohort of patients with major stroke over time

In this section, I describe how the cohort of patients progressed over time (from baseline, to early follow up and final follow up). I report:

- Complications and treatments by early follow up
- mRs over time
- BI over time
- HRQoL over time
- Specific abilities (either based on single items from measures/scales or by asking specific questions on their abilities) at baseline and at six months

At early follow-up, 386/403, 95.8% were alive, and at six months, 291/402, 72.4% were alive.

2.11.4.1 Complications and treatments by early follow up

Table 2.16 shows the complications incurred and treatments received by the cohort of patients by early follow up.

Table 2.16 Complications and treatments by early follow up

Variable	n=403	%
Complications		
Infection	132	32.8
Recurrent stroke	12	3
Treatments		
Parenteral fluids	284	70.5
Intermittent pneumatic compression	275	68.2
Antibiotics	129	32
Urethral Catheterisation	112	27.8
Enteral tube feeding	78	19.4
Escalation above ward level	3	0.7
Neurosurgery	0	0

By day 10 of stroke, 89/403 (23.2%) had a DNAR form instated in hospital. Another few, 33/403 (8.6%) had a DNAR form from the community.

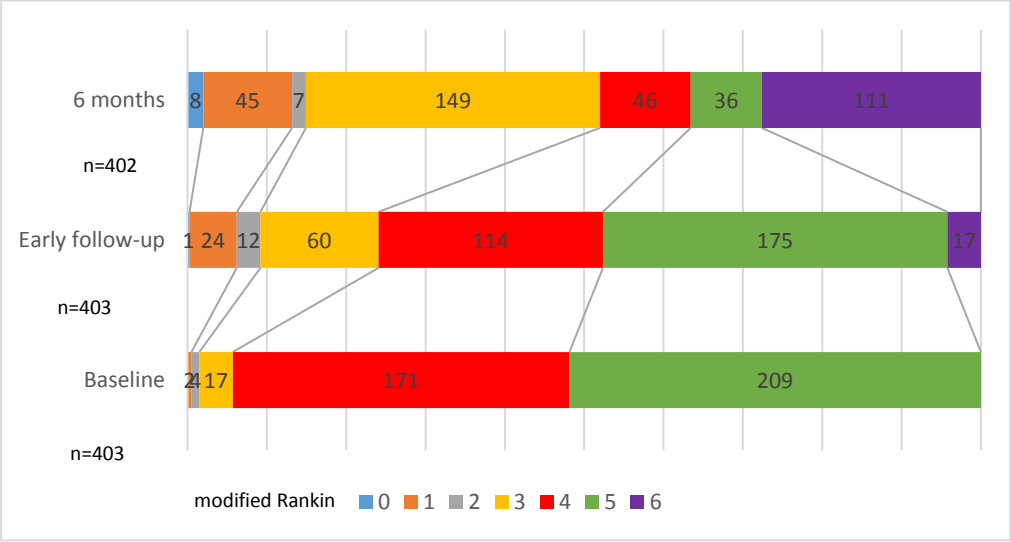
2.11.4.2 mRs measured by smRsq

A small proportion of patients, 37/403 (9.3%) had an mRs 0-2 at early follow up. Few more, 60/402 (13.1%) had mRs 0-2 by six months. However, a proportion, 82/402 (20.3%) remained significantly disabled (mRs 4-5) at six months. There was a high proportion of patients with mRs of 3 at six months. (Table 2.17) The figure below shows the number of patients in each mRs level over time. (Figure 2.9)

Table 2.17 mRs of the cohort of patients with major stroke over time

mRs	Baseline		Early follow-up		Six months	
	n	%	n	%	n	%
0	0	0	1	0.3	8	2
1	2	0.5	24	6	45	11.2
2	4	1	12	3	7	1.7
3	17	4.2	60	14.9	149	37
4	171	42.4	114	28.3	46	11.4
5	209	51.9	175	43.4	36	8.9
6	0	0	17	4.2	111	27.5
Missing	0	0	0	0	1	0.3
All	403	100	403	100	403	100

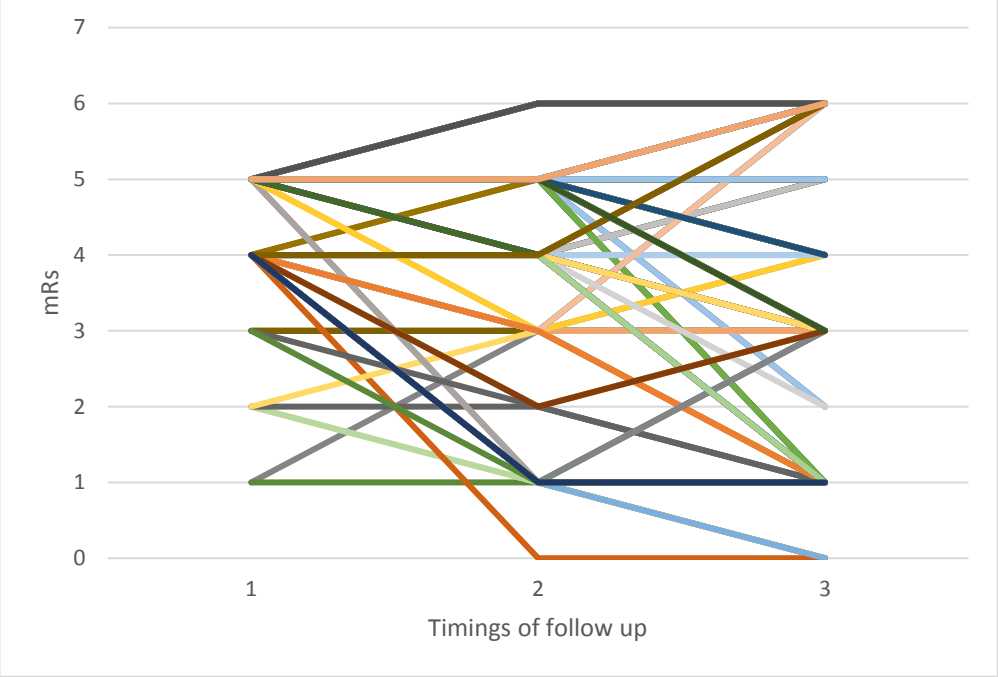
Figure 2.9 mRs of cohort of patients with major stroke over time



While the above represents grouped data, the progress of each individual patient varied greatly. The line plot (Figure 2.10) shows the changes in mRs

of each patient over the three time periods (baseline, early follow up, six months) in a sample of 200 (50%) out of the 403 patients. This diagram provides a pictorial representation of how individual patients may vary in their progress over time rather than being intended as a full representation of my data. There were overlaps of lines as some patients took the same mRs pathway over time. It was not possible to draw a line plot for all 403 patients due to restrictions on the number of values that the programme used to draw this line plot could handle.

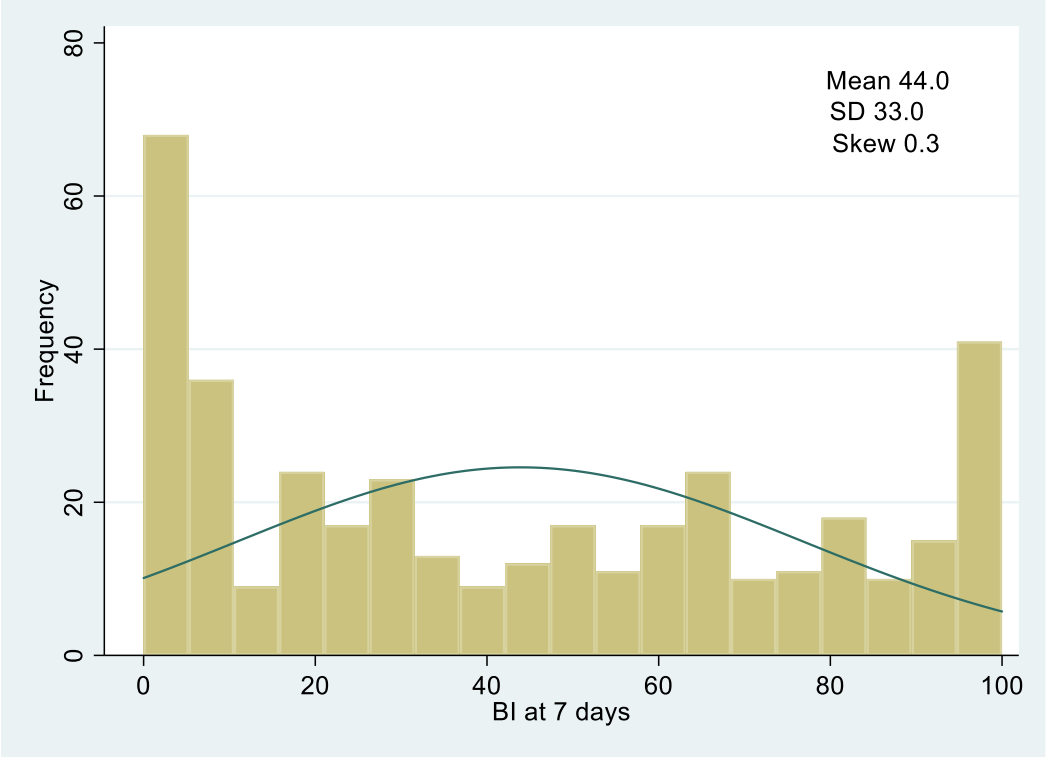
Figure 2.10 Individual patient data, n=200: mRs pathway taken by each patient over the three time periods



2.11.4.3 BI over time

At early follow up, BI scores were normally distributed for surviving patients (n=386) [Mean 44.0, SD 33.0]. Median score was 40 (10-70) [95%CI]. (Figure 2.11)

Figure 2.11 Distribution of BI of surviving patients (n=386) at early follow up.



At six months, the distribution of BI of surviving patients (n=291) was skewed. Median 75 (50-90) [95%CI]. Mean 67.5, SD 29.3. (Figure 2.12)

Figure 2.12 Distribution of BI of surviving patients (n=291) at six months

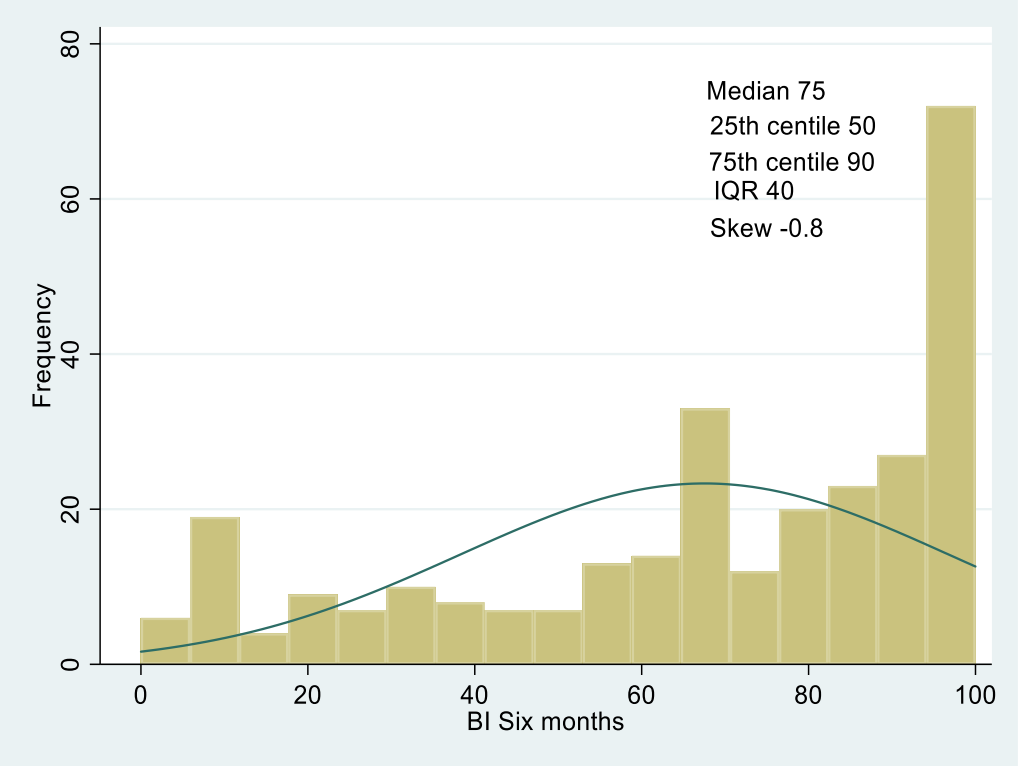
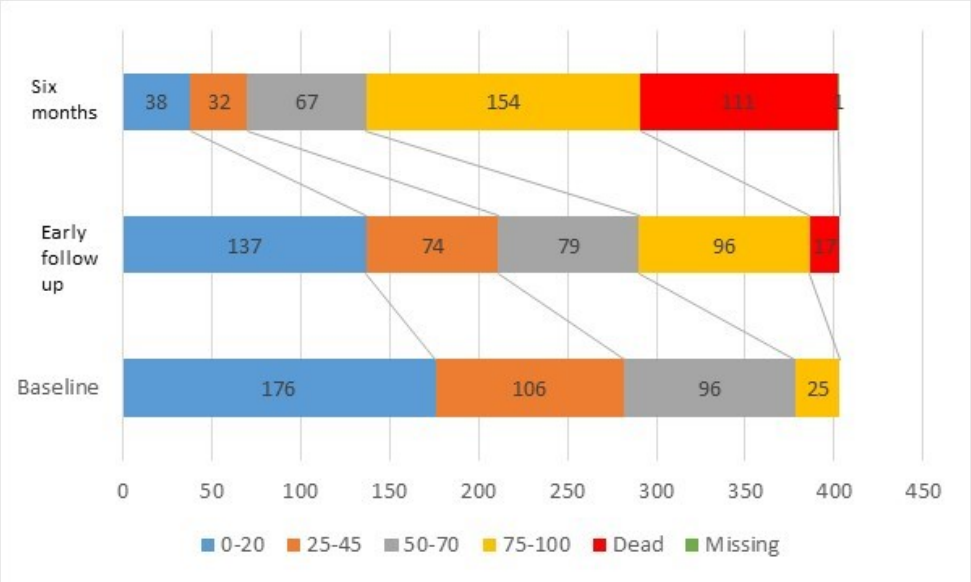


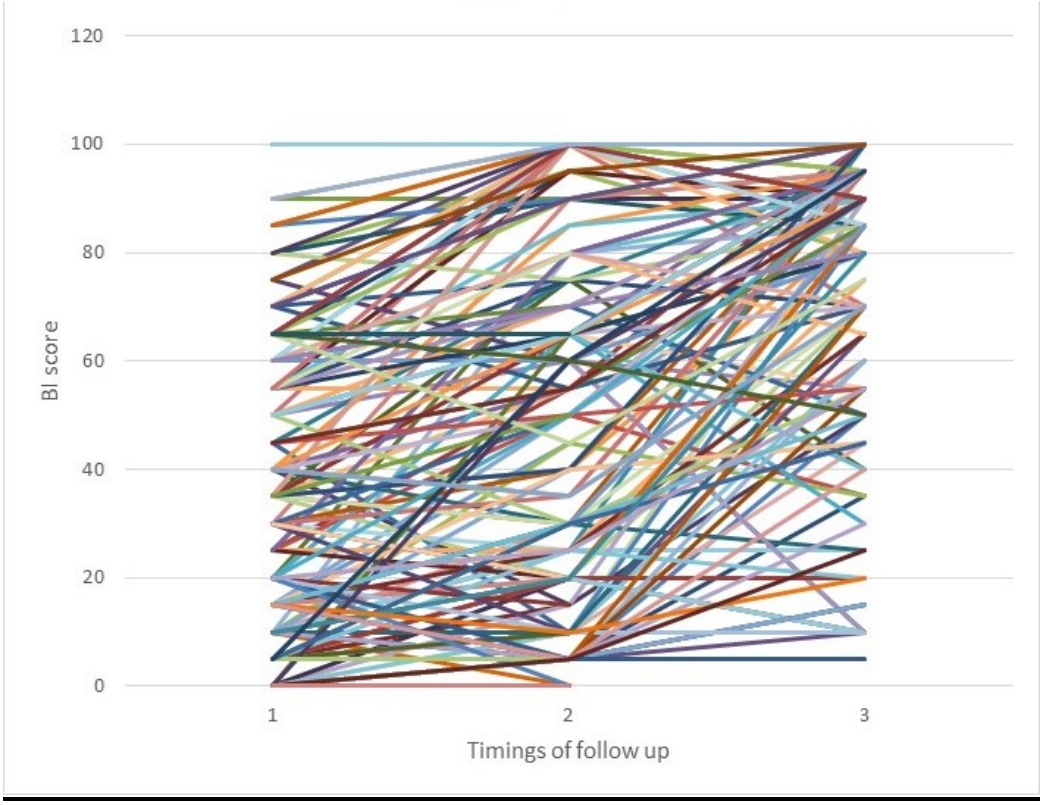
Figure 2.13 shows the distribution of BI, categorised, over time. While 154/402 (38.3%) of patients were considered to 'be independent' at six months (BI 75-100), a proportion: 38/402 (9.5%) of the cohort were functionally severely dependent (BI 0-20) at six months.

Figure 2.13 Number of patients in each category of BI over three time points



The line plot (Figure 2.14) shows the pathway 200 patients (50% of the cohort) took with respect to their BI scores at the three follow up times. This figure is indicated as a pictorial representation of how individual patients progressed, rather than a full representation of my data.

Figure 2.14 Individual patient data, n=200: pathway taken by each patient with respect to their BI over three time periods (baseline, early follow up and six months)



2.11.4.4 Comparison of two disability scales: mRs and BI

As described in Section 2.10.1, to compare how mRs and BI may vary with respect to categorising patients into levels of disability, I chose BI cut-offs based on my review of literature to allow a comparison to be made with mRs. (12,13,144,145)

At all follow up times, BI grouped more patients into the no/mild disability group when compared to mRs. BI also grouped fewer patients into the moderately severe and severe disability groups when compared to mRs. (Table 2.18) I describe the ‘’floor ceiling’’ effects of BI in my discussion.

Table 2.18 Grouping of patients into disability categories: mRs and BI of surviving patients at three follow up times

Timing	Number of patients n	Categories of physical disability	Definitions	mRs n	BI n
Baseline	403	No/mild disability	mRs 0-2 /BI 75-100	6	25
		Moderate disability	mRs 3/ BI 50-70	17	96
		Moderately severe disability	mRs 4/ BI 25-45	171	106
		Severe disability	mRs 5/ BI 0-20	209	176
Early follow up	386	No/mild disability	mRs 0-2 /BI 75-100	37	96
		Moderate disability	mRs 3/ BI 50-70	60	79
		Moderately severe disability	mRs 4/ BI 25-45	114	74
		Severe disability	mRs 5/ BI 0-20	175	137
Six months	291	No/mild disability	mRs 0-2 /BI 75-100	60	154
		Moderate disability	mRs 3/ BI 50-70	149	67
		Moderately severe disability	mRs 4/ BI 25-45	46	32
		Severe disability	mRs 5/ BI 0-20	36	38

2.11.4.5 HRQoL: EQ5D-5L and VAS

At early follow up, 255/403 (63.3%) of patients and 131/403 (32.5%) of proxies completed HRQoL assessments. Few, 17/402 (4.2%) patients had died by early follow up. Proxies completed HRQoL assessments on behalf of the patient where the patient had a higher mRs (i.e. 4 or 5).

Table 2.19 Completion of HRQoL assessments by patients or proxies based on patients' mRs at early follow up

Completed by	**mRs at early follow up**							**Totals**
	0	1	2	3	4	5	6	
Patient	1	24	12	45	90	83	0	255
Proxy	0	0	0	15	24	92	0	131
Dead	0	0	0	0	0	0	17	17
Totals	1	24	12	60	114	175	17	403

At six months, patients completed 193/402 (48.0%) of HRQoL assessments and proxies completed 98/402 (24.4%). As reported, 111/402 (27.5%) of patients had died by six months. Similar to baseline and at early follow up, proxies completed most of the assessments where the patient had a mRs of 5 (31/402, 7.7%) and only 5/402 (1.2%) of patients who had a mRs of 5 were able to complete these assessments themselves. (Table 2.20)

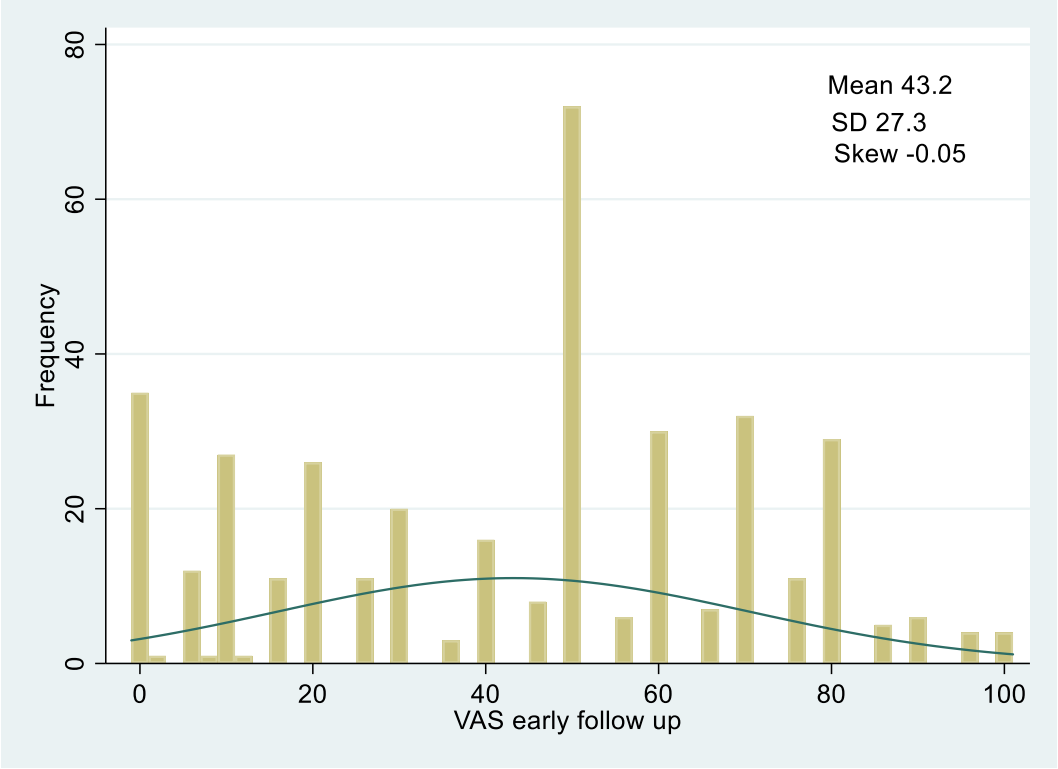
Table 2.20 Completion of HRQoL assessments by patients or proxies based on patients' mRs at six months

Completed by	mRs at six months							Totals
	0	1	2	3	4	5	6	
Patient	8	44	6	118	12	5	0	193
Proxy	0	1	1	31	34	31	0	98
Dead	0	0	0	0	0	0	111	111
Totals	8	45	7	149	46	36	111	402

2.11.4.5.1 Visual analogue scale (VAS)

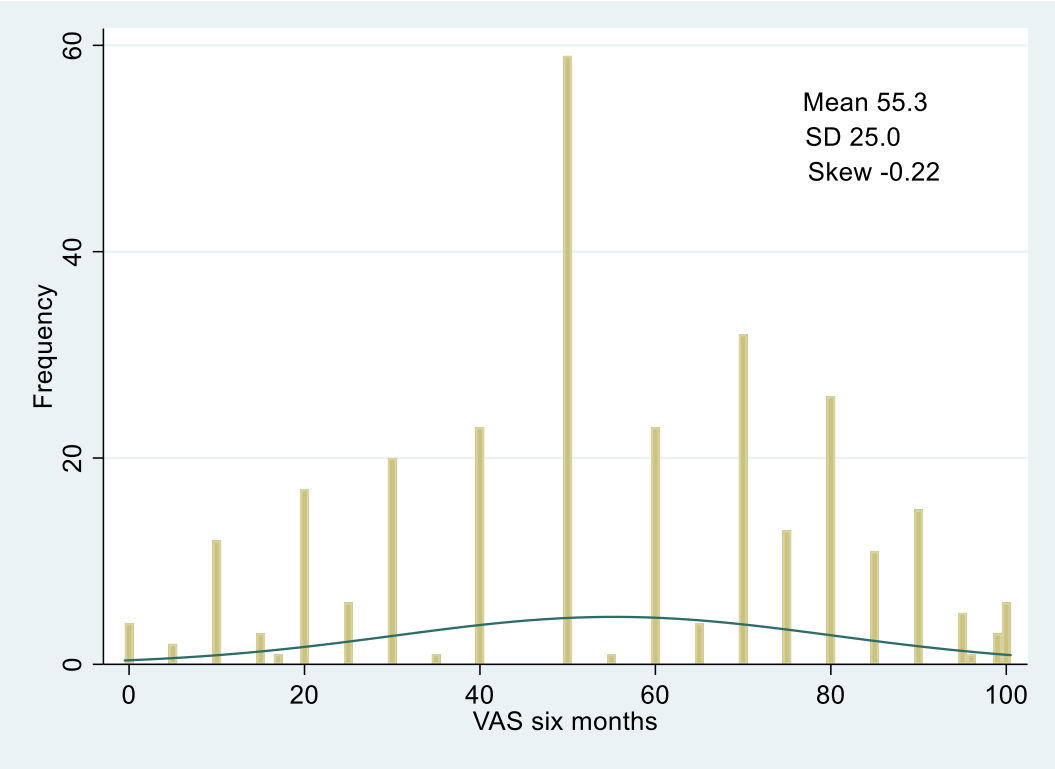
At early follow up, VAS data were not available from n=24 participants (17 patients had died, and 7 did not complete). The distribution of available VAS (n=379) was normally distributed with a mean VAS of 43.2, SD 27.3. Median was 50 (20-65) [95%CI]. (Figure 2.15)

Figure 2.15 Distribution of VAS of patients with major stroke at early follow up, n=379



At six months, VAS data were available from 288 participants (111 patients had died, 1 was lost to follow up and 3 did not complete). The scores were normally distributed: mean 55.3, SD 25.0. Median 50 (40-75) [95%CI]. (Figure 2.16)

Figure 2.16 Distribution of VAS at six months, n=288



2.11.4.5.2 Individual EQ5D-5L dimensions

Table 2.21 summarises the responses provided by participants in each EQ5D-5L dimension over the three time points. The proportion of patients reporting severe/ extreme problems or 'unable' reduced over time. This could be explained by the virtue of patients with more severe problems dying.

Table 2.21EQ5D-5L dimensions of patients with major stroke over three times (baseline, early follow up and six months), n=403

Dimension	Levels	Timing					
		Baseline		Early follow-up		6 months	
		n	%	n	%	n	%
Mobility	No problems	27	6.7	48	11.9	60	14.9
	Slight problems	58	14.4	60	14.9	69	17.1
	Moderate problems	63	15.6	65	16.1	65	16.1
	Severe problems	64	15.9	51	12.7	53	13.2
	Unable to perform	190	47.2	162	40.2	44	10.9
	Dead	0	0.0	17	4.2	111	27.5
	Missing	1	0.3	0	0.0	1	0.2
Self-care	No problem	43	10.7	82	20.4	104	25.8
	Slight problem	72	17.9	65	16.1	49	12.2
	Moderate problem	80	19.9	65	16.1	60	14.9
	Severe problem	43	10.7	41	10.2	27	6.7
	Unable	164	40.7	132	32.8	51	12.7
	Dead	0	0	17	4.2	111	27.5

	Missing	1	0.3	1	0.3	1	0.2
Usual activities	No problems	13	3.2	25	6.2	33	8.2
	Slight problems	41	10.2	72	17.9	85	21.1
	Moderate problems	54	13.4	60	14.9	62	15.4
	Severe problems	28	7.0	21	5.2	17	4.2
	Unable	267	66.3	208	51.6	94	23.3
	Dead	0	0	17	4.2	111	27.5
	Missing	0	0	0	0	1	0.2
Pain	None	257	63.8	252	62.5	199	49.4
	Slight	69	17.1	72	17.9	41	10.2
	Moderate	52	12.9	38	9.4	35	8.7
	Severe	20	5.0	23	5.7	16	4.0
	Extreme	3	0.7	0	0.0	0	0.0
	Dead	0	0	17	4.2	111	27.5
	Missing	2	0.5	1	0.3	1	0.2
Anxiety/depression	None	133	33.0	145	36.0	111	27.5
	Slight	111	27.5	110	27.3	100	24.8

	Moderate	99	24.6	91	22.6	41	10.2
	Severe	52	12.9	38	9.4	36	8.9
	Extreme	7	1.7	2	0.5	3	0.7
	Dead	0	0	17	4.2	111	27.5
	Missing	1	0.3	0	0	1	0.2

2.11.4.5.3 Utilities (derived from EQ5D dimensions)

I calculated the utility (the desirability of a specific health outcome, where a utility of 1 represents excellent health and one that is negative (less than 0) to be worse than death) using the crosswalk calculator published in the EuroQol website, (147) for each of the patients in our cohort. Missing data (n=1) have been excluded from this part of the analysis.

Table 2.22 shows the mean utilities of our cohort of patients (n=402). I have reported two results: one including those patients who had died (and given a utility of 0) and one excluding those who had died. The rationale behind including those who had died, and giving them a utility value of 0, was to account for the people who had died and acknowledge that there may be disability states that were better or worse than death for some individuals. The rationale for excluding those who had died was that their utility was not measured, and therefore, the utility of those who had died was assumed to be 0.

Table 2.22 Mean utilities of patients with major stroke at three time points

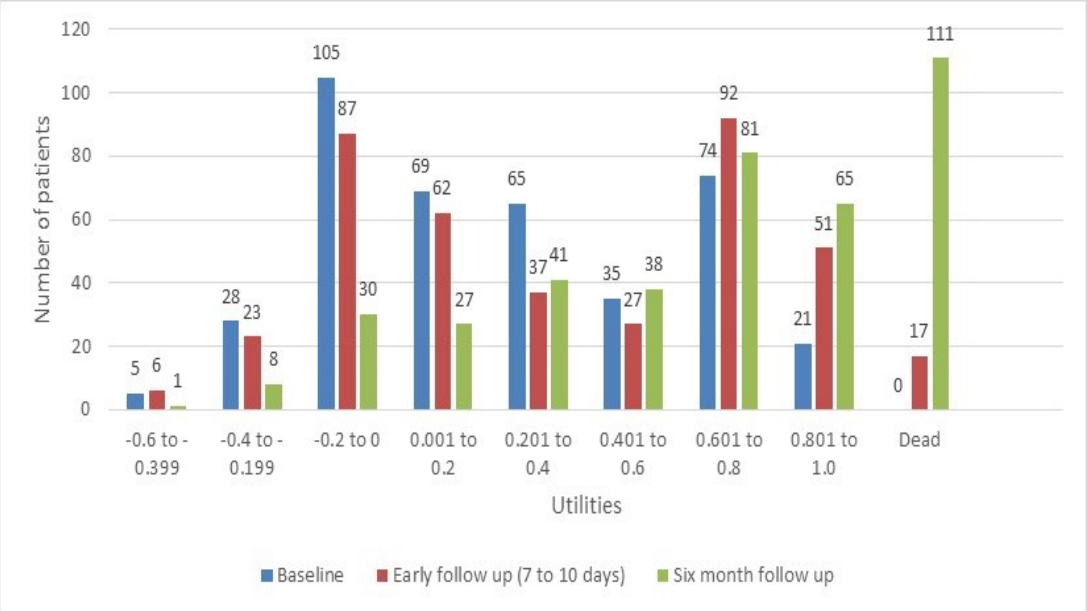
Timings	**n died**	**Including those who had died**		**Excluding those who had died**	
		Mean utility	**SD**	**Mean utility**	**SD**
Baseline	0	0.23	0.36	0.23	0.36
Early follow up	17	0.30	0.40	0.32	0.40
Six months	111	0.36	0.37	0.50	0.36

Figure 2.17 shows the number of surviving patients within categories of utilities at three time points. This shows that 138 participants indicated the patient's HRQoL to be worse than or equal to being dead at baseline. (i.e.

utility less than, or equal to 0) This was reported by 91 patients and 47 proxies.

At six months, 39 participants indicated the patient's HRQoL to be worse than or equal to being dead. This was reported by 8 patients and 31 proxies. Of these 8 patients, four had mRs 5, three had mRs 4 and one had mRs 3.

Figure 2.17 Number of patients within each category of utility at three time points



2.11.4.6 Specific abilities: based on single items from measures/ scales or by asking specific questions.

In this section, I make comparisons between the specific ability of the patient at baseline and at six months

2.11.4.6.1 'To walk'

As I described in Section 2.6, based on my data, three measures could be used to report the ability of patients 'to walk'. These are smRsq, BI (mobility on a level surface) and EQ5D-5L (mobility). Each measure defines 'to walk' differently and therefore, the number of patients with 'good' and 'poor'

outcomes (as defined in Section 2.6) would be different when different measures/scales are used. (Table 2.23, Table 2.24, Table 2.25, Table 2.26)

- Using specific question from smRsq ('Can you walk from one room to another without the help of another person'?)

Table 2.23 Using specific question from smRsq to report the specific ability 'to walk' at baseline and six months

smRsq		**Six months**		
Baseline	Yes	No	Dead	Totals
Yes	22	0	0	22
No	187	82	111	380
Total	209	82	111	402*

*n=1 loss to follow up

- Using single item from BI (Mobility on a level surface)

Table 2.24 Using single item from BI to report the specific ability 'to walk' at baseline and six months

Baseline	**Six months**					
	Independent over 50 yards	Walks with the help from another person over 50 yards	Wheelchair independent over 50 yards	Immobile or less than 50 yards	Dead	Total
Independent over 50 yards	16	0	0	1	0	17
Wheelchair independent over 50 yards	0	0	0	0	0	0
Walks with the help from another person over 50 yards	36	9	1	30	7	83
Immobile or less than 50 yards	61	32	11	94	104	302
Total	113	41	12	125	111	402*

*n=1 loss to follow up

- Using single dimension from EQ5D-5L (Mobility)

Table 2.25 Using single dimension from EQ5D-5L to report the specific ability 'to walk' at baseline and six months

EQ5D-5L: Mobility			**Six months**				
Baseline	No problems	Slight problems	Moderate problems	Severe problems	Unable	Dead	Totals
No problems	14	5	2	2	2	2	27
Slight problems	15	18	12	5	2	5	57
Moderate problems	16	16	12	7	4	8	63
Severe problems	5	15	16	11	6	11	64
Unable	10	15	22	28	30	85	190
Missing	0	0	1	0	0	0	1
Totals	60	69	65	53	44	111	402*

*n=1 loss to follow up

Table 2.26 'To walk' defined by three different scales/measures

'To walk' at six months	**Good outcome**	**Poor outcome**
Measure/Scale	n (%)	n (%)
smRsq	209 (52.0)	193 (48.0)
BI	154 (38.3)	248 (61.7)
EQ5D-5L	194 (48.3)	208 (51.7)

2.11.4.6.2 'To be continent'

- Urinary continence

  This is based on a single item from BI (urinary continence).

Table 2.27 Using single item from BI to report urinary continence at baseline and at six months

Baseline	**Six months**				
	Continent	Occasional accidents	Incontinent/ catheterised	Dead	Totals
Continent	102	32	15	15	164
Occasional accidents	18	11	8	6	43
Incontinent/ catheterised	42	25	38	90	195
Total	162	68	61	111	402

- Bowel continence

This is based on a single item from BI (bowel continence).

Table 2.28 Using single item from BI to report bowel continence at baseline and at six months

Baseline	**Six months**				
	Continent	Occasional accidents	Incontinent	Dead	Totals
Continent	205	5	13	26	249
Occasional accidents	5	0	1	3	9
Incontinent	33	11	18	82	144
Total	243	16	32	111	402

2.11.4.6.3 'To talk'

Using our own specific questions (Section 2.6), I determined the ability of patients in the cohort 'to talk' at baseline and at six months:

Table 2.29 Using specific questions to report the ability of the patient 'to talk' at six months according to whether the patient was able 'to talk' at baseline

Baseline	**Six months**					
Ability to talk affected?	No dysphasia	Mild to moderate dysphasia	Severe dysphasia	Mute	Dead	Total
Yes	105	60	12	0	96	273
No	105	8	0	1	15	129
Total	210	68	12	1	111	402*

*n=1 loss to follow up

There were 105/402, 26.1% of patients who had recovered their ability to talk (i.e. had no dysphasia) by six months.

The one patient who did not have a problem with their ability to talk at baseline but was mute at six months had been readmitted to hospital with a major haemorrhagic stroke, and at time of final follow up, was in hospital on an end of life pathway.

For the eight who did not have a problem with their ability to talk at baseline but had mild to moderate dysphasia at six months, I reviewed the patients' notes to find out the reasons for this. For two patients, a problem with their ability to talk was not noticed at baseline, but noticed a few days later. It is unclear from the documentation whether this may have been related to the stroke that precipitated hospital admission, or another stroke within the first few days. Three patients had had another stroke between early follow up and six months. The other three had other documented possible causes for a problem with their ability to talk e.g. delirium or dementia, and since these patients were frail and deteriorating (mostly in care homes, or in the process

of looking for alternative placements), this problem had consciously not been investigated.

2.11.4.6.4 'To eat normally'

Using our own specific questions (Section 2.6), I determined the ability of patients in the cohort 'to eat normally' at baseline and at six months. As reported, this is based on swallow assessments only, independent of the patient's physical ability.

Table 2.30 Using specific questions to report ability 'to eat normally' at six months according to whether the patient was able to eat at baseline

At baseline	**At six months**					
Ability to eat normally affected?	Normal	Oral modified	Nasogastric	PEG/ RIG	Dead	Total
Yes	66	20	0	3	86	175
No	185	15	0	1	25	227
Total	251	35	0	4	111	401*

*missing data n=2 (1 unknown at six months, 1 loss to follow up)

Some, 66/401 (16.5%) had recovered their ability to eat by six months.

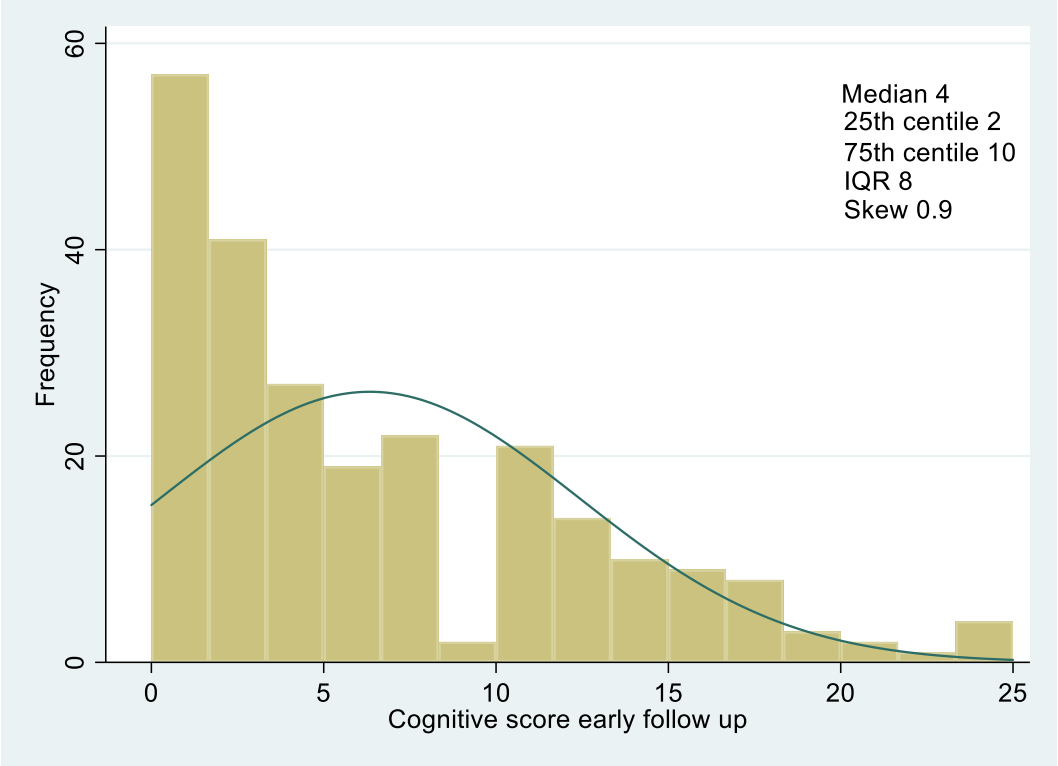
I reviewed the notes of the patients who did not have a problem with their ability to eat normally at baseline but either required a modified diet (n=15) or were PEG/RIG fed (n=1) at six months.

The one patient who was PEG/RIG fed was a patient who had become frailer in the six months after stroke, had worsening dementia and was awaiting a care home placement. There was no clear documentation of a second stroke, but anticipatory care planning had taken place not to investigate any such diagnosis. With respect to the 15 patients who needed oral modifications of their diet, nine had dementia which had deteriorated, and this was documented as a reason for their problems with ability to eat normally. For the other six, there was no clear recurrence of stroke, or alternative diagnosis provided. However, a problem with their ability to eat normally had been noted between day 10 of stroke and six months.

2.11.4.6.5 To live without major cognitive problems

At early follow up, 6CIT scores were available from 240 patients (17 had died, 146 were not able to complete). Scores ranged from 0 to 28. Data was skewed: median 4 (2-10) [95%CI]. Mean 6.3, SD 6.1.

Figure 2.18 Distribution of 6CIT scores (0-28) at early follow up, n=240



At six months, 189 patients were able to complete the 6CIT. (111 had died, and 103 were unable to). Data was skewed: median 4 (0-8) [95%CI]. Mean 4.4, SD 4.8.

Figure 2.19 Distribution of 6CIT scores (0-28) at six months, n=189

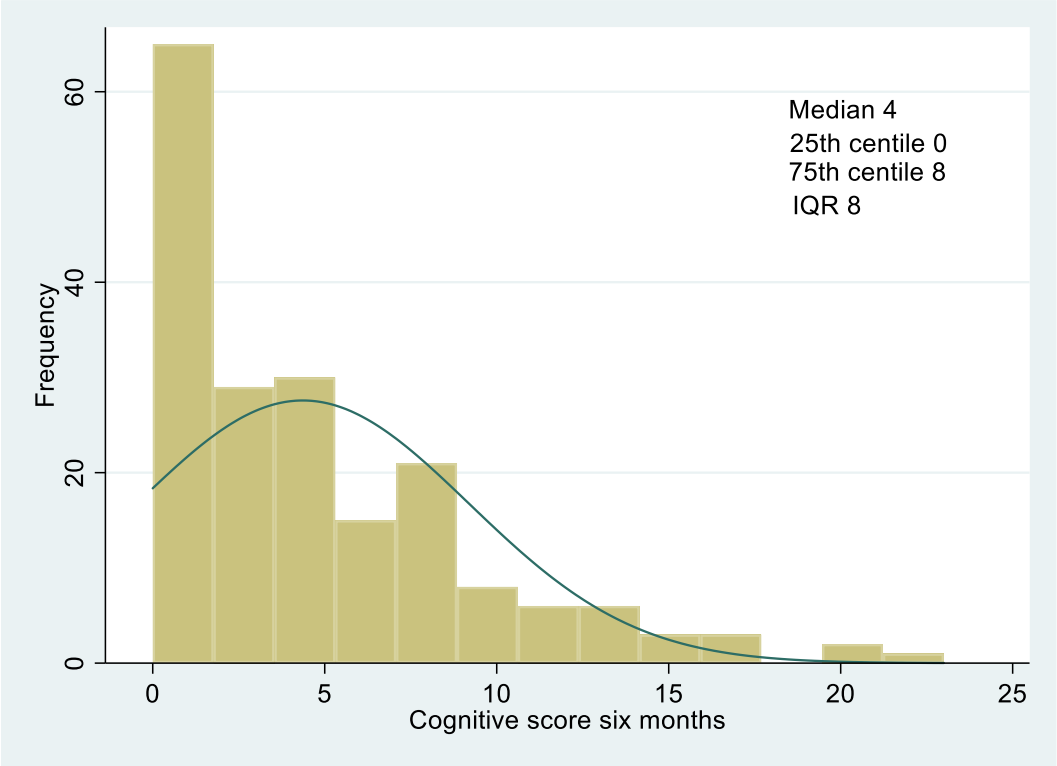


Table 2.31 shows the number of patients in each category of 6CIT scores over the three time periods.

Table 2.31 6CIT scores over three time periods, categorised to no or mild CI, Moderate CI and severe CI.

		Baseline		Early follow up		Six months	
Score	**Interpretation**	**n**	**%**	**n**	**%**	**n**	**%**
0 to 7	No or mild CI	129	32.0	148	36.7	139	34.7
8 to 9	Moderate CI	23	5.7	21	5.2	21	5.2
10 to 28	Severe CI	80	19.9	72	17.9	29	7.2
	Could not perform (e.g. lack of capacity)	171	42.5	146	36.2	102	25.3
	Death	0	0	17	4.2	111	27.5
	Missing	0	0	0	0	1	0.2
	Totals	403	100	403	100	403	100

Table 2.32 shows the cognition of patients at six months according to their cognition at baseline. The majority had no/mild CI at baseline and at six months (97 patients). There were 17 patients who had severe CI both at baseline and at six months, and few (6) had no or mild CI at baseline but had severe CI at six months. On review of the patients notes, the few (5) who had severe CI at six months, but no or mild CI at baseline were patients who either had a recurrent stroke (n=2), or were in the process of being assessed for possible vascular dementia. (n=3)

Table 2.32 6CIT scores: cognition of patients at six months according to their cognition at baseline

Cognitive impairment	**Six months**					
Baseline	**No/mild**	**Moderate**	**Severe**	**Missing**	**Dead**	**Total**
No/mild (score 0-7)	97	11	5	12	4	129
Moderate (score 8-9)	10	0	1	7	5	23
Severe (score 10-28)	22	7	17	22	11	79
Missing	10	3	6	61	91	171
Total	139	21	29	102	111	402*

* n=1 lost to follow up

2.11.4.6.6 'To live at home'

Using specific questions, (As described in Section 2.6) I recorded patients' place of residence at six months.

Out of the 384/403 (95.3%) patients who lived at home prior to the stroke (either alone, with family or with carers), 209/384 (54.4%) were able to return to their own home, with or without carers. However, at six months, there was a rise in patients in care homes (14/403 (3.5%) to 44/402 (10.9%)) and some patients 27/402 (6.7%) were in NHS institutions due to ongoing care needs; either because their demands on care were being best met in a hospital setting, or they were being assessed for appropriate placements. (Table 2.33)

Table 2.33 Patients' place of residence at six months, according to their place of residence prior to hospital admission

	Place of residence at six month follow up							
Prior to hospital admission	**Own home**	**Relatives home**	**Other**	**Sheltered home**	**Care home**	**NHS care**	**Dead**	**Totals**
Home	209	8	1	1	38	26	101	384
Sheltered	0	0	0	0	1	0	1	2
Care home	0	0	0	0	5	0	9	14
Prison	1*	0	0	0	0	0	1	2
Total	210	8	1	1	44	27	111	402**

*completed prison sentence and was discharged with care package four times a day

**excludes n=1 lost to follow up

2.11.5 To relate patients' BI, HRQoL and specific abilities to their mRs at six months after major stroke

In my introduction, I mentioned how patients in the same mRs level may differ with respect to their specific abilities. In Table 2.34, I summarise the BI, HRQoL and specific abilities of our cohort of patients according to their mRs at six months.

This shows that patients with higher mRs had lower mean/median BI and lower utilities. However, the range of utilities within each mRs level varied, indicating heterogeneity of HRQoL. Also, patients' specific abilities varied greatly in each mRs level at six months.

Although patients with a 'poor' outcome according to mRs (3-5) also tended to have other 'poor' outcomes, there were exceptions. As highlighted in

yellow, there were proportions of patients in mRs 'poor outcome' category who had a 'good' outcome with respect to their specific abilities. For example, 149/402 (37.1%) were able 'to walk' based on smRsq, 96/402 (23.9%) had a 'good outcome' with respect 'to walk' based on BI, 135/402 (33.6%) indicated no, slight or moderate problems with their walking on the EQ5D-5L, 36/402 (9.0%) were continent of urine or had occasional accidents only, 366/402 (91.0%) were continent of their bowels or had occasional accidents only, 218/402 (54.2%) did not have major problems talking, 226/402 (56.2%) were able to eat normally, 217/402 (54.0%) were living without severe pain, 193/402 (48.0%) did not have major anxiety/depression, 102/402 (25.4%) did not have major cognitive problems and 158/402 (39.3%) were able to live at home.

Table 2.34 Specific abilities of patients at six months after major stroke according to their mRs

mRs	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**All**
n	**8**	**45**	**7**	**149**	**46**	**36**	**111**	**402**
Mean BI (SD)	98.8 (2.3)	96.9(4.2)	92.9(8.1)	76.6(15.0)	40.4(19.0)	15.8(11.1)	0	67.5 (29.3)
Median BI (Total range)	100 (95 to 100)	100 (80 to 100)	95 (75 to 100)	80 (25 to 100)	42.5 (10 to 85)	10 (0 to 45)	0	75 (0-100)
Mean utilities (SD)	0.90 (0.09)	0.82 (0.14)	0.78 (0.12)	0.37 (0.37)	0.20 (0.19)	-0.08 (0.15)	0	0.50 (0.36)
Median utilities (Total range)	0.88 (0.74 to 1)	0.84 (0.32 to 1)	0.84 (0.61 to 0.91)	0.32 (-0.01 to 1)	0.21 (-0.26 to 0.72)	-0.08 (-0.35 to 0.43)	0	0.62 (-0.35 to 1)
Specific ability (measure)								
To walk (smRsq question)								

Able	8	45	7	149	0	0	0	209
Unable	0	0	0	0	46	36	0	82
Dead	0	0	0	0	0	0	0	111
To walk (BI)								
Independent over 50 yards	8	44	6	55	0	0	0	113
Able to walk with help from another person over 50 yards	0	0	0	41	0	0	0	41
Wheelchair independent over 50 yards	0	0	0	0	9	3	0	12
Immobile or under 50 yards	0	1	1	53	37	33	0	125
Dead	0	0	0	0	0	0	111	111
To walk (EQ5D-5L)								

No problems	6	23	4	27	0	0	0	60
Slight problems	2	18	2	45	2	0	0	69
Moderate problems	0	4	0	52	9	0	0	65
Severe problems	0	0	1	25	23	4	0	53
Unable	0	0	0	0	12	32	0	44
Dead	0	0	0	0	0	0	111	111
To be continent of urine (BI)								
Continent	8	43	7	85	17	2	0	162
Occasional accident	0	2	0	49	12	5	0	68
Incontinent/ catheter	0	0	0	15	17	29	0	61

Dead	0	0	0	0	0	0	111	111
To be continent of bowels (BI)								
Continent	8	45	7	141	348	8	0	243
Occasional accident	0	0	0	6	4	6	0	16
Incontinent	0	0	0	2	8	22	0	32
Dead	0	0	0	0	0	0	111	111
To talk without major problems								
No problem	8	39	6	100	34	23	0	210
Mild/moderate dysphasia	0	6	1	45	9	7	0	68
Severe dysphasia	0	0	0	4	3	5	0	12
Mute	0	0	0	0	0	1	0	1
Dead	0	0	0	0	0	0	111	111

To eat normally								
Normal	8	45	6	139	34	19	0	251
Oral modified	0	0	1	10	11	13	0	35
NG	0	0	0	0	0	0	0	0
PEG/RIG	0	0	0	0	1	3	0	4
Unknown	0	0	0	0	0	1	0	1
Dead	0	0	0	0	0	1	111	111
To live without severe pain (EQ5D-5L)								
No pain	6	33	7	101	35	17	0	199
Slight pain	1	8	0	24	3	5	0	41
Moderate pain	1	2	0	18	3	11	0	35
Severe pain	0	2	0	6	5	3	0	16
Extreme pain	0	0	0	0	0	0	0	0

Dead	0	0	0	0	0	0	111	111
To live without major anxiety or depression (EQ5D-5L)								
No problems	6	25	3	55	15	7	0	111
Slight problems	2	17	3	51	17	10	0	100
Moderate problems	0	3	0	28	5	5	0	41
Severe problems	0	0	1	15	8	12	0	36
Extreme problems	0	0	0	0	1	2	0	3
Dead	0	0	0	0	0	0	111	111
To live without major cognitive problems								
No/ Mild CI	8	41	6	73	8	3	0	139
Moderate CI	0	3	0	18	0	0	0	21

Severe CI	0	0	0	23	4	2	0	29
Unable	0	1	1	34	34	32	0	102
Dead	0	0	0	0	0	0	111	111
To live at home								
Own home	8	43	7	130	17	5	0	210
Relatives home	0	2	0	6	0	0	0	8
Sheltered	0	0	0	1	0	0	0	1
Care home	0	0	0	8	17	19	0	44
NHS care	0	0	0	3	12	12	0	27
Other	0	0	0	1	0	0	0	1
Dead	0	0	0	0	0	0	111	111

2.12 Discussion

2.12.1 Summary

I have recruited a cohort of patients with major stroke (defined as mRs 3-5 or 0-2 with two specific abilities affected by the stroke). I have reported their progress and abilities with respect to global scales (mRs, BI and EQ5D) and derived their specific abilities (to be independent, to walk, to be continent, to talk, to eat normally, to live without severe pain, to live without major anxiety/ depression and to live at home), either based on single items from these measures/scales or by asking specific questions. (As described in Section 2.6)

I listed my aims in Section 1.3. Here, I summarise my findings based on my aims.

- **To describe the baseline characteristics of a cohort of patients admitted with major stroke (n=403)**

The mean age of the patients in our cohort was 77.5 SD 11.8, with a large proportion of recruited patients in the 80-89 age group. Most (340/403, 84.4%) had an ischaemic stroke.

Over half (209/403, 51.9%) had an mRs of 5 at baseline. The mean BI was 31.6 (SD 25.6) and many (176/403, 43.7%) had a BI score between 0 and 20. The mean utility at baseline was 0.23 SD 0.36.

Under half (165/403, 40.8%) were continent of urine, and 250/403, 62.0% were continent of their bowels at baseline. A third (130/403, 32.3%) did not have a problem ‘to talk’ and over half (228/403, 56.6%) did not have a problem ‘to eat normally’ at baseline. The median score of 6CIT of those who were able to complete this cognitive assessment was 6 (IQR 10).

The majority of patients (384/403, 95.3%) lived at home (rather than in supported accommodation e.g. care home or sheltered housing) before hospital admission.

- **To describe the progress of patients after major stroke at three time points**

By early follow up, a third (132/403, 32.8%) of patients admitted with major stroke had had an infection and many had had life-extending treatments. For example, 284/403, 70.5% had had at least 24 hours of parenteral fluids and 275/403, 68.2% had had IPC.

A small proportion (60/403, 14.9%) had mRs 0-2 by six months. The mean BI score of surviving patients improved over time. At six months, the mean BI score was 67.5 (SD 29.3) but 154/403, 38.3% were classified as independent according to BI. (Score 75-100) BI grouped more patients into the no or mild disability group when compared to mRs. The pathway that individual patients took with respect to their mRs or BI varied over the three time points.

The mean utility of surviving patients improved over time: Mean utility 0.50 SD 0.36 at six months.

Nearly two thirds (102/164, 62.2%) of patients who were continent of urine at baseline were continent of urine at six months. The majority (205/249, 82.3%) of patients who were continent of bowels at baseline were continent of their bowels at six months.

Of the patients who were able to complete the 6CIT, median score at early follow up and at six months was 4 (IQR 8).

Over a third (105/273, 38.5%) of patients who had a problem with their ability to talk at baseline had recovered their ability to talk and had no dysphasia at six months. Over a third (66/175, 37.7%) who had a problem with their ability to eat normally at baseline were able to eat normally at

six months. Over a half (209/384, 54.4%) of patients who lived at home prior to their stroke were able to live at home at six months after major stroke.

- **To relate patients' BI, HRQoL and specific abilities to their mRs at six months**

The general trend was that patients with lower mRs had higher BI and higher utilities. However, the range of utilities within each mRs level was wide, indicating heterogeneity.

Specific abilities of patients varied greatly within each mRs level; for example, two patients in the same mRs level varied with their abilities to talk, eat normally, etc.

Using different measure/ scales to report a specific ability (e.g. 'to walk') would cause further variation in results.

2.12.2 Stroke outcome scales such as mRs, BI and EQ5D

There is no single perfect stroke outcome scale. The mRs and BI have both been used to report patient outcomes in clinical trials and are good measures of physical dependency. (12)

The mRs has several strengths: it covers a range of functional outcomes from no symptoms to death, its levels are intuitive to clinicians and it has been used in clinical trials to assess efficacy of acute stroke therapies.(42) Although it has a limited number of levels (i.e. 0 to 6), a single point change on the mRs has been reported to be clinically relevant.(148) However, the optimal cut-off for 'good' and 'poor' outcomes depends upon the anticipated distribution of mRs outcomes based on the initial severity of illness, which informs the level of the scale at which a treatment effect is most likely to be observed. Unfortunately, researchers may not know this distribution when planning a trial; and trials have either used 0-2 or 0-3 as 'good' outcomes. (42) As I acknowledged, 'good' and 'poor' outcomes may also be judged differently by different individuals.

A limitation of the mRs has been the reproducibility of the score by different individuals. (148,149) To improve consistency in scoring, various interventions have been tried e.g. structured mRs interviews (118,150) and staff training (151) but with limited improvements. In order to simplify, standardise and increase the reproducibility of the mRs score, the smRsq was developed. This simple questionnaire yields similar results to the mRs, and is easily performed over the telephone, thereby saving researchers time when conducting patient follow up. (133,152) However, I found that a significant proportion (149/403, 37.0%) of patients in our cohort were categorised to mRs 3 at six months. The 'Effects of fluoxetine on functional outcomes after acute stroke' (FOCUS) trial also reported similar findings when using smRsq to report patient mRs. (153) It is unclear if, or how, this grouping had any impact on my overall results.

The mRs has been reported to be superior to BI for describing extremes of disability; (154) the well-known ''floor'' and ''ceiling'' effects of BI makes the scale less discriminating in patients with severe or minor strokes. (12,155) ''Floor ceiling' effects describes the phenomenon by which the BI score does not change from minimum or maximum despite clinical change. (156) For example, a stroke patient who is discharged from hospital and is independent may still have substantial functional problems but will score 100 on the BI, and a patient may have made substantial functional gains but still score 0 on the BI. As I reported, when compared to the mRs, the BI categorised more patients as ''no/mildly disabled''. However, the cut offs for comparing BI scores to mRs levels are not standardised (13,145,157,158) and therefore, my results would be different if different cut-offs had been used.

While the mRs and BI provide a general overview of the physical ability of patients, individual patients' progress varied greatly (Figure 2.10 and Figure 2.14). Therefore, describing prognosis based on grouped data may not be accurate.

More recently, the focus has been on patient-centred outcomes or HRQoL. (159) As described in Chapter 1, to relate physical disability to HRQoL,

several attempts have been made to assign utility scores to mRs levels. (40–43) My findings broadly agree with the trend; i.e. decreasing utilities with higher mRs. (Table 2.34) However, I have also reported the wide range of utilities within each mRs level, indicating heterogeneity of HRQoL. A limitation of utilities is that these are derived based on assessments completed by healthy (non-disabled) individuals rather than those who are disabled.

The use of VAS in the major stroke setting may be limited. Although the VAS has been suggested to be an accurate measure of continuous subjective variables such as pain and analgesia, (137,160–162) global well-being (163) and functional capacity, (164) older people (165,166) and people with aphasia (167) may find the VAS difficult to complete. Price et al also demonstrated that patients with any stroke (but especially those with more severe stroke subtypes, and those who had cognitive and visuospatial impairments) found it challenging to complete the VAS. (168)

In our study, proxies completed HRQoL (EQ5D-5L and VAS) assessments where the patient was unable to do so. The completion of EQ5D by proxies in the context of a stroke is valid and widely used. (169) However, there is also evidence that agreement between patient and proxy on the VAS is low, (169) patients and proxies may agree better on physically based observable attributes rather than psychosocial attributes (170–173) and that proxies tend to report more problems than the patient on the EQ5D dimensions at six months for self-care, pain/discomfort and anxiety/depression. (169) While I was unable to make any direct comparisons between patient and proxy responses in the EQ5D 5L and VAS in this study, I did find that, a significant proportion (31 out of 39) of participants who had indicated the patients quality of life to be equal to, or worse than death (i.e. utility less than or equal to 0) at six months after major stroke were proxies. This may be unsurprising, as most HRQoL assessments completed by proxies at six months were on behalf of patients who were significantly physically disabled (mRs 4-5) who may also have problems with various specific abilities including cognition.

However, it is also possible that family members may be placing their (more pessimistic) judgement on the patient's HRQoL.

Only 8 surviving patients reported their HRQoL to be equal to or worse than being dead while the majority of those who were 'dependent' (mRs 3-5) [127/402, 31.6%) had a utility above 0. A possibility for this finding is the phenomenon 'response shift' (explained in chapter 1) where patients had adapted to their new baseline and therefore, report a quality of life that is higher than previously anticipated. (67,72,174) It is also possible that these patients, though physically disabled, may have retained specific abilities (e.g. their ability to eat normally or be continent) which had led them to rate their HRQoL as being better than anticipated.

I acknowledge the limitations of utilities and VAS in my study, but to preserve patient autonomy and in the absence of other ways of obtaining answers to assessments which the patient was unable to complete, it is difficult to know how this may have been improved. Perhaps alternative tools incorporating both patient reported outcome measures and patient reported experience measures may more accurately present the patient's perceptions of both the process and outcome of their care. However, their validity and reliability in stroke and use by proxies would need to be determined. (175)

2.12.3 Describing prognosis by specific abilities rather than based on global scales

As I have shown, while ''poor'' outcomes tended to group together (Table 2.34), there were exceptions and patients may differ with respect to their specific abilities even though they had the same mRs. It is also possible that these different specific abilities, and combinations of abilities may contribute to the heterogeneity I found in their HRQoL. Therefore, describing prognosis in terms of specific abilities may be more appropriate rather than outcomes (e.g. disability) using global scales (e.g. mRs).

As I described, different measures/scales may be available to describe one specific ability. (Table 2.2) Furthermore, we could have used different dichotomies to define the specific abilities. Different measures/scales and dichotomies would give us different results. (Table 2.26) It would be useful to agree on a standardised approach towards defining specific abilities. It may also be appropriate to develop and validate predictive models to give a probability of a specific ability to patients/ families six months after major stroke. I will describe the development and validation of new models predicting some specific abilities in Chapter 7.

2.13 Limitations

2.13.1 Recruitment

The patients I recruited were based on my inclusion criteria. Therefore, there is a possibility of selection bias as not all consecutive stroke admissions were eligible to be recruited.

2.13.2 Data collection

I collected data on specific abilities judged to be useful to patients and their family members. This was based on expert opinion of stroke doctors in the hospital where recruitment took place, and my own clinical experience. Ideally, I would have engaged doctors, patients and family members in focus groups and/or performed qualitative interviews with patients/family members before the recruitment and follow up of our longitudinal cohort. However, this was not possible due to time constraints. Some outcome scales and variables that I collected were also determined by those available in our large trial datasets- this was to allow external validation of developed prognostic models. (Which I describe in Chapter 7)

2.13.3 Assessments

While the EQ5D-5L (176) and smRsq (133) are acceptable for use through interview in the stroke population, literature describing telephone assessment to elicit BI scores is limited. Existing literature indicates that when compared to face-to-face assessments, determining BI over the telephone was able to

identify those who had high BI scores and in some cases, provided optimistic scores (indicating less disability) for those with identified moderate to severe disabilities in face-to-face assessment. (12,177,178) Therefore, in this study, where I performed six month assessments over the telephone, it is possible that the ‘’floor’’ and ‘’ceiling’’ effects of BI may have been accentuated.

The 6CIT has not been tested for use over the telephone in major stroke. Therefore, the appropriateness of this test in our study is debatable.

2.14 Conclusions

- Major stroke has significant mortality and morbidity
- Global scales such as mRs, BI and EQ5D provide an overview of patient outcome over time. However, individual patients progress differently over time
- Specific abilities and HRQoL of patients in the same disability level vary greatly. Therefore, it is likely that different patients would have different experiences of major stroke in hospital, views on survival and on treatments and needs (i.e. of information and support)

Therefore,

- Describing prognosis by specific abilities may be appropriate. We will develop predictive models to give patients/ families a probability of having a specific ability at six months. This may improve communication of prognosis.
- Understanding each individual’s experiences after major stroke, wishes and preferences for information and treatment would give us insight into how doctors can support patient needs

2.15 Next steps

Since each individual patient varies with respect to their abilities and HRQoL, it is likely that each patient would have different experiences in hospital after major stroke, and their views and needs (e.g. regarding information, survival and treatments) may differ.

In my next chapter (Chapter 3), I will report findings from qualitative interviews with patients admitted to hospital who retained mental capacity after major stroke. Specifically, I will focus on their background prior to hospital admission to set the scene and provide context to their description of their early experiences in hospital and information and support needs at a time when treatment decisions were being made. At six months, I explore their reactions to living with significant physical disability and explore their retrospective views on information needs in the early period after a major stroke.

I will discuss the development and validation of prognostic models to predict specific abilities after major stroke in Chapter 7.

Chapter 3 A longitudinal qualitative study of patients' experiences, views, information needs and approaches towards making treatment decisions.

3.1 Publication status and acknowledgement of contribution

This chapter has been published in PLoS One. (119) The publication can be found in Appendix A.

I designed the study including topic guides and performed all the interviews. My supervisor JL supported data analysis; this was necessary to comply with the 'Consolidated criteria for reporting qualitative research' (COREC) requirements for qualitative data reporting. I wrote this manuscript with comments and guidance from JL. All co-authors commented on the final manuscript before submission.

3.1.1 Brief summary of this chapter

In chapter 1, I described how the knowledge of patient preferences and communication between doctors and patients are thought to be key aspects to effective shared decision-making. I also noted the challenges of implementing shared decision-making in the context of a major stroke and expressed the need to explore patients' experiences after major stroke and their views regarding treatments, especially where treatments may increase the chance that they survive, but be left with significant disability.

In chapter 2, I then showed how patients varied with respect to their specific abilities (e.g. to walk, to talk) and this could relate to the observed heterogeneity in their reported HRQoL. These variations may influence their

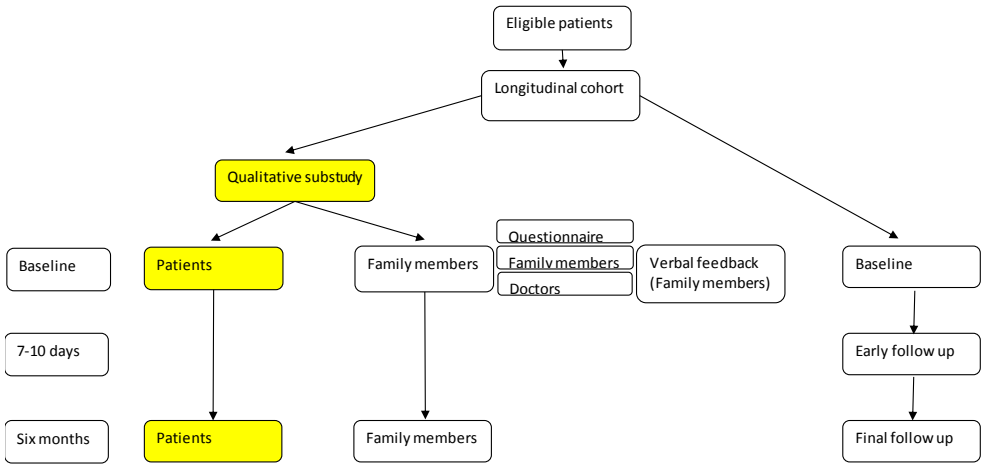
experiences, views, needs and approaches towards being involved in decision-making regarding treatments.

Therefore, in this chapter, I explore the early experiences, views, needs (information and support) and approaches towards decision-making of patients who retained capacity after being admitted with a major stroke (a sub-group from our longitudinal cohort of patients I recruited and described in Chapter 2). I followed patients up at six months to assess their ongoing experiences and retrospective views on how their needs could have been better met during their time in hospital.

Since this chapter is a publication, there is overlap in the material in several sections (e.g. introduction, methods) and Chapters 1 and 2. I have made minor editorial changes in this chapter to acknowledge this overlap where appropriate.

The flow diagram below (boxes coloured in yellow) indicates the part of my study this chapter relates to.

Figure 3.1 Study schematic: Chapter 3



3.2 Introduction

In Chapter 1, I described the burden of stroke. Each year approximately 150,000 people have a stroke in the UK. (14) In the UK, stroke is the leading cause of reported severe disability. (179) Almost two-thirds of stroke survivors leave hospital with a disability. (4) More than half are left dependent on others for everyday activities and may require long-term, institutional care (e.g., in hospital or a care home). (4,180) Therefore, suffering a stroke can be life-changing and stroke patients need to access appropriate treatment during the acute phase as well as follow-on rehabilitation.

In Chapter 1, I also described how different treatments may influence patient outcome differently. In the UK, acute treatment of stroke and follow-on rehabilitation has improved in recent years. (19,181) Relative to 20 years ago, patients generally have better access to treatment and care. (20) Yet there remain significant challenges with respect to stroke care. Notably, there are different options for treatments during the acute phase, which are each associated with different outcomes. Some treatments (e.g. thrombolysis (182) and mechanical thrombectomy(22)) improve functional outcomes for patients who survive the stroke (i.e. it is less likely for patients to be left with significant physical disability as a result of these treatments). However, other treatments (e.g., intermittent pneumatic compression for prevention of deep venous thrombosis, (35) antibiotics for treating infections, (183) parenteral fluids (184) and enteral feeding [feeding through a tube placed into the stomach through the nose or surgically into the abdomen] (24)) increase the likelihood that patients who have suffered a severe stroke and been left with significant disability will survive longer. Therefore, the net effect is that more patients will survive with significant disability as a result of these latter treatments.

Therefore, a key decision that patients, along with their doctors need to make is: should the patient receive treatment that increases the likelihood that s/he will survive the stroke but with a significant disability *or* forego such treatments and, in turn, accept the increased risk that s/he will die. This is a

difficult question and there are no easy answers. Making decisions regarding stroke treatments typically warrants careful discussion between the patient, their family, their doctor and the multidisciplinary team– a “shared decision-making” process. (30) Yet, in practice, (particularly, in the early period after an acute disabling stroke) implementing effective shared decision-making can be challenging. (49) This issue has been under-studied with respect to acute stroke. Exploring these challenges goes to the heart of the issues considered in this paper.

I described the challenges associated with involving patients in shared decision-making in Chapter 1. These are reiterated below.

Firstly, acutely unwell patients may be in shock as result of having been given a life-changing diagnosis. Literature from critically unwell patients (185) including in coronary care (64) have highlighted how a sudden deterioration in health may leave patients fearful and distressed; (65) especially when they have not considered a situation where they may be left disabled. Critically ill patients, such as those who have suffered a severe stroke, may lack capacity (that is, lack the ability to understand, process and weigh up information to make a decision) [17] and their inability to engage with health professionals may make them ineffective partners in a shared decision-making process. (65) However, much of the research around this issue has focused on the experiences of patients with chronic, progressive conditions such as dementia (186) (rather than stroke) and how these patients engage with health professionals to make treatment decisions. The experiences and reactions to diagnosis of those who have suffered an acute disabling stroke are under-reported – we go on to explore this key area in this paper.

Secondly, an important step in shared decision-making is for health professionals to provide necessary information to patients. This is intended to enable patients to arrive at an appropriate treatment decision having properly weighed the outcome-related risks, such as those outlined above. In conditions such as cancer and dementia, providing information to patients

has been shown to help them understand their diagnosis and make decisions regarding treatments. (187–189)Decision aids (such as leaflets and educational programmes) in stroke have been reported to help patients understand their diagnosis. However, most of these aids have been tested just before patients are discharged from hospital or in the outpatient setting. Moreover, those severely affected by the stroke had been excluded from these studies. (190) Hence, the transferability of these interventions to an acute setting and to patients severely disabled as a result of their stroke is uncertain. While guidelines published by professional bodies such as the General Medical council,(44) American Heart Association (191) and Royal College of Physicians (192) iterate the need for early, timely and tailored information delivery to patients, we need to consider how this recommendation may affect those who have had a severe stroke who, like many critically unwell patients, may not be able to fully process this information. (64) Overall, the information needs of acute disabling stroke patients to make decisions about their treatments have not been fully considered. This is therefore a key focus of study in this paper.

Thirdly, literature in stroke, (72) brain injury (193) and older patients (194) has reported how patients, who have survived these illnesses and been left with a significant disability, when asked several months later, appear to have learnt to adapt to their situation (a process termed ‘response shift’) and therefore, report higher quality of life than anticipated. (67,174) In contrast when individuals who are well are asked about their preference for treatment which could leave them significantly disabled, they often report that they do not wish to receive such treatment: that is, they do not want to survive if they will be left significantly disabled. (195) Therefore, patients’ treatment preferences appear to be inconsistent. This so-called ‘disability paradox’ adds to the challenges associated with decision-making in acute stroke. (196) For doctors to be able to support patients in making treatment decisions, they need in-depth insight into each individual’s values, preferences and goals and how, and why these may change over time.

In this longitudinal qualitative study, we aimed to address several gaps in research involving acute stroke patients. Specifically, we explored how decisions were made regarding treatments in the context of an acute severe disabling stroke. To better understand this, we explored the early experiences of patients with a disabling stroke in hospital, their needs *[for information]* in the early period after a life-changing diagnosis and their views about surviving, potentially with significant disability. To gain deeper insight into their ongoing wishes and needs, at six months post-diagnosis, we explored their feelings about their situation *[being significantly disabled]* and views regarding information that would have been useful to them in the early period in hospital after their stroke.

As acknowledged in Chapter 1, while shared decision-making in acute stroke is a team approach, where various members of the multidisciplinary team (e.g. doctors, nurses, physiotherapists and dieticians) have input into patient management, the focus of our study is on decision-making regarding treatments that extended survival of the significantly disabled patient. These discussions are primarily conducted between the patient and their hospital doctor. Therefore, our recommendations are intended specifically for doctors taking care of acute severe stroke patients in hospital.

3.3 Materials and methods

3.3.1 Research design and methods

This study was informed by an epistemological position which recognises that illness experiences and, relatedly, treatment decision-making are socially and contextually informed. (197) This position informed our approach to both data collection and analysis. For instance, we developed topic guides (Table 3.1) which allowed us to explore what patients' lives were like before suffering a stroke. We also explored their experiences soon after their admission in order to set the context for understanding the treatment decisions which were subsequently made.

Initial interviews took place within a week of a patient's admission to the stroke unit. This time point was chosen to capture their early experiences after a disabling stroke. Also, we recognised that most treatment decisions that we were interested in exploring (such as initiation of enteral feeding) should have been taken within a week of admission.

Where possible, we undertook follow-up interviews at six months following first admission to the stroke unit. We chose this time frame because we recognised that, by six months, most patients would have plateaued with respect to their functional recovery.(23,198,199) Had we interviewed them at an earlier point in time (for example, at three months following first admission to the stroke unit), their recovery might have still been ongoing. By contrast, had we interviewed at a later point in time (for example, at one or two years following first admission to the stroke unit), this might have meant that other factors (for example, increasing age and frailty, recurrent stroke, declining cognition or death) might have adversely affected patients' ability to be interviewed.

Table 3.1 Guide to the topics covered in patient interviews

Baseline	
Background	• The pre-stroke functional status of the patient: how they were managing at home before the stroke, any formal or informal care required, and their interactions with their family. • Reported preferences on surviving with significant disability: if they had made any advanced statements or had any thoughts of what they may want in terms of treatments if they had an illness that may result in them surviving with potentially significant disability.
Experiences	• Patients' feelings about their situation post stroke: how they felt about their diagnosis and

	how they felt they were coping with the situation • Patients' experiences in hospital in the early phase after the stroke: their interactions with staff
Needs	• Patients' perception of information in general: whether this may help them understand their diagnosis, potential prognosis and help them make treatment decisions. • Their understanding about the goals of treatments that were being offered after acute stroke and what they would need to make decisions about these treatments
Six month follow up	
Experiences	• Patients' thoughts and feelings having survived a physically disabling stroke, how they were managing on a day to day basis, their thoughts on their recovery process since hospital discharge
Needs	• Looking back to their time in hospital, their thoughts on what (for example, information or support) could have been given to them in hospital which may have been useful to them.

3.3.2 Recruitment and data collection

We recruited adult patients who had been admitted to a stroke unit in a large teaching hospital in the United Kingdom. These patients were a sub-group of patients recruited into our longitudinal cohort (described in Chapter 2). Our aim was to explore decision-making regarding stroke treatments that

increased the likelihood that the patient who has been left with significant disability as a result of stroke will survive longer; to be eligible to participate, the stroke needed to have caused significant physical disability and the patient needed to have had decisions made regarding treatments (such as enteral feeding, parenteral fluids, antibiotics or intermittent pneumatic compression). Therefore, we recruited patients whose extent of disability was at least a modified Rankin scale score of four as a result of the stroke (i.e. they were unable to walk or attend to their own bodily needs without assistance).

The medical team (consultants, registrars and other trainee doctors who looked after the patients on a daily basis) identified eligible individuals who had the capacity to consent to participating in the study (i.e. the patient was able to understand and retain information and communicate decisions). If the patient's speech or swallow was affected, the medical team assessed them to ensure this did not affect their decision-making capacity and that they were able to fully participate in an interview. In each case, before approaching the patient regarding in this study, the medical team also considered whether participating might cause distress.

Once the medical team determined that the patient was suitable to participate, they asked the patient for permission for the researcher (me) to approach them and provide further information about the study. I am a clinical doctor specialising in geriatric medicine and had previously worked in the stroke unit. However, patients were not informed about my clinical background and they were advised that I would not be able to provide any treatment advice or medical information specific to their care.

I then provided information about the study and obtained the patient's formal written consent to participate. We made every effort to recruit patients of different ages, genders and ethnic backgrounds. However, we recognised that patients with an acute disabling stroke are a group who are hard to recruit: many patients are medically unwell and the impact of the diagnosis was noticeably distressing to some of them. Therefore, we made a

pragmatic decision to interview all eligible individuals who had agreed to take part. As the clinical team did not keep a log, it is not possible to report the total numbers approached and, of those, how many declined to participate.

We endeavoured to recruit sufficient participants to address our study aims while not creating a dataset which would be too large and unwieldly to analyse in-depth. In practice, this meant that we stopped recruitment after on-going analysis of the interviews indicated that sufficient data had been obtained to address the study aims and that a point had been reached where patients were volunteering similar views. Hence we recognised that recruiting additional patients would not enhance the quality or diversity of the data collected.

Prior to the start of each interview, I reassessed patients' capacity to participate. This was done because we recognised that patients' capacity might have changed from when they had initially been assessed as suitable to take part. Initial interviews were conducted in a private room in the stroke unit at a time convenient to the patient. Table 3.1 summarises the main areas explored. Where possible, we conducted six month follow-up interviews in the patient's place of residence (i.e., either own home or care home). Telephone interviews were considered where the multidisciplinary team felt that it would not be safe for me to visit the patient. Before contacting the patient to arrange the interviews, I phoned their general practitioner to check the patient still had capacity to participate. This was part of the consent process at recruitment. Prior to follow-up interviews, I reassessed the patient's capacity.

I kept a reflexive diary. This detailed my interactions with the participants, including a record of why, based on what patients said in interviews, I had decided it would be insensitive or inappropriate to pursue certain lines of questioning. For instance, when I explored patients' feelings about potentially living with disability, only physical aspects of disability were discussed (for example, immobility and inability to perform activities of daily living). This was because recruited patients were assessed to have physical

disability only, and exploring irrelevant disabilities (such as cognitive or intellectual) may cause the patient unnecessary worry. Also, as we will go onto describe, it became apparent to me that, in the early stages post stroke, some patients did not appear to understand that the goals of some stroke treatments were to extend their life but they will be significantly disabled and that decisions needed to be taken regarding these treatments. Making this known to them either acutely or six months later could have caused undue distress.

Initial interviews took place between September 2017 and January 2018 and lasted 25 to 66 minutes. Six month interviews took place between April 2018 and July 2018 and lasted 32 to 56 minutes. All interviews were digitally recorded and transcribed in full with the patient's consent.

3.3.3 Data analysis

I (who received training in qualitative methods, including qualitative data analysis) and JL (a very experienced, non-clinical qualitative researcher) undertook data analysis. All data were analysed thematically using the method of cross-comparison.(200) This approach entailed repeated read through of all interviews to allow familiarization with the data (immersion). Interviews were then cross-compared to identify key findings which cut across different accounts (themes). Both inductive and deductive approaches were used; this allowed unanticipated themes to emerge from data as well as identification of material needed to address the study aims. Data were also analysed longitudinally to establish whether, and why, peoples' needs and views changed over time. JL and I analysed the data separately and wrote separate reports. We then met to discuss their interpretations, resolve any areas of disagreement (which were found to be minimal), and reach agreement on the main findings and themes. A coding frame was then developed which captured these findings and themes. Coded datasets were subjected to further analysis to allow development of more nuanced interpretations of the data and identification of illustrative quotations. Nvivo

11, a qualitative software package produced by QSR International, was used to facilitate data coding and retrieval.

3.3.4 Ethical approval

This study was approved by Scotland A Research Ethics Committee (Ref: 17/SS/0029).

To safeguard participants' confidentiality, pseudonyms are used.

3.4 Results

Fifteen patients were interviewed within a week of their stroke. None were able to mobilise independently or wash and dress themselves without help after the stroke. Five also had speech impairment. The medical team assessed and confirmed that this did not affect their capacity to participate in interviews. Although we tried to include patients of varying backgrounds, most were of similar ages (70s) and ethnicities (White British).

At six months, thirteen patients had survived. Eleven had capacity to take part in an interview. All surviving patients had varying degrees of physical disability. Of these, two had ongoing speech problems but this did not affect their ability to participate in an interview. Eight of the eleven patients with capacity were living at home, two in care homes and one in hospital. Ten interviews took place in person. One interview took place over the phone due to safety concerns raised by the multidisciplinary team in hospital and the patient's general practitioner.

Table 3.2 summarises the characteristics of our sample.

Table 3.2 Characteristics of study participants

Patient characteristics	Number of participants (n=15)
Mean age in years (range)	79 (53-93)
Female/Male	9/ 6
Independent prior to stroke	11

Formal care package prior to stroke	4
Do not Attempt Resuscitation order (in the first week)	3 in hospital, 2 from the community, 10 none
First stroke	15
Comorbidities (Charlson index: 0, 1-2, 3-4, >=5) Max score=33	Score 0(no comorbidities)= 6
	Score 1-2(mild comorbidities)=5
	Score 3-4 (moderate comorbidities)=3
	Score 5 and above (severe comorbidities) =1
Type of stroke (128)	Total anterior circulation: 7
	Lacunar: 5
	Partial anterior circulation: 2
	Posterior: 1
Post stroke	
Modified Rankin score (mRs) (Scores 0-6) (149)	mRs 4[a] =4
	mRs 5[b]=11
Speech problem not affecting capacity or participation in interview	5
Fed enterally (Nasogastric or gastrostomy)	5
At six months	
Survived	13; 11 with capacity
Modified Rankin score (mRs) Scores 0-6 (149)	mRS 1 [c]=1
	mRs 3[d] =7

	mRs 4=2
	mRs 5=3
	mRs 6 [e]=2
Place of residence	At home=8
	Nursing home=4 (2 did not have capacity to be interviewed)
	Hospital=1
Speech problem not affecting capacity or participation in interview	2
Fed enterally (nasogastric or gastrostomy)	0

Footnotes

a- Moderately severe disability; unable to walk or attend to own bodily needs without assistance
b- Severe disability; bedridden, incontinent and requiring constant nursing care and attention
c- No significant disability despite symptoms; able to carry out all usual activities
d- Moderate disability; requiring some help but able to walk without assistance
e- Dead

We found that patients' pre-stroke functional status; specifically, whether they were largely independent or dependent on others for their activities of daily living (for example, showering and dressing), appeared to influence their experiences, views and involvement in making treatment decisions. Therefore, where appropriate, we have separated our reporting according to these two groups.

We begin by describing patients' backgrounds and pre-stroke functional status. We then explore patients' experiences and reactions to their diagnosis in hospital in the early period after a disabling stroke. We describe

how patients' need for hope appeared to influence their needs *[for information and support]* and views *[regarding treatments]* in the early period after a disabling stroke.

We then go onto consider how patients' pre-stroke background and functional status appeared to affect their feelings about their situation six months later and how, and why, on reflection of their time in hospital, their needs *[for information]* may have changed based on the situation they now found themselves in.

3.4.1 Pre-stroke background and early reactions to diagnosis of stroke

3.4.1.1 Patients who were independent pre-stroke

The majority of patients reported either living alone or with their family and described how they were constantly doing things for others. While this kept them busy, these patients also described how being part of a close network of family and friends gave them a sense of purpose. For instance, Dorothy, who was in her late 70s, described her role as a helper to her disabled friend:

'I'm always helping other people. I've got…my friend…I usually drive her about because she's in a wheelchair. '(Dorothy).

Likewise, Edith, who was in her early 80s, described how she loved cooking and being involved in the lives of her grandchildren:

"I go away shopping an awful lot. And I make, like, pots of soup and I give it to my grandchildren."

These patients described how they had never considered a situation where they might be left disabled and how the stroke had come as a surprise to them:

'*And life so far, never had any problem. It's just come as such a surprise, 'cause I'm not a person to give in to anything.' (Dorothy)*

The sudden loss of independence resulting from the stroke was described as devastating and as having given rise to a sense of loss, uselessness and profound apprehension relating to what other people would think about them

in their disabled state. This included Colin, a man in his 70s who had lived alone and previously worked in healthcare. He described his feelings of anguish as he reported how he felt he had lost his dignity:

'Not walking, talking. I feel embarrassed when I meet people. They'll say to me, look at the state of him. Well, there was today a girl came and washed me and it was the first time. It's just that I'm not used to it. I feel absolutely terrible.
I told her though, I'm so sorry...to see me in such a state, you know, all your private parts just hanging out and she's washing it all….I was just lying there and I was shutting my eyes hoping that she wouldn't be long....' (Colin)

However, many described how they had quickly transitioned from shock and distress to focusing on regaining their pre-stroke functional abilities. This included Edith who reported wanting to be able to do her own shopping again, '*I don't want to get restricted from anything*' and Larry, a man in his 50s, who reminisced about his independent past where he cared for his wife and children, and described wanting '*the use of my arm and leg again*'.

While continuing to focus on regaining their independence, these patients also reported that, should the circumstances arise where they were unable to independently care for themselves at home, they would accept formal or informal care. These patients suggested that they had family and friends to live for and, therefore, for them, survival, even with disability, seemed acceptable. For instance, Larry expressed his wish to '*be part of the family again so [my] wife don't have to do everything*'. Similarly, Edith, who often helped her family by caring for her grandchildren, described how she felt she had so much left to live for, and also how she had people in her life who would care for her if necessary:

'I like to be amongst my family all the time. I can revolve round it (referring to disability). Obviously if I find out I need a lot of help, I can get one of my granddaughters to stay with me and that, you know.' (Edith)

3.4.1.2 Patients who were dependent pre-stroke

These patients described prior restrictions to their mobility and ability to care for themselves, which had meant that they already had a formal care package which allowed them to live at home. In contrast to the group above, these patients described a general deterioration in their quality of life over the preceding years and also lacking a strong family network. In addition to a formal care package, some of these patients required help from friends and family with shopping and housework. This included Harriet, a woman in her late 80s, who was largely housebound. Harriet described how her nephew (her next of kin) visited her once a year and dealt with her finances and how she was reliant on the kindness of her neighbour who came in and helped her on a regular basis:

'*Oh he [nephew] visits, yeh, he does the 'big stuff' you know, like me house, money and that but [name of neighbour deleted] she's brilliant, she is. Does my shopping and all that, keeps an eye on me*''.

These patients reported how their pre-stroke illnesses had led to them leading very restricted lives. They also described how, while they had not been content with this situation, they had adapted to it. For example, Nigel, a man in his 70s, described what it was like to have a neurological condition which had meant that his life had been dictated by his illness:

'I don't go out nearly as much. I don't have as many circle of friends. I used to go out every six weeks to a lunch at [Place name removed]. I've had to curtail that, because my carers clash with the times.' (Nigel)

Due to their generally poor (and deteriorating) health, these patients reported multiple previous hospital admissions, where, on discharge, they had not returned to their previous level of functioning. Therefore, they described being mentally prepared for, and unsurprised by, a further deterioration in their abilities because of the stroke. Consequently, these patients, in contrast to those who were independent prior to the stroke, reported having thought about a situation where they might be left significantly disabled. In the event of this happening, Nigel, like others, described how he would not like his life to be prolonged:

'I don't relish that idea to get spoon-fed……on a permanent basis. I hate the idea of being shut up in my own house. No, I would hate to be a vegetable.' (Nigel)

3.4.2 Trying to cope with the diagnosis: generating and sustaining hope

Regardless of their pre-stroke functional status, all patients described looking for hope of functional recovery. This included Nigel who described how: '*I am, I can and I bloody well will: where there's breath, there's hope*' and Graham, a man in his 60s who, prior to the stroke, owned his own business, and enjoyed outdoor activities, who described how:

(Re: recovery) 'I'll say [I am at] about 20% now. I can see the future higher up the ladder is there for me to climb up to it.' (Graham)

In-keeping with their wish to maintain a positive outlook, patients reported using different coping mechanisms to generate hope. Some reported comparing their functional state to that of other patients in hospital, and described how they thought that others were less fortunate than themselves as they had impairments that they felt were more severe. Such patients reported how this fuelled their hope that they may return to their pre-stroke state:

'When I was sitting in bed and watching the others, I kept thinking I'm lucky I've not got it as bad as they have, you know. I can swallow but I've just got to watch not to take a big mouthful.' (Dorothy, a woman in her 70s, who was unable to mobilise or independently self-care post stroke)

Others described how they valued speaking to stroke survivors they knew who had made full functional recovery and been discharged home. Indeed, such patients described seeking out stroke survivors, often with help from their family and friends, and welcoming hearing encouraging stories about their recovery:

'That was what she [friend] went through. I mean, I know that she's okay. She's a hundred per cent recovered but she was in a bad way. So that was

good to understand that, just that there is light at the end of the tunnel, if you like. So that's a positive experience, positive discussion I've had with someone who I know and I know she's not lying to me. She's looking good. She talks good. She's not got any signs of a stroke.' (Graham)

Most patients also described how they needed information that was framed positively in order to help them maintain an optimistic outlook. In keeping with their need for hope, patients also described not wanting to engage with information that was 'negative'; that is, which alluded to a lack of recovery or the possibility of living with significant disability. Many, like Graham, described even being prepared to accept information that was not necessarily correct, as long as it gave them hope:

'I want to know I'm going to get back to a hundred per cent; that's what I believe inside that I'll get back to. I think it's vital to move forward, even if it's…I was going to say even if it's not completely true, but you've got to have a positive outlook. But if you come along and say, well you've got no chance, you're going to be, you know, wrapped up in a wheelchair for the rest of your life, that's not going to help me.'(Graham)

Indeed, some described how they might lose trust in health professionals if given discouraging information. For example, Olivia, a woman in her early 80s recalled a situation where potentially dispiriting information would have been unhelpful:

'Well if somebody had said to my friend who died of the stroke, oh this is a very serious condition you've got yourself into, I don't know if we'll be able to get you out of this, well it wouldn't have done him any good at all would it? I mean, where's the trust that staff are helping?'(Olivia)

3.4.3 Decision-making regarding treatments following diagnosis

It was against the above backdrop, that decisions about treatments such as intermittent pneumatic compression, enteral feeding, parenteral fluids and antibiotics were made.

3.4.3.1 Patients who were independent pre-stroke

Patients in this group generally reported taking all treatments that were on offer and, in their interviews, appeared to be unaware of the purposes of these

treatments or even that treatment decisions had needed to be made. In keeping with their need for hope, many described assuming that treatments they were given were to help them make a full functional recovery. For example, Edith who was bed-bound after the stroke and needed a hoist to transfer from bed to chair described how she had been happy to take antibiotics for a urine infection because she assumed that these would help improve her mobility:

'Oh, I'll take anything like that. Well, to get me on my feet.' (Edith)

Given their understanding of these treatments, some patients, including Graham, expressed their surprise that others might refuse them:

'*I overheard someone very recently saying that if they're not getting better they'd not want to be treated you know, they want to die, not me; I'm a fighter to the end, you know'.(Graham)*

3.4.3.2 Patients who were dependent pre-stroke

In contrast, these patients described having recalled the conversations with their doctors where treatment plans relevant to their situation had been discussed. They reported how they had informed their doctor that they would not want to have treatments that might leave them significantly disabled and therefore, when offered, they had declined these treatments.

This included Harriet, who declined enteral feeding as she felt that this might impact negatively on her already deteriorating health and quality of life:

'Oh gosh, no. That would be the last straw. I'd ask the Lord to take me away if that [referring to accepting enteral feeding] happened'. (Harriet)

Similarly, Nigel, described how he had decided he did not want any treatments (referring to enteral feeding and intermittent pneumatic compression) that would increase the possibility of him being more dependent than he already was:

'I hate the idea of being shut up in my own house, no. I hate not knowing what is happening around me' (Nigel)

3.4.4 Six month follow-up

3.4.4.1 Reactions to living with disability

At six months, none of the surviving patients had returned to their pre-stroke functional state and, since hospital discharge, many had experienced a further deterioration in their health and functional abilities.

3.4.4.1.1 Patients who were independent pre-stroke

Nearly three quarters of patients who were independent prior to the stroke required a formal care package to be able to manage at home at six months. This was a cause for despair for many such patients who described how, when they had left hospital, they had remained hopeful that they were going to be independent again. This included Brenda, a woman in her 80s, who shared her upset and grief at now needing carers to help her with daily care:

'Everyone kept saying, well, it'll improve, but you don't really realise how bad you're going to be. I didn't realise how much of a setback it was going to be. When people said they had a stroke, I didn't realise what they were going through, whereas I certainly do now.' (Brenda)

Brenda, like many others who had been independent pre-stroke, reported a mixture of disbelief and frustration and described feeling unprepared for the reality of the situation she was now in:

'Very frustrating, because I can't do what I normally do, like I went onto the computer yesterday to put in [husband's name] prescription as I normally do, and I couldn't press the bracket key, you know, the upper case.' (Brenda)

Indeed, it was evident from these patients' accounts that their inability to do things they had previously taken for granted was a source of considerable grief. This included Irene, a woman in her 80s, who was previously independent and had regularly cared for her grandchildren. She now shared the anguish, embarrassment and distress she felt because of being unable to look after herself:

'I'm always embarrassed about asking somebody to help me do things that I feel I could be able to do myself, you know. For instance my left leg just now

is sore because the way I've been lying I was...it's over and I've got to get somebody to straighten it out for me. I can't do that myself which I get quite annoyed about.' (Irene)

Some described how they were struggling to cope on a day-to-day basis and expressed their grief with their current situation:

'My walking and my balance is terrible. Well sometimes...I've fell a couple of times and my leg...got bruises on my other...while I was trying to collect things.
I'm just...how can I say...depressed. My words don't come out right. My sentences don't come out right.' (Colin)

Some patients also described having felt abandoned by staff once they were discharged from hospital. They noted how all therapy (specifically physiotherapy) had stopped following hospital discharge and suggested that if this therapy had been continued, they would not have been in the situation (disability requiring help from others) they were now in. This included Edith who described feeling alone and hopeless as a consequence:

'Oh, they're finished with you once you're out of the hospital. They don't entertain you at all after that. To me they should carry it [referring to physiotherapy] on.'(Edith)

This feeling of abandonment caused patients considerable upset. Edith, for instance, who had previously found meaning and purpose in her life by caring for her grandchildren now needed a hoist to transfer in the care home. Like others, she shared her feelings of despair and of not having anything left to look forward to in her life:

'I can go out when my sons come up if they've got…they take me outside in a wheelchair Some days they're getting me in the car and I lower myself into it but I don't ever get out of the car, nothing like that. They'll open the windows and take me to the seaside and open the windows and let me look out and things like that but I feel it's like a wasted life. You're here for a wee while, the next place you go to that's your dying off place that's that. That's what I feel.' (Edith)

Despite reporting feeling helpless and upset, some patients also described clinging onto hope of some functional recovery. This included Irene who recounted how she wished for an improvement in her balance:

'The physiotherapists were trying to get my balance sorted but it was hopeless. I kept falling back or to the side. So, unless I get that done there's no way I can stand even, you know. I would like to improve on that, you know. Even just to stand up and get out of bed, just to move from here to the chair without having to use the stand aid, you know.'(Irene)

A similar account was provided by Edith who described how she battled to cling onto hope and the possibility of some improvement:

"Well, I can't imagine myself being like this to the end. It's not me. Oh, yes, definitely. They said apparently you can't get any better but I did. I can get better. My brain's fine and if I got help, through time I'd get this leg moving more because I'd like to be a wee bit more independent when it comes to the toilet and that if I can use…get on to one of these things that you push anyway. To be able to walk, maybe with a Zimmer. (Edith)

3.4.4.1.2 Patients who were dependent pre-stroke

These patients, like those who were independent pre-stroke, described needing more help than before to be able to carry on with basic daily activities (such as showering, dressing and mobilising to the toilet) However, in contrast to those who were independent pre-stroke, it was evident from their accounts that this group of patients had given up battling for hope of further functional recovery. This included Nigel, who, six months previously, had already described a situation where he was largely housebound but had been able to mobilise independently (though slowly) indoors, was able to prepare a simple lunch and had got out (albeit only occasionally) to see his friends. Now, he described being fully housebound and needing help from his carers to get to the toilet and perform simple kitchen tasks. Despite this deterioration, he described, in a very 'matter-of-fact' manner how he:

'Would like just to have a more active life, If it (his mobility) comes, it comes, and if it doesn't come, well that's fair enough.' (Nigel)

Likewise, Harriet, described how, against a background of deteriorating health, she had previously been able to shower herself and entertain friends for afternoon tea but was now needing help to shower and was no longer able to invite her friends over. She reported that, while she wished to improve, she had accepted her situation:

'I have a minder who comes in; my only visitor really... She comes and gives me a shower in the morning. I'd like to do that you know…but I'm coping with all that. I've got a special seat in my bathroom, where I sit for the shower'. (Harriet, a woman in her late 80s)

3.4.4.2 Retrospective views regarding information in the early period after the stroke

When patients were asked to consider what would have been useful for to them to have known before they were discharged from hospital, all patients, regardless of their pre-stroke functional status, reported their wish to have been given information which would have helped them better understand and prepare for the situation they were now in. For instance, Irene, in her current state, was in a care home and required hoist for transfers and a catheter to manage urinary incontinence. She reported:

"Well, I think we wanted more information, you know. Excuse me. Just to understand why we're like this, you know." (Irene)

Likewise, Brenda who was now needing carers to help her mobilise to the toilet and to shower, described how she wished she had been given information on what her future may have looked like:

'An idea. You can't precisely say when it's going to happen, an idea of what image of what's ahead.' (Brenda)

However, while these patients described their wish to have had information in hospital, they were not specific about the type and timing of this information.

3.5 Interpretation

In this study involving patients who had an acute disabling stroke but retained mental capacity, we have highlighted how the functional status of

patients prior to their stroke and their need for hope of functional recovery appeared to impact on their experiences, views and involvement in decision-making. First, patients who were functionally independent prior to their stroke were emotionally devastated in the early period post stroke and described feeling abandoned and struggling to find a sense of purpose six months later. They also appeared to be unaware that treatments in the early period post stroke might extend their life, but that they might be significantly disabled. These patients did not engage in shared decision-making and took all treatments in the hope of functional recovery. In contrast, those who were dependent prior to the stroke were more stoic, had considered treatment implications and were more involved in decision-making. They often chose not to have treatments that might prolong their already deteriorating health and poor quality of life. While they reported adapting to and accepting their increased need for care six months later, they were also saddened by their increased disability and social isolation.

Second, in the early stages post stroke, stroke survivors looked for various ways to cultivate and maintain hope that they would recover to their pre-stroke functional state. This included seeking positive information from doctors and other sources. At six months, many of the same patients (especially those who had been independent prior to the stroke) continued to be hopeful of improvement in their functional abilities. However, they also reported wishing they had been given realistic information in the early period after their stroke in order to prepare for the situation they were now faced with. Therefore, there appeared to be a mismatch between patients' need to maintain hope of functional recovery and their retrospective wish to have had realistic information in the early period after their stroke. We refer to this as the "hope-information paradox".

3.5.1.1 Reactions to diagnosis- and the need for support

Our study corroborates with existing literature that stroke survivors have ongoing unmet needs (physical, psychological and social) after hospital discharge. (73,201) Our study also provides empirical support for

recommendations provided by the Stroke Association (4) and Harrison et al (202), that stroke survivors may benefit from psychological support on discharge from hospital. Psychological support has been shown to be beneficial in patients with dementia (203), cancer (204) and myocardial infarction (205) because it reduces rates of depression, improves patients' ability to cope with their situation, better optimises patients' remaining abilities and improves their quality of life. This would be an important consideration for stroke patients, who, as we observed, had unmet psychological needs which seemed to contribute to a poor or suboptimal quality of life. In addition, our findings suggest that the type and amount of support required by patients who had suffered a disabling stroke may depend upon their functional status prior to the stroke and may also change over time. Therefore, different forms of psychological support (e.g. counselling(206), support groups (207), clinical psychology (208) and be-friending services(209)) may be appropriate for different patients at different time points. For example, those who had been functionally independent prior to the stroke may initially benefit from attending clinical psychology services and emotional support groups in order to come to terms with their diagnosis and loss of independence. Such patients would also benefit from be-friending services and peer support in the longer term to address social isolation as would patients who were functionally dependent prior to the stroke. A stepped care approach to psychological care after a stroke (that is, where patients are identified and treated and 'stepped up' to more intensive treatments based on their clinical need) was proposed by the National Institute of Health and Excellence in 2011 (210,211). Although there are pathways into psychological services for stroke patients in the U.K, (202,212), patients in our study did not seem to have benefited from this. We recommend that the multidisciplinary team in hospital, in collaboration with specialist neuropsychology services if appropriate, assess the type and amount of psychological support each patient needs prior to hospital discharge and collaborate with community services to assess ongoing patient needs with respect to ongoing rehabilitation and social support.

3.5.1.2 Involving patients in making treatment decisions

Similar to acutely unwell patients in the intensive care unit (65), we also found that it may not be possible to involve some patients in shared decision-making in the early period after their stroke. This was especially the case for those who had been functionally independent prior to their stroke. As we have shown, such patients may not appreciate that, in the early stages post stroke, some treatments might extend their life, but with significant disability. They may also struggle to engage with health professionals in order to make treatment decisions in the early stages post-stroke. We have also highlighted how the emotional impact of a life-changing diagnosis and patients' need for hope may not be conducive to them receiving and understanding realistic information, rationally weighing up the pros and cons of treatment and/or expressing their preferences for these treatments (65,185) – these all being key to effective shared decision-making as described early on in this paper. Trying to involve these patients in making collaborative decisions may cause unnecessary psychological distress. (213) By contrast, patients who were already significantly disabled before the stroke, like frail older patients with chronic progressive conditions, may be mentally prepared for further deteriorations in their health, have considered consequences of different treatment options and have often decided not to have treatments that may prolong an already unsatisfactory quality of life. (214–217) Hence these patients may be in a better position to be more engaged in the shared decision-making process. We recommend that health professionals explore patients' pre-stroke functional status and consider if and whether the emotional impact of diagnosis may prove it challenging to involve them in making treatment decisions.

3.5.1.3 The hope- information paradox

The need for hope which we have reported in this paper is not exclusive to stroke patients: for cancer patients and older patients too, communication of hope by health professionals is said to help such patients adjust to their diagnosis and improve their welfare and quality of life. (188,218,219) Striking a balance between providing a patient hope that s/he will functionally recover

while not providing false hope is challenging. (220) We report two further dilemmas for health professionals. First, shortly after their stroke, some patients volunteered that if their doctor were to provide them unfavourable information regarding the likelihood of their recovery at that point, they would lose confidence in their doctor, thereby detrimentally affecting the doctor-patient relationship. Second, when asked at six months to look back to the period shortly after their stroke, patients described wishing that their doctors had given them realistic information that could have prepared them better for their current (unfavourable) functional status.

While there are no easy answers with respect to resolving the "hope-information paradox", one potential solution is to consider using existing cancer communication strategies in the stroke context. Potentially relevant cancer communication approaches include 'Ask-Tell-Ask' and 'Hope for the Best, Plan for the Worst' approaches. For example, under the 'Ask-Tell-Ask' approach, a doctor would communicate poor cancer prognosis, then respond to the patient's emotions and finally transition to talking about next steps. Under 'Hope For The Best, Plan For The Worst' approach, a doctor would join with the patient in embracing their hopes while simultaneously asking them to explore a back-up plan based on their prognosis. This could help cultivate the patient's hope by seeking to understand their diagnosis and prognosis and thereafter re-orient the patient's care based on the patient's goals and objectives. (220) Yet there are some challenges to directly adapting cancer communication strategies for using in the stroke context: the illness trajectories for cancer and stroke are different. (220) Specifically, relative to cancer, stroke is an acute medical condition, many treatment decisions need to be taken early, and the trajectory of the patient's condition is difficult to predict.(100) By appreciating that stroke patients too, like other patients, may require different types of information at different points in their illness trajectory,(187,221) health professionals may consider reassessing stroke patients' need for information at different points during their hospital admission. I will discuss communication strategies further in Chapter 9.

While it is difficult to make concrete conclusions from our small study, we recommend doctors consider the following:

(1) Exploring the social context and early experiences of patients to gain an understanding of their views and needs.
(2) Being aware that patients may need ongoing support, and that this best assessed prior to hospital discharge.
(3) Being aware that, while guidelines exist, they may not apply to acute stroke patients: a shared decision-making approach may not always be appropriate.
(4) Adapting strategies used in cancer when communicating hope but maintaining realism for patients who have had an acute disabling stroke.
(5) Assessing the information needs of acute disabling stroke patients at various points during their hospital admission.

3.6 Strengths and limitations

We were successful in engaging and interviewing a group of patients at a time when they are often 'hard to reach' and therefore excluded from research. Following up these patients at six months has given us important insight into their ongoing (and changing) needs for information and support. However, due to the impact of a disabling stroke on patients' physical and psychological states, it sometimes proved challenging to probe and explore some of their experiences and views in-depth. Our sample size was relatively small and all participants were recruited from one tertiary teaching hospital. This reduced the diversity of our sample and hence, potentially, the transferability of the findings to other populations. (222) We considered data saturation to have occurred as no new themes were emerging from our sample and purposive sampling was not possible; we accept the uncertainty of this and therefore, the conclusions drawn. Patients in this study had capacity: our findings are therefore not applicable to those without mental capacity.

3.7 Recommendations for further research

Future researchers could consider investigating the views and needs of stroke patients from different socio-economic and ethnic minority backgrounds who may have different information and support needs. Future work may also consider using specific communication tools to involve patients with aphasia. Interviewing doctors who look after severe stroke patients could give us important insight into how, and why, doctors may have made decisions on behalf of the patient or what other factors they may have considered in the context of treatment decision-making.

3.8 Conclusions

Whilst acknowledging the limitations of this study, we report several findings and suggest some recommendations.

Survivors of an acute disabling stroke have unmet psychological needs which may contribute to a poor quality of life post stroke. These needs must be identified and addressed to help patients cope with their situation. A shared approach with respect to decision-making regarding treatments may not always be possible or appropriate for patients who have had an acute disabling stroke, especially when they may be emotionally distressed and wishing to maintain a hopeful outlook. Health professionals should therefore exercise professional judgement when trying to involve patients in decision-making in the early period after a disabling stroke. The mismatch between patients' ongoing need to maintain hope of functional recovery at six months, but retrospectively wishing they had been given realistic information in the early period after their stroke further adds to challenges of shared decision-making. In order to achieve a balance between maintaining hope while not providing false hope, communication strategies used in cancer may be adapted to the acute stroke setting. We also recommend reassessing the information needs of patients at different time points in hospital.

3.9 Next steps

As I have shown, it may not be possible to ascertain patient preferences or involve them in effective shared decision-making in the early period after major stroke. Therefore, doctors may often turn to proxies (usually family members) to obtain information about patient preferences and involve them in the decision-making process. I explore family members' experiences, needs and involvement in shared decision-making in my next chapter. (Chapter 4)

Chapter 4 A longitudinal qualitative study of the considerations, experiences and needs of family members involved in decision-making

4.1 Publication status and acknowledgement of contribution

I wrote this chapter following comments from my supervisors. This chapter contains a paper that has been published in 'BMC Informatics and Decision-making'. This paper can be found in Appendix A. I wrote this manuscript with comments and guidance from JL. All co-authors commented on the manuscript before submission.

I designed the study including topic guides and performed all the interviews. In keeping with COREC guidelines, my supervisor JL supported data analysis.

4.2 Summary of this chapter

In Chapter 1, I described how some treatment decisions after major stroke would need to be made early and proxies (usually family members) may be consulted regarding patient preferences where the patient does not have capacity to participate in shared decision-making. I also summarised reasons why it may be appropriate to involve family members in decision-making but also acknowledged the challenges they may face. I will detail this in the background section below.

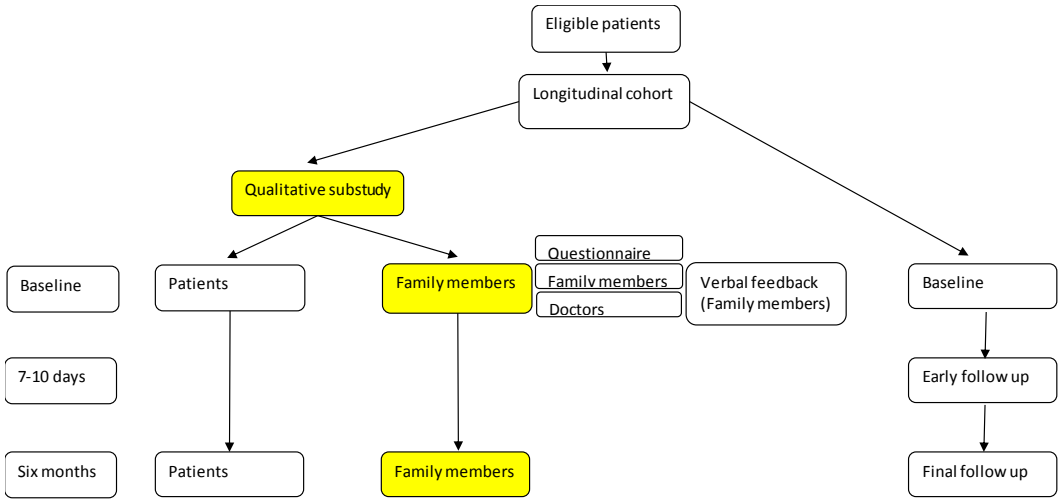
In Chapter 3, I described the experiences, views and needs of patients, and found that in the early period after major stroke, patients were looking for hope and often not ready or able to participate in decision-making. However, at six months, their preferences and needs had changed; they said they wished they had been given realistic information and many were still upset and distressed due to their inability to function as they did prior to the stroke.

Following on from these, in this chapter, I will explore the experiences, views and needs of family members involved in decision-making where the patient admitted with major stroke did not have capacity. Six months later, I will explore their thoughts and feelings on reflection back to their time in hospital.

These family members are a subgroup of participants who had provided consent on behalf of the patient to be included in our longitudinal cohort (described in Chapter 2).

The flow diagram below (boxes coloured in yellow) indicates the part of my study this chapter relates to.

Figure 4.1 Study schematic: Chapter 4



4.3 Background

As I described in Chapter 1, some treatment decisions need to be made early after a major stroke. Treatments such as hemicraniectomy (22) enteral tube feeding (24) and IPC (23) increase the likelihood the patient will survive but with significant disability. However, declining these treatments may increase the likelihood of death. Shared decision-making regarding treatments following major stroke is particularly challenging because most patients do not have the mental capacity and/or are too medically unwell to understand the consequences of treatments. (As described in Chapter 3) To ascertain patient preferences in these situations, professional organisations such as

the General Medical Council and The American College of Critical Care Medicine encourage doctors to involve proxies (often family members) in decision-making. (44,223) This recommendation is supported by literature which suggests that families know patients' preferences the best, (79–83) and seeking patients' preferences from others is a way of extending patients' autonomy. (77,78) Furthermore, patients generally want their family members to be involved in decision-making (87) and most families want to be involved. (84–86)

In Chapter I, I also acknowledged how being involved in decisions concerning life and death may not be easy for families for several reasons. I expand on this below.

Firstly, family members may not know the patient's preferences and hence they may voice preferences based on their own values rather than those of the patient. (50,51) They may also find it difficult to be involved in decisions that are potentially not life-extending, even if these are consistent with what patients may have previously expressed. (52) Patients may also change their views regarding the acceptability of treatments and potential outcomes once they are faced with a situation of critical illness or significant disability. (67,72,224)

Secondly, families may be in shock and being involved in decision-making under these circumstances may be overwhelming. This challenge has been reported in various contexts, including in intensive care and severe stroke settings. (223,225,226)

Thirdly, an important step in facilitating decision-making is for doctors to provide necessary information to families. (44,227,228) In the early period after a major stroke, families may be distressed. Hence, too much information may be overwhelming (229) and, families may want information that is specific to their situation along with support from doctors. (88–90) Recognising the information and support needs of families in the context of a

major stroke is crucial to doctors who may need to tailor their communication to facilitate shared decision-making. (49,201,230,231)

A mixed methods study has acknowledged the need for effective communication of prognosis and psychological support for family members in the context of dealing with consequences of severe stroke. (73) Literature in stroke have also indicated that family members wish for information on prognosis. (232,233) However, to our knowledge, there is a lack of research exploring how and why certain treatment decisions are made in the early period after a major stroke.

Months, or even years later, family members may feel unprepared for the consequences of a major stroke such as patient death or patient survival with significant disability. Literature from severe stroke and intensive care (73,231) has highlighted the ongoing support needs of family members over time. (201,231) For instance, where the patient may have died, family members may still be grieving months later and may not have been prepared for this outcome. (73)

The patient who may have survived major stroke may also have ongoing emotional and support needs. (Chapter 3) Family members who may have taken on a caregiving role for the stroke patient with significant disability may feel ill prepared for their role and concerned about their own competence. (234–236) Taking on a carer role may also result in physical and emotional problems (234,237,238) and cause the carer to feel isolated and their own needs neglected.(235) Different family members may require different level of psychological support.(239) Some patients and family members may even reflect back to the early period after diagnosis and wonder if death would have been preferable to survival with disability. (73,193,240)

Exploring the ongoing thoughts and feelings of family members and their perception of the feelings of the patient (who had survived the stroke with significant disability) would give insight into how their ongoing needs may be better supported. By asking them to reflect back to their time in hospital, we

may gain insight into how they may have been better prepared for the consequences of major stroke during their time in hospital.

Thus, in this longitudinal qualitative study, we aimed to address gaps in research on involvement of family members in shared decision-making regarding treatments after major stroke. We only recruited family members of patients who lacked capacity after major stroke. Specifically, we explored how family members were involved in decisions regarding treatments in the early period after a stroke that may increase the likelihood of the patient surviving longer, but with significant disability. We explored the factors considered by family members when deliberating about treatments, their early experiences in hospital when these decisions were made and their information and support needs. At around six months after the patient's admission to hospital with major stroke, we explored family members' thoughts and feelings about their and the patient's situation and asked them to reflect on their experiences in hospital six months previously.

Based on our results, we provide recommendations for doctors communicating with family members of patients with major stroke who lacked capacity.

4.4 Methods

4.4.1 Study design

We used semi-structured interviews informed by a topic guide to allow flexibility for participants to discuss issues and experiences which were important to them, including those unforeseen at the study outset and ensure the discussion remained relevant to addressing the study aims. (241) Based on reviews of the literature and discussion with clinical colleagues, we developed a topic guide (Table 4.1) which allowed us to explore, with families, what the patients' lives were like before the stroke and how this may have influenced their views. We also explored their experiences soon after the patient's admission to hospital in order to set the context for

understanding the treatment decisions which were made. We then explored their ongoing thoughts and feelings at six months on reflection of their time in hospital six months previously. Data collection and analysis took place concurrently, enabling issues identified in early interviews to inform areas explored in later ones.(242)

Initial interviews took place within the first two weeks of the patient's admission to hospital with a major stroke. This time point was longer than the time point for patient interviews (a week of admission to hospital with major stroke) because as we will go on to describe, some family members needed more time to consider what the patient may have wished for. Therefore, early on in the study (After three interviews), we extended our recruitment window. We also recognised that most treatments we were interested in exploring (i.e. hemicraniectomy, enteral tube feeding, intermittent pneumatic compression, antibiotics and parenteral fluids) should have been discussed, and decisions made, during this time.

Follow up interviews took place at around six months after the patient's hospital admission. We chose six months as our follow up time as we anticipated that this would be a compromise between giving family members enough time to come to terms with their situation but not too long that their experiences in hospital became too vivid that they would no longer be able to reflect on this.

Table 4.1 Topic guide: Initial and six month interviews with family members after major stroke

Interview time	Topics explored
Initial	• How family members saw the patients' life before the stroke; how patients were coping and if they required any help for their day to day activities. The patients' previous medical illnesses and experience with health care.

	• Whether patients had made any pre-stated wishes about treatments in the event of a critical illness and if so, the context in which these wishes were stated. • The emotional reactions of family members to stroke diagnosis and their initial experiences in hospital; if and how they reacted to, and came to terms with, the diagnosis and potential poor prognosis • The factors considered by family members when decisions needed to be made on treatments that were life-extending, but may leave the patient with potentially significant disability; how a decision was made, and why • Based on family members' experiences in hospital, their early needs; how and why information or support may be useful to them, whether these changed over the first two weeks in hospital and if so, how and why.
Six months	• How family members were feeling and coping with their current situation; where the patient may have died or survived with significant disability • Where the patient had survived, how they thought the patient was feeling or coping with significant disability • Their thoughts reflecting back to the early period in hospital when the patient was admitted with major stroke • Their thoughts on how they may have been better prepared for the consequences of major stroke while they were in hospital

4.4.2 Recruitment and sampling

We recruited adult family members of patients admitted with major stroke to a large teaching hospital in the United Kingdom. To be eligible for the study, the patient needed to be significantly disabled as a result of the stroke and not have mental capacity to participate in decision-making. This is in contrast to our patient interviews (described in Chapter 3) where the patient retained capacity after stroke. Treatments (such as hemicraniectomy, enteral tube feeding, parenteral fluids, antibiotics or intermittent pneumatic compression) also needed to have been discussed and decisions made between the doctor and family member.

The medical team identified eligible patients. They considered whether the family member would be appropriate to approach regarding the study (i.e. participation would not be too distressing for them) and, if considered suitable, they asked them if they would be interested in taking part. Where family members were agreeable to being approached, I then provided them with further information and if family members agreed to take part, I then obtained informed written consent. As described in Chapter 3, participants were not informed about my clinical background.

Recruitment continued till data saturation was achieved; that is when no new findings were identified in new data collected. Initial interviews were conducted in a private room in the ward where the patient was admitted at a time convenient to the family member. These interviews took place between May 2017 and November 2017 and lasted 20 to 55 minutes. Family members were given the option of six month follow up interviews in person or over the telephone. Six month interviews took place between November 2017 and April 2018 and lasted 15 to 60 minutes. All interviews were digitally audio recorded and transcribed in full.

Table 4.1 summarizes the main areas explored in these interviews.

4.4.3 Data analysis

Similar to that described in Chapter 3, JL and I analysed the interviews thematically using the method of constant comparison.(200) Both inductive and deductive approaches were used, which allowed unanticipated themes to emerge from data as well as identification of material needed to address the study aims. JL and I read the interviews repeatedly and cross compared them to identify issues and themes that cut across different individuals' accounts. Upon discussion and agreement, a coding frame was developed that captured key themes.

We further analysed coded datasets to develop more nuanced interpretations of the data and identify illustrative quotations. We used a qualitative analysis

software package (Nvivo version 11, QSR International Pty Ltd.) to facilitate data coding and retrieval.

4.4.4 Ethics approval

The study was approved by Scotland A Research Ethics Committee (Ref: 17/SS/0029).

To maintain anonymity, pseudonyms are used below.

4.5 Results

4.5.1 Initial interviews

We interviewed 24 family members. Demographic information and relevant patient data is presented in Table 4.2.

Table 4.2 Characteristics of family members (participants) and the patients

Characteristics of family members (participants) n=24	
Mean age in years (range)	62 (32-75)
Gender	8 male, 16 female
Relationship to the patient	3 partners, 19 children, 2 others (cousin, sister)
Ethnicity	All British white
Occupation	13 retired from work, 11 still working
Characteristics of patients (n=24)	
Mean age in years (range)	85 (55-101)
Gender	7 male, 17 female
Occupation	22 retired, 2 working

Functional status prior to the stroke	11 independent, 13 required care (either a package of care at home or in a care home)
First stroke	23
Had community do not resuscitate order (DNAR)	7
Had pre-existing major comorbidities including dementia, heart failure and renal failure	11

Based on family members' interpretation of the patients' treatment preferences, decisions regarding treatments lay on a spectrum. At one extreme, family members (the majority) described how they felt that the patient would have chosen not to initiate treatments from the outset. In the middle of the treatment decision spectrum, were family members who felt that the patient would have chosen to continue all treatments initially but later, expressed that the patient may no longer find life-extending treatments to be appropriate. At the other end of the spectrum, family members described feeling that the patient would wish all treatments to continue at all costs.

Below, we will consider the factors determining these different preferences and therefore, treatment decisions. We will then explore how this seemed to influence family members' early experiences in hospital, and their accompanying information and support needs both in the early period after major stroke and at six months. Where possible, we will report our findings based on where family members were on the treatment decision spectrum we have identified.

4.5.1.1 Reflecting on patients' health pre-stroke, and preferences for life-extending treatments

4.5.1.1.1 Family members who felt that the patient would have chosen not to initiate life-extending treatments

Family members at one end of the treatment decision spectrum described how the patient who had been admitted to hospital, many of whom in their eighties or nineties, already had chronic progressive conditions (e.g., dementia and arthritis) prior to their stroke. They described how, over the years, these conditions had resulted in gradual decline in their health and quality of life. Hence, family members noted how these patients had not been fully independent prior to stroke and how some had either lived in a care home or had been reliant on others for aspects of their care, such as washing and dressing. Family members further noted how this dependence on others had been a source of frustration and distress to the patient.

For example, Paul, the son of a woman in her nineties noted how his mother had various chronic medical conditions including arthritis and heart disease, and although she had lived at home, she had needed carers to come in four times a day. He also described how her dependency on others had led to her being unhappy with her life and extremely low in mood:

'*She's depressed… every time I go up she'll say to me I don't want to be here, [name removed]. I seem to get it every week In fact..... she had said to me I love you but I want you to put the pillow over my head...' (Paul)*

According to these family members, which included Paul and Imogen (who is quoted below), patients' increasing frailty and dependence on others had meant that, in many cases, they had indicated their preference, either to their family or their doctor, for not wanting their already poor quality of life to be extended:

'Well, my mother has been very unwell for the last nine months now. She had caecal carcinoma, so we have been involved with the hospital for a long time. So, we have had all the discussion about, what interventions she would want, so...I was in no doubt about what she wanted, which is not much.' (Imogen)

Many of these family members also reported how the patient had thought ahead to a circumstance where a decision might need to be taken regarding resuscitation:

'Mum already has a DNR in place. She's a very strong woman.. She knew...well told us this is what...if it comes to a point where all the numbers stack up against her, and she finds herself requiring a DNR, which she wants, that would be the line to take. Do not resuscitate'. (David)

4.5.1.1.2 Family members who felt that the patient would have chosen to withdraw life-extending treatments over time

Family members who were in the middle of the treatment decision spectrum described how, although the patient had generally been quite old (late seventies or early eighties), they had been determined and able to maintain moderately independent lives. This included Moira who described how her husband, in his eighties, had continued to lead a busy and active life right up to his stroke:

'*When we got to 80, and [name removed] said he retired; well, he continued to work whenever he got the chance – he couldn't retire – and what he's done since he was 80 is he's chopped wood and split logs…and even on Sunday, the day before this, he was working splitting logs. So he was very, very active and very strong'. (Moira)*

Colin, likewise, described how his father had been a very determined man and, despite having had multiple health problems and hospital admissions, had only needed minimal help to live independently:

'Well, he's physically very strong, mentally very strong and he's had things before which he's come back from, in the hospital, heart attacks and quadruple bypass surgery and so on and he's quite tenacious about life in general. We just do some shopping and cleaning for him.' (Colin)

In keeping with their relative independence, family members noted how they felt that the patient had not generally thought about a circumstance where they may be left significantly disabled in any meaningful way. Hence, as Martha, the daughter of a woman in her eighties noted, any comments the patient had previously made which had alluded to treatment preferences could not

necessarily be interpreted as their true preferences, because they felt that these individuals had not properly considered a future situation of critical illness and/or significant disability:

'Her friend had a stroke and went into a home…and that allowed me to introduce the subject of what would you like to do in the long term if you weren't able to live in your own home? And her response was, oh, I've never really thought about it. But well, if I couldn't stay in my own home I'd probably want to come and live with you. But I said that won't be possible as I work full time, and she says 'oh well, I'd go to a home then.'(Martha)

4.5.1.1.3 Family members who felt that the patient would have wished for all treatments to continue at all costs

The minority of family members at the other end of the treatment decision spectrum reported how the patient had been relatively young and independent prior to their admission. Hence, family members reported that they did not feel that these individuals had considered a situation of critical illness and, therefore, they were not aware of them having articulated their own wishes for treatments in a situation where they might be left significantly disabled. This included Jenna the stepdaughter of a man in his 50s:

'*Not really something that he would speak about; like, we like to get away every now and again, sort of, just we go camping and stuff like this; we'll walk at weekends. It's not really something that he…I don't think he's thought about the, sort of, long term'. (Jenna)*

4.5.1.2 Early hospital experiences and accompanying needs

4.5.1.2.1 Family members who felt that the patient would have chosen not to initiate life-extending treatments

Family members of patients who had already been physically dependent before the stroke, described how these patients had had multiple previous hospital admissions and therefore, how these previous experiences had made it easier for them to understand and accept that the patients' prognosis might be very poor. For instance, Susan, the daughter of a woman in her nineties who had had a previous stroke, described how she was familiar with

being in hospital and was accepting of the fact that her mother was very unwell and might not survive:

'*I mean, we kind of predicted that this was maybe the way it was going to go with this second stroke Mum's had, the second time she's been here; so there's a bit of history, so it's easier for all of us to understand the predicament we're in'. (Susan)*

Given these experiences, and their confidence in knowing what the patient would have wanted with respect to life-extending treatments, these family members reported how such treatments would not be in the patient's best interests. This included Murray who described how he had considered his mother's preferences and had concluded that the situation his mum was now in (significantly disabled and requiring 24 hour care) would not be the kind of life she would want to endure:

'*She said she did not want people looking after her and I think the point with Mum's situation is that massive stroke – it's unlikely she will recover from it. If she does recover …she's going to need full-time care, so that's…for Mum that's not an option; she wouldn't want that.' (Murray)*

These family members thus described how, based on what the patient may have expressed previously, initiating life-extending treatments would not be in line with the patient's wishes even before the doctor had provided their opinion on the patient's prognosis. Hence, as Linda, the daughter of a woman in her eighties, described, a discussion with the doctor on what the patient would have wished for was often used to support a treatment preference and decision that had already been made by the patient::

'*So, we've (referring to Linda, her mother and family) been very open about it and feel very strongly that no prolonging of life, given the quality of life that she has. So, that was the conversation I had with the consultant and it was rather nice and refreshing that he was very open to listening and in total agreement with that, and also being quite honest as to the implications of the stroke, in terms of swallowing and the options, and things like that'. (Linda)*

4.5.1.2.2 Family members who felt that the patient would have chosen to withdraw life-extending treatments over time

Family members of patients who had been moderately independent and had not formally expressed their preferences for life-extending treatments, described having been shocked and distressed by the diagnosis of a major stroke with poor prognosis. This included Jack who shared his astonishment at how, on the same day as the stroke, his mother had been leading a group tour of a historical site:

'*Especially since she was, you know, completely fit and healthy one day, and, well, the same day, just suddenly, wallop. It was completely…changed her, you know. So, yeah, it was a bit of a shock to the system'. (Jack)*

These family members discussed how, because of their shock and distress, and not really knowing what the patient's preferences were, they had initially felt that the patient would wish all treatments that might have given them a chance of survival:

'So after two days of deterioration, so Doctor [name removed], he said, what is your position on treatment and antibiotics; and I didn't really have…I didn't feel that I was in a…couldn't not doing treatment. So I was trying to think about what would [the patient's name removed] say. She's really committed to life; so I said, well, I think if you felt it was okay I think [name removed] would want, she wants to get better, she's not ready to die'. (Lorna)

Having initially voiced a preference that the patient may wish for all treatments, these family members reported how, over the days which followed this decision and as they got over their initial shock, they had reassessed the situation the patient was in and gathered evidence to make further decisions about (withdrawing) treatments. This included having discussions with family and friends about what the patient might have wanted with respect to treatments and future quality of life:

'And…initially my view was that because I didn't have enough medical knowledge, I thought that feeding her and giving her the antibiotics and the

other medication, we would start to see an improvement. And, you know, I had a hope…whether it was a forlorn hope or not that the treatment would have an effect. But her condition got worse- I'd spoken to various relatives and various friends of hers and explained the situation and all of them said, oh she wouldn't want to carry on living like that.' (Jack)

They also described how such discussions had jogged their memory about situations where the patient had previously made informal comments about life-extending treatments or surviving with disability. They then reported how these remarks had led them to conclude that the patient would not have wanted to have been kept alive by tube feeding or if they needed full-time care. For example, Collete described how her mother had been the main carer for her father who had had a stroke, and had, based on her interpretation of his preferences, expressed that no life-extending treatments be given to him:

'*I don't think she would be very happy to be constantly fed and kept alive with tubes. My father died with a stroke and she said the same thing, your dad wouldn't want this, your dad wouldn't want that, he wouldn't be happy if he couldn't do XY and Z. So she was probably the most calm out of the whole family when my father died.' (Collete)*

Many also described how, when they were visiting the patient in hospital, they had observed them making gestures, such as removing oxygen masks and feeding tubes, which they interpreted as them wanting to reject these treatments:

'*I think a lot of it was informed by the fact that she kept taking the feeding tubes out … And…just other signs. I mean, as her son, I know her facial expressions. And I just got the impression looking at her that she really wasn't happy in the situation that she was in. She'd had enough and she wanted it come to an end. She wouldn't want to be in a care home lying there, you know, effectively unable to do anything. And I think she was telling us that by removing the feeding tube and…she's telling us again by removing the oxygen'. (Jack)*

While reflecting on the situation, and realising that the patient might not survive the stroke, many of these family members described how they had moved away from their initial hope that the patient would recover to a more pragmatic approach of looking for potentially realistic information from the

doctor on the patient's likely (poor) prognosis. They then described how they used this information, along with their interpretation of what the patient may now wish for, to decide that it would now be appropriate to withdraw various life-extending treatments:

'Well each time a decision came along, I sat down with either Dr [name removed] or Dr [name removed] in the main and the main decision was on feeding and whether they should persist with it. So…yeah, I was given information. I asked them questions. We came to a judgment...' (Jack)

Although these family members described how, having reflected on the situation, they had felt that withdrawing treatments had been appropriate, they also noted how this process of decision-making (and treatment withdrawal) had been very upsetting for them. Some expressed how formal psychological support from hospital staff might have been helpful to them during this distressing time:

'You know, this is hard, very tough… some, kind of, counselling service available, preferably with people with some medical knowledge'. (Jack)

4.5.1.2.3 Family members who felt that the patient would have wished for all treatments to continue at all costs

The minority of family members, where patients had been young and independent before the stroke, described how they had felt shocked, overwhelmed and emotionally unprepared for the situation they now found themselves in. For example, Andrea, the daughter of a previously independent woman in her sixties, described how she and her father had felt helpless and extremely distressed seeing her mother in hospital in a physically dependent and agitated state:

'I saw my mum, my dad was in shock basically. It was quite upsetting to see her being sick and she looked like she was not comfortable. It just felt yesterday nobody was helping her to try and get this bleed under control and trying to get my mum back. So it's, kind of, upsetting [sounding upset].' (Andrea)

These family members expressed how, while feeling extremely distressed, they had looked for ways to maintain hope that the patient would survive. For example, Andrea described how she thought back to instances in the past

where her mother, based on her determination to improve, had recovered well from minor illnesses. She expressed how she felt that, based on these previous situations, the current situation her mother was in would be one from which she would be able to pull through:

'I think she would cope with a lot. My mum can cope with a lot. She did have an operation on her arm and she had to get a plate put in and they did say to her that she would only get…likely 45/50 per cent usage. But she pushed on and pushed on and she's got 90 per cent usage in her arm. They say she would only manage to get her arm to here [lifting arm up from the table]. She can actually get her arm to there [extending arm to 60 degrees]. And, you know, she's a determined woman.'(Andrea)

In a related example, Jenna described how she had looked for information from the doctor that gave her hope that her step-father would survive:

'*To have heard from the doctor when he had said to us, you know, some people will survive, kind of, gave us a bit of hope; like, well, there is hope.' (Jenna)*

In their situation of extreme anguish, they expressed how they thought that the patient would have wished for all treatments and therefore, it would be appropriate that all treatments be given to the patient to promote the possibility (however small) of them surviving the major stroke:

'When it's a family member like you don't want them to withdraw treatment, you want them to give a 100 per cent and keep going no matter what. If a patient needs to be fed through a tube then they need to be fed through a tube and I don't think that's a decision that should be given to the family. It should just be...it should just happen'. (Jenna)

These family members also expressed how they felt isolated at this difficult time and reported that emotional support would have been helpful:

'Dad's not coping, we were just left, left like that. There's no one…Some sort of support would have been helpful, you know…but there was nothing..' (Andrea)

4.5.2 At six months

At six months, 21 patients had died and three had survived. All surviving patients were significantly physically disabled and did not have mental

capacity. I interviewed 23 family members by telephone at six months. One withdrew consent. We found that their thoughts and feelings appeared to be related to their interpretation of the patients' preferences, how those impacted on treatment decisions that had been made, and if the patient had died or survived at six months. Therefore, where possible, I have related my findings to these.

4.5.2.1 Feelings and thoughts about their (and the patients') situation while reflecting back to their time in hospital

4.5.2.1.1 Where the patient had died by six months

Based on their interpretation of the patients' preferences, family members who had felt that the patient would have chosen not to initiate treatments at the outset described how they were largely coping with the patient's death. For instance, Sophie, who had, six months previously, expressed her mother's preference on not to initiate treatments described her feelings:

'We've been fine, actually. As a rule, we're always a very, very busy family so there have been many distractions going on, but obviously you have your quiet moments when you think about mum, but we've been managing.' (Sophie)

Many family members who were in the middle of the treatment decision spectrum (i.e. where treatments were withdrawn over time) expressed how things had been difficult for them after the patient had died. They described looking back to their time in hospital, and voiced how distressed they had felt then and were still feeling.

For example, Jack, the son of a previously independent woman in her early eighties who had eventually died from the stroke after treatments were withdrawn, expressed his ongoing feelings of upset:

'It is obviously a difficult time. I think the process of mum dying after treatment was withdrawn was quite a long, drawn out and painful process for the family. When she finally passed, I think it was something of a relief that the suffering

was ended. And so, we could get on and grieve. Yeah. It was a difficult time. We're still grieving'. (Jack)

While grieving their loss, many of these family members also described being confused and distressed by certain aspects of the patients' care in hospital. For example, Murray described the confusion he had felt when tube feeding had been stopped for his mum, but she had not died immediately after this was done:

'Yeah. I was quite frustrated then for a time, because the way I was looking at it was that we're basically starving her to death. And, you know, just drugging her up on morphine to keep her from being distressed through the process. There should be a kinder way to allow people to slip away.' (Murray)

Similarly, David described how he felt puzzled when fluids were withdrawn from his mother, but his mother had continued to survive for weeks after this:

'When they withdrew fluids from my mother.. that went on for nearly two weeks, and our mum was still with us. And then they put her back on the fluids, just really to make her comfortable. So, that was rather confusing. Because, clearly they (referring to doctors) didn´t expect mum to last as long as she did when they withdrew fluids, as it were. But she kept, you know, living'. (David)

Such family members described how direct realistic communication would have been useful to them to better understand and be prepared for the patient's death:

'The knowledge that I had, or we had, of the situation would probably have been made clearer to us, look, your mum´s not going to recover. I know, they want to be tactful about this, but there´s sometimes you just need to be told. I mean you just need to be told so we can come to terms with it, because my mum´s there but she´s not alive. So, really, we know she´s going to die. So, it was more a case of telling us that… Be more direct'. (David)

Some families also expressed their regret at not being by the patient's bedside when s/he had eventually died. This appeared to be important to them to be able to grieve:

'I missed my mum passing by about two or three minutes I think, because we had just gone home again. We had been there a lot in and out, and they said, oh, you could just go home and we'll give you a call when anything is happening, and which they did, but that was just too...slightly too late… I'd like to have been there to hold her hand'. (Mark)

4.5.2.1.2 Where the patient had survived to six months

In the very few circumstances (three) where the patient had survived, these patients were significantly physically disabled. Two were living in care homes, requiring 24 hour care while one patient was still in hospital, being assessed for an appropriate discharge destination.

Where the family members had felt that the patient would have chosen not to initiate treatments for the patient, but the patient had survived, these family members described how they felt that the patient was very upset due to their inability to function as they did prior to the stroke. This is similar to my findings in Chapter 3. For instance, Lindsay described how her mother's mood had been very low mainly due to her lack of mobility, which had led to consequent feelings of loneliness and isolation:

'Well, she's not what she was before she had the stroke, but sometimes she's quite depressed and says she's lonely. I don't think she will ever have muscle power to walk...that's what upsets her most I think not being able to walk...just sitting there in the chair, in the wheelchair day after day. Anyway, she has not got the concentration that she had. She has got her telly in her room, and she watches it, but falls asleep …' (Lindsay).

These (two) family members seemed quite reluctant to discuss their feelings about their current situation. For example, Lindsay dismissed the question:

'Well, we are where we are, aren't we? I mean, what can I say…' (Lindsay)

In the one circumstance where the family member had felt that the patient would have wished for all treatments to continue, and the patient had survived but with significant disability, the family member described how she thought that the patient was not content with the situation:

'I think he feels a bit useless. And he can't walk or use his left arm at the moment, they've had to put him on antidepressants. But, I mean, we were told he was going to die and we had prepared...like, you know, we were switching off his food and stuff. We just remind him of that and he does know, he does know how lucky he is to still be here, and it must be hard because it is...like he said it is a completely different life to what he's used to, but it still is life and he's still here'. (Jenna)

This family member was also reluctant to fully detail her situation but reported that her mother (who was the main carer) was not coping with her new role as a carer:

'Mum's back at work. She's just part-time at the moment. I think she's maybe struggling a bit. It's not just [patient's name removed] life that's changed, it's mum's as well. She's doesn't want to be his carer but she is going to have to take on that role and it's just, sort of….different…. but I think she has to be very very happy that he's still with us...' (Jenna)

4.6 Discussion

4.6.1 Summary of key results

This longitudinal qualitative study explored early decision-making regarding treatments involving family members of patients who lacked capacity in the context of a major stroke and family members' ongoing thoughts and feelings six months later.

Early decisions regarding treatments after major stroke lay on a spectrum, based on the patient's pre-stroke functional status and prior experiences of illnesses, and any views they had expressed about treatment preferences in the event of a critical illness which might result in significant disability or death. At one extreme of the treatment decision spectrum, there were family members who felt that the patient would have chosen not to initiate life-extending treatments at stroke onset due to the patients' deteriorating health pre-stroke and stated treatment preferences pre-stroke. These family members looked for information from doctors to support a treatment

preference that had already been expressed by the patient. In the middle of this spectrum were family members of patients who were relatively independent, who felt that the patient would have chosen to withdraw treatments over time, once they got over the initial shock of the diagnosis and had time to gather relevant information from family, friends and doctors. At the other end of the spectrum were family members of previously independent patients whose treatment preferences were unknown. These family members felt that the patient would have wished all treatments to continue at all costs and reported the need for hope of patient survival from doctors and psychological support.

At six months, some family members (especially those in the middle of the treatment decision spectrum) often appeared to be confused by and unprepared for the process of the patient dying after all treatments had been withdrawn. Family members also had ongoing emotional needs, either to cope with the patient having died or to cope with the patient having survived with significant disability, and hence requiring more care.

Below, we place these findings into context of existing literature, and make recommendations for clinical practice.

4.6.2 The need to explore the patient's state of health before stroke

Our results agree with sociological literature reporting that the experiences of health and illness of individuals and relatedly, decision-making regarding treatments, are socially and contextually informed. (197) Our findings also corroborate results from studies involving family members of patients admitted to intensive care which have reported that, in addition to information regarding prognosis from doctors, the majority of family members estimated the patient's prognosis depending on their perceptions of the patient's strength of character, unique story of illness and survival and previous experiences and choices of treatments.(76,243)

Family members who felt that the patient would have chosen not to initiate life-extending treatments appeared to have already experienced some anticipatory grief (244) and seemed to be prepared for the possibility that the patient might not survive. During the decision-making process, they had drawn on their previous experiences with those of the patient (for example, of the patient's multiple hospital admissions, and declining health and quality of life), and knowledge of the patient's treatment preferences. In contrast, where family members were unaware of the patient's preferences, they were generally in shock and unprepared for a situation of critical illness (52), and therefore, found being involved in decision-making more difficult . (243) Our study therefore further reiterates the need for doctors to explore the patient's preferences by gathering information from family members, perhaps through a narrative approach, i.e. by developing the patient's story. (245)

4.6.3 Providing tailored information

As we have reported, the type of information that a family member might wish for varied depending on the patient's health state and stated preferences pre-stroke. Though we accept that family members may not respond in predictable ways, our findings provide some insight to doctors to help them better prepare for discussions about prognosis with family members. For example, before meeting with families of older and dependent patients, doctors may be able to prepare themselves by ensuring that they can provide realistic information about the patient's (likely poor) prognosis.

For families of (relatively) independent patients, several meetings may be needed to share sufficient and relevant information, discuss preferences, weigh up pros and cons of available treatments and then arrive at decisions. (59,230,246)

In contrast, before meeting with families of young, previously fit and independent patients, who may well be very distressed by the situation, doctors should be ready to respond to the likely emotional response (e.g. profound shock) as a result of the diagnosis, and share bad news about poor

prognosis sensitively. For example, doctors may consider using the 'SPIKES' protocol used in oncology which provides a six step strategy for breaking bad news and dealing with emotional responses. (247) Specifically, approaches such as active listening, observation of non-verbal communication, choosing words that may not be perceived negatively, breaking down information into small pieces and offering another meeting at an agreed time may help families understand the situation of major stroke with poor prognosis better and help them cope with their emotions. (247,248) As I described in Chapter 3, doctors should also consider how to balance the communication of hope with that of realism (53). This can be complex.(249) Some family members may maintain a strong sense of hope that the patient may survive and recover despite accepting poor prognosis. (250,251) Others may find hope by being overly optimistic about the patient's prognosis (89,250,252) and may not wish to obtain realistic information.(253) In contrast, some individuals may find hope when doctors discuss preparations for possible death and optimising comfort at end-of-life.(254) This further highlights the need for tailored communication, and doctors may consider adapting some communication strategies used in intensive care to the major stroke setting. For example, the use of the phrase 'hope for the best and prepare for the worst' can help manage expectations. (255) Using 'I wish' statements (e.g. I wish things were different) may also acknowledge the limits of available options while expressing empathy in a situation which may be futile, or where individuals may have unrealistic hopes. (255,256) .

Where appropriate, doctors should also consider communicating the uncertainty of the process of dying i.e. inability to predict duration and the possible protracted course even after treatments had been withdrawn. Despite recommendations on communication techniques on approaching conversations about dying in stroke, (45) e.g. 'firing a warning shot' and using 'I wish' statements, doctors do not find it easy to convey uncertainty (53) and tend to focus on communicating active treatments including rehabilitation, rather than preparing individuals for the possibility of the patient dying. (73) I will return to these communication strategies in Chapter 9.

4.6.4 The need for psychological support

Our results indicate that the shock of stroke diagnosis and being involved in decisions not to continue life-extending treatments can be upsetting for family members. (257–259) Therefore, when meeting with family members, doctors may consider exploring if they had support from friends and other family (260) and if they may wish counselling and emotional support from clinically trained staff (e.g. psychologists) to help reduce their distress. (261,262)

As I have reported, the distress individuals may feel can even linger for months. (263) Therefore, similar to patients who had survived a major stroke (described in Chapter 3), family members too appear to need ongoing emotional support. Although family members who had taken on a carer role for the patient who had survived major stroke are inadequately represented in this study, in keeping with existing literature, it is apparent that these individuals have support needs that do not appear to have been adequately met. (235,237,238)

A stepped approach towards psychological support, where level of intervention is 'stepped up' according to necessity (211) may be helpful. Grief and bereavement services which have been stressed in other carer groups such as after head injury and in dementia may also be appropriate. (264,265) The Stroke Association (266) provides support and advice to bereaved families of stroke patients and therefore, family members could be encouraged to contact this organisation.

4.7 Recommendations for clinical practice

We recommend doctors communicating with family members of patients with major stroke to consider the following:

1. To gather evidence regarding the patient's functional status pre-stroke and any previously stated preferences for life-extending treatments.

2. To tailor their communication of information to the individual's needs: i.e. information to confirm poor prognosis and support a treatment preference that the patient had already made, that to facilitate shared decision-making, information to maintain hope (while being realistic and not offering false hope) or to communicate the possibility of dying, and the uncertainties of this process. This can be done by exploring their understanding of the patient's condition, eliciting their hopes, concerns and expectations, and finding out what they know about any wishes or views the patient may have expressed previously.
3. To be aware that family members may have unmet psychological and emotional needs both in the early period after stroke and at six months which would need identified and addressed. Some may require more specialist input, e.g. clinical psychology. Others may require information on how to access support services e.g. by contacting the Stroke Association.

4.8 Recommendations for further research

Future research could consider investigating the experiences, views and needs of families from different socio-economic and ethnic backgrounds, who may have different experiences and views on being involved in treatment decisions. Future research may also focus on interviewing family members of patients who have retained mental capacity after a major stroke. Qualitative interviews with family members in different hospital settings may increase generalisability of our results. Staff training on communication strategies in major stroke would be helpful, and future research could consider further adapting and evaluating these strategies in the context of major stroke. I will discuss this further in Chapter 9.

4.9 Strengths and limitations

We engaged with a group of family members at a time which can be emotionally distressing for them and therefore, we were able to gain novel and important insight into their early experiences, needs and involvement in

decision-making. Their thoughts and feelings six months later provided us with insight into how their information and support needs may have been, or could be better supported. However, our sample size was homogenous; all participants were of similar ethnicities and were recruited from one tertiary teaching hospital. Furthermore, since this study relied on participants 'opting-in', it is possible that individuals who participated were those who were more able to voice their experiences. Therefore, our sample of family members may not be representative of all family members of patients admitted with major stroke which may reduce the transferability and generalisability of our findings to other populations. (222)

4.10 Conclusions from chapter

- We identified a spectrum of treatment decisions made for patients who lacked capacity after major stroke, defined by the patient's state of health and stated preferences pre-stroke. This influenced information and support needs of family members involved in this process both in the early period after major stroke and at six months.
- Family members need tailored information from doctors; in the early period after major stroke they may require information to support a treatment preference and decision that the patient had already made, be involved in the decision-making process or maintain hope that the patient may survive. They may also require information and preparation for the possibility that the patient may die, and uncertainties in prognosis and the dying process.
- Family members and patients may have early, and ongoing unmet emotional needs. These need to be identified and addressed.

4.11 Next steps

As I have described, communication between doctors and family members in the context of a major stroke where the patient lacked mental capacity appears to be important to family members.

In my next chapter, I will compare how these family members and doctors perceive current communication between them in the context of a major stroke, aiming to identify areas where communication may be improved.

As I described in Chapter 1, the doctor's view regarding appropriateness of treatments for the patient may also affect the way they communicate. Therefore, in my next chapter, I will also explore if the doctor's view of appropriateness of specific treatments for the patient admitted with major stroke may influence the decisions made about these treatments.

Furthermore, as I have described in this chapter, for some family members, information on prognosis from doctors may be important to facilitate shared decision-making regarding treatments. In Chapter 6, I will explore family members' views regarding prognostic information and their views on how information may be presented to them.

Chapter 5 Doctors' views on appropriateness of specific treatments for the patient and communication between doctors and family members in the context of major stroke: an evaluation using questionnaires

5.1 Acknowledgement of contribution

I designed the questionnaires with my supervisors and piloted them before their use. I analysed all the questionnaires. I wrote this chapter and made changes following comments from my supervisors.

5.2 Introduction

In Chapter 1, I reported how doctors and patients may have different preferences for treatments. For example, doctors have different thresholds for accepting treatment for themselves in conditions such as hypertension (267,268) and cancer (269) when compared to patients. Doctors may also express different preferences for end of life treatments for themselves.(116,270) It is possible that doctors' preferences, behaviours and styles of communication may influence the decisions that are made. (271)

In Chapter 1, I described how shared decision-making is considered a gold standard of care and that communication between doctors and patients/ family members was important. (29,30,45) Related to this, I reported how patients looked for hope and positive information from doctors (Chapter 3). Then in Chapter 4, I found that family members (where the patient with major stroke did not have mental capacity) looked for information from doctors.

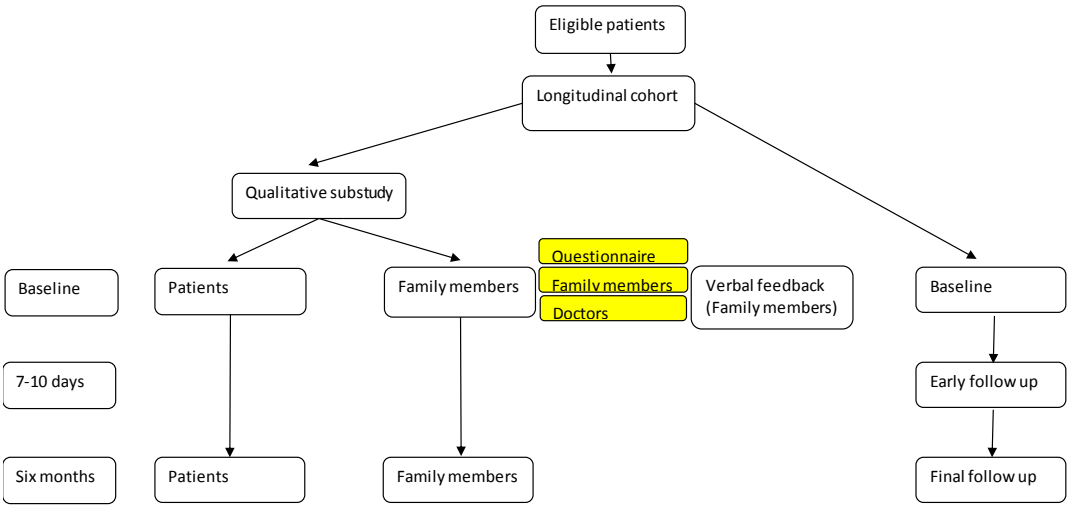
In this chapter, using questionnaires, I address five aims related to doctors' views of appropriateness of treatment(s) for the patient admitted with major stroke (and lacked mental capacity) and communication between doctors and

family members* in the context of major stroke. This evaluation is based on a single meeting between a doctor and a family member where the patient's diagnosis, prognosis and appropriateness of life-extending treatments were discussed for the patient admitted with major stroke and who lacked capacity. (Chapter 4)

*As I reported in Chapter 3, after a major stroke, many patients (who had capacity) were overwhelmed and distressed having received, and trying to come to terms with their diagnosis. Therefore, while they were able to narrate their experiences (reported in Chapter 3), they were not able to engage with questionnaires.

The flow diagram below (boxes coloured in yellow) indicates the part of my study this chapter relates to.

Figure 5.1 Study schematic: Chapter 5



5.3 Aims

Prior to meeting with the patient's family member(s):

a) To ascertain the doctor's views regarding the appropriateness of specific treatment(s) for the patient

After meeting with the patient's family member(s):

b) To ascertain if doctor's views of the appropriateness of specific treatment(s) for the patient influenced the treatment(s) agreed (in)appropriate for the patient
c) To elicit the family member's perception of the communication that had taken place between the doctor and them
d) To elicit the doctor's perception of their communication with the patient's family member(s)
e) To compare family member's and doctor's perception of communication between them

5.4 Methods

Each family member (n=24) who took part in qualitative interviews (Chapter 4) consented to complete a questionnaire evaluating the communication that had taken place between them and a doctor. Each senior doctor working on the stroke unit (n=9) [6 consultants, 3 registrars] who were involved in communicating with these family members completed two questionnaires (one prior to meeting with the patient's family member(s) and one after).

As described above, the questionnaires were completed based on a single meeting between the doctor and family member(s) where the patient's diagnosis, prognosis and appropriateness of life extending treatment(s) were discussed. This meeting took place within the first two weeks of the patient's admission to hospital with a major stroke (As described in Chapter 4). I handed out the questionnaires to the doctors once they informed me that a meeting was scheduled between them and a family member. I handed a questionnaire to each family member after their initial qualitative interview. (Chapter 4) Questionnaires were returned to me or the ward clerk in person as soon as they were completed.

The questionnaires were based on Likert type questions (where participants indicated their answer [one of five options] from strongly agree to strongly disagree). No composite score was calculated from the questionnaires. This was because, although the two main focuses of the questionnaires were to assess treatment preferences and communication, each question on the questionnaire tested different aspects and therefore, it would not have been possible to combine them to derive a total score to describe one domain. My supervisors and I designed these questionnaires based on what we thought would be clinically relevant and on evidence that Likert type questionnaires are useful in reporting self-reported outcomes such as quality of life (272), mood and fatigue (273) in several neurological conditions including stroke.

I piloted the questionnaire to be completed by family members on ten family members and the questionnaire to be completed by doctors on five doctors on the stroke unit before the start of the study. Their feedback had indicated that Likert type questionnaires were suitable in this context. The doctors and family members who were involved in the questionnaire pilot did not participate in our study.

The questionnaire completed by family members contained questions relevant to this chapter and my next chapter. To avoid an excessively long chapter, I have split my analysis of this questionnaire between two chapters.

The statements in the questionnaires relevant to this chapter are as follows:

<u>To address aims (a) and (b):</u>

Prior to meeting with the patients' family, doctors completed a questionnaire. For each patient, doctors indicated their views on the appropriateness of either introducing or continuing eight possible treatments for the patient: fluids, thrombo-prophylaxis (particularly, neurosurgery (particularly, hemicraniectomy), intermittent pneumatic compression [IPC]), enteral tube feeding, escalation to the high dependency unit, cardio pulmonary

resuscitation [CPR], use of antibiotics for treatment of infections and end-of-life care with prescription of medications to optimise comfort.

Immediately after the meeting between the doctor and family member(s), I reviewed the patient's notes to find out what was discussed and agreed as the most appropriate treatment plan for the patient.

To address aims (c) to (e):

Family members completed a questionnaire after the meeting between them and the doctor.

The statements on this questionnaire relevant to this evaluation were:

i) The explanation of the stroke was difficult to understand
ii) The predictions of likely outcomes after stroke were clear
iii) The decisions we made with the clinical team were appropriate
iv) The meeting was very upsetting
v) The information provided was sufficient

Doctors completed a questionnaire after discussing patient diagnosis, likely prognosis and specific treatments with the patient's family member(s). Statements in this questionnaire were:

i) They understood the explanation of stroke I gave
ii) They understood the information on prognosis I gave
iii) They understood the choices we have about treatment
iv) We agreed on the most appropriate care plan
v) The meeting went as well as could be expected

I then compared the answers provided by family members and doctors.

Based on the small number of questionnaires, I present my findings descriptively and in tables and figures.

To assess if there was a link between answers provided by family member(s) on these questionnaires and their position on the treatment decision spectrum (Explored with qualitative interviews in Chapter 4), I reviewed the responses of individual family members to the questionnaires in the context of treatment decisions that were made.

5.5 Results

Questions relevant to this evaluation were well completed. All 24 family members returned the questionnaire. Out of a total possible of 120 responses (based on 5 questions, each with 5 possible responses), 114 responses were received. All nine doctors returned the questionnaires they completed; i.e. two questionnaires for each meeting based on a total of 24 meetings. All 48 questionnaires were fully completed.

Out of the 24 meetings between nine different doctors and 24 different family members, 13 were conducted by consultants (A to F) and the other 11 (G to I) by registrars. As shown, there was a range of number of meetings conducted by each doctor (1 to 5 meetings each with the family member of 24 different patients). (Table 5.1)

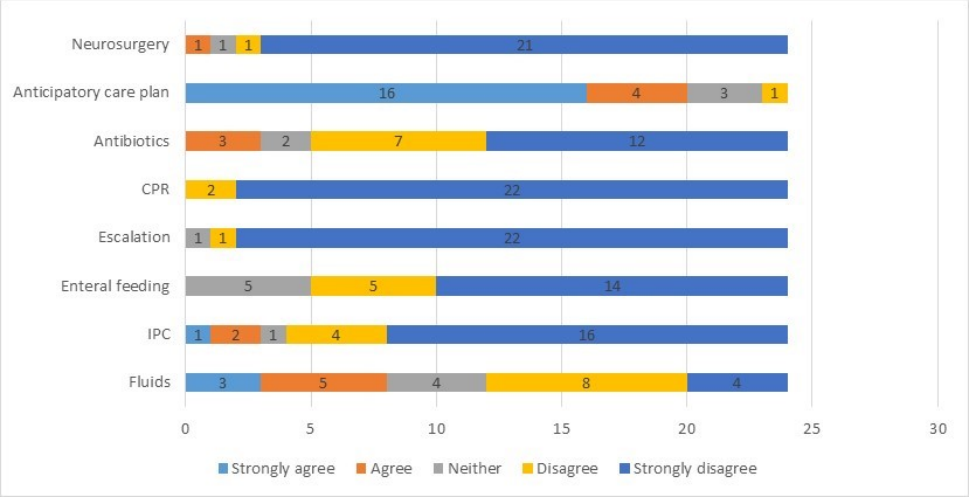
Table 5.1 Number of family meetings conducted by each doctor, and their grades

Doctor	Grade	Number of family meetings
A	Consultant	3
B	Consultant	5
C	Consultant	2
D	Consultant	1
E	Consultant	1
F	Consultant	1
G	Registrar	4
H	Registrar	4

I	Registrar	3

a) To ascertain the doctor's views regarding the appropriateness of specific treatment(s) for the patient
(Prior to meeting with the patient's family member(s))

Figure 5.2 Doctor's view on appropriateness of specific treatments for the patient prior to meeting with the patient's family member(s).



As shown in Figure 5.2, all doctors had strong views on the inappropriateness of treatments such as neurosurgery, resuscitation (CPR), escalation and intermittent pneumatic compression (IPC) for the patient admitted with major stroke who lacked capacity. However, for treatments such as enteral tube feeding, fluids and antibiotics, doctors' views were less strong.

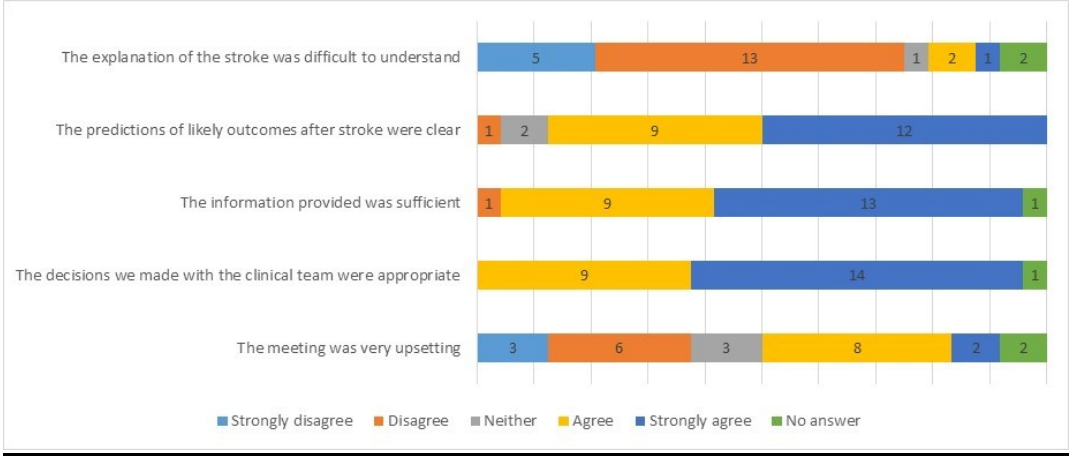
b) To ascertain if doctor's views of the appropriateness of specific treatment(s) for the patient influenced the treatment(s) agreed (in)appropriate for the patient

On review of the patient's medical notes immediately after the meeting, I found that there was only one difference in opinion regarding appropriateness of treatment for the patient between a family member and doctor. In this instance, the doctor (C) had indicated that fluids were

inappropriate for the patient, but the family member had expressed that the patient would have wished for fluids to be given. In 12 and 17 meetings respectively, IPC and neurosurgery were not discussed in this meeting.

c) To elicit the family member's perception of communication that had taken place between the doctor and them

Figure 5.3 Family members' perception of communication between the doctor and themselves in the context of major stroke



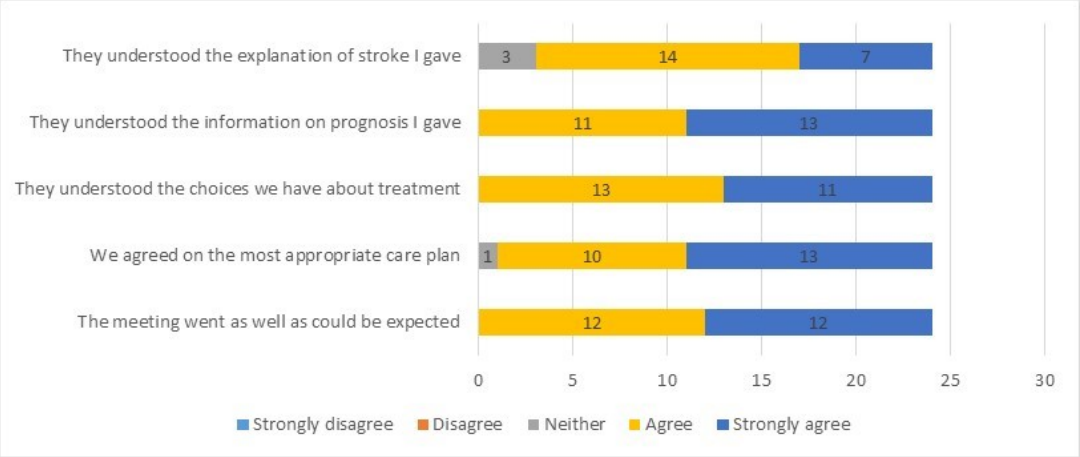
As shown in Figure 5.3, a few family members (n=3) found the explanation of stroke diagnosis difficult to understand. One family member did not think that the communication of prediction of likely outcomes after stroke was clear. However, nearly all (n=22) thought that information provided was sufficient and 23 out of 24 felt that appropriate decisions had been made for the patient.

Ten family members indicated that they found the meeting very upsetting. (On the questionnaire, eight agreed and two strongly agreed with this statement)

d) To elicit the doctor's perception of their communication with family member(s)

Figure 5.4 shows the doctors' perception of their communication with family member(s) based on the questionnaire they completed.

Figure 5.4 Doctors' perception of their communication with family member(s)



Except in three instances, doctors indicated that they thought that family members understood the explanation of diagnosis they had given. Doctors also indicated that they thought all family members understood the information regarding prognosis and treatment choices that they had given and that appropriate treatment decisions had been made at the meeting. Overall, doctors indicated that communication between them and the family member(s) of the patient admitted with a major stroke had gone as well as they felt could be expected.

e) To compare family member's and doctor's perception of communication between them

In most instances, doctors and family members seemed to agree that communication between them had gone well. Since doctors and family members did not complete the same questionnaire, I was not able to make a direct comparison between the two.

Here I have highlighted the few instances where there appeared to be a disagreement in perceptions. In brackets, I have indicated which doctor was involved in these discussions since there was a possibility that, due to

individual doctors' communication styles, disagreement may have occurred with one or two specific doctors.

There were three instances where family members indicated that they found the explanation of stroke diagnosis difficult to understand, (meetings conducted by doctors D, G and H) but doctors involved in these discussions had thought that the family members had understood their explanation of stroke diagnosis. There was one instance where the family member indicated that the information about predictions was not clear (meeting conducted by doctor A). However, in all instances, doctors had thought that the family members had understood the information they had given on predictions of outcomes after stroke. One family member did not indicate a response on the questionnaire for the statement on appropriate treatment decisions having been made. Correspondingly, the doctor (G) conducting this meeting indicated a response of 'neither' on his/her questionnaire.

Ten family members had indicated that the meeting was very upsetting for them; these meetings were conducted by various doctors; two by doctor A, two by doctor G and one each by doctors C, D, E, F, H and I.

Reviewing responses in the context of family members' position on the treatment decision spectrum (Chapter 4)

The few (n=3) who indicated that the explanation of stroke diagnosis was difficult for them to understand, the one who did not find the communication of prediction of outcomes to be clear and those (n=10) who found the meeting to be very upsetting were generally family members where a decision had been made to withdraw treatments over time or where all treatments had been continued. This is not surprising given how these family members had described their shock and distress in the early period after the patient's hospital admission with major stroke. In the one instance where there was difference in opinion between the doctor and family member about fluids for the patient, this was a family member who had expressed that the

patient may wish for all treatments to continue and was holding onto all hope for patient survival.

5.6 Discussion

5.6.1 Summary of results

In these 24 patients who did not have mental capacity after major stroke, doctors did not think that treatments such as neurosurgery, escalation, IPC or CPR were appropriate for the patient. However, doctors did not have such strong views about treatments such as fluids, feeding or antibiotics for these patients. Doctors and family members mostly agreed on the (in) appropriateness of specific treatments for the patient.

Based on a single meeting between doctors and family members, responses on questionnaires indicated that communication between them was largely satisfactory. In the few instances where there was a difference in perception or difference in opinion related to treatment, this was more likely associated with family members where treatments were withdrawn over time or where all treatments had been continued (Reported in Chapter 4). These family members were also more likely to indicate the meeting between them and the doctor to be very upsetting. There were no discernible differences between meetings conducted by different individual doctors with respect to these findings.

5.6.1.1 Doctor's views on appropriateness of specific treatment(s) for the patient with a major stroke

In most instances, there was agreement between the doctor's views on appropriateness of treatments for the patient and that which was agreed with the patient's family member at the meeting. This could be due to:

a) For this group of patients, doctors and family members had similar views on (in) appropriateness of life extending treatments. As I reported in Chapter 4, most family members had, from the outset, already accepted the patient's poor prognosis based on the patient's state of health and stated preferences

pre-stroke. Independently, doctors may have also judged these patients to have poor prognosis (either with regards to survivability, quality of life, or both)

b) Doctor's own views regarding preferences of treatment for the patient may have affected the way in which they communicated with family members and therefore influenced the treatment decisions that were made.

From my results, it is difficult to speculate which of the above (a) or (b) was more likely, if my results are likely to be a combination of both possibilities, or due to other possibilities which have not been recognised.

The ethics of feeding and hydration is complex. (274) Family members have previously reported seeing nutrition and hydration as a basic form of nurturing for their dying relative (44) and have narrated distressing experiences of withdrawal of enteral nutrition and hydration.(275) This appears to be reflected in the range of views indicated by different doctors on the appropriateness of fluids and feeding for different patients with major stroke.

Despite national guidelines recommending a shared decision-making approach when considering the use of IPC post stroke, (47,48) in many instances, this was not discussed with family members. This could be related to either one or a combination of three possibilities: a) a conscious decision by the doctor not to discuss a treatment that they felt to be inappropriate for the patient b) not being aware of the guideline; and/or c) a limitation of using a questionnaire based on a single meeting.(i.e. it is possible that the treatment was discussed at another meeting between the doctor and family member).

5.6.1.2 Communication between doctors and family members in the context of major stroke

Professional bodies such as the General Medical Council (GMC) emphasise the importance of communication between doctors and patients/ families to

arrive at appropriate treatment decisions. While I found that communication was largely satisfactory between doctors and family members, I also found some instances where communication of stroke diagnosis and of predictions may be improved. Existing recommendations from the GMC (44) and evidence from many other medical and surgical specialties (276–286) including stroke (103), indicate that doctors should consider, where appropriate, using tools to enhance communication between them and patients/families. This includes using visual aids, offering audio recordings and written information to those who may find this helpful to their understanding of diagnosis, prognosis and treatment options. I will report the views of family members regarding these communication aids in my next chapter (Chapter 6). I will also report their views with respect to prognostic information in Chapter 6.

Communicating realistic information with empathy may be helpful to family members who found the meeting between them and the doctor to be upsetting. (287) I discussed multiple communication strategies which could be considered by doctors in Chapter 4 e.g. 'Hope for the best and prepare for the worst' (255) and 'I wish' statements (e.g. I wish things were different). (255,256) The use of a 'warning shot' by doctors (247) may also help family members prepare for news that they may not have been expecting. The communication of uncertainty of stroke prognosis is also important. I will discuss this further in Chapter 9.

5.6.1.3 The use of questionnaires to seek opinions of doctors and family members in the context of major stroke

Strengths

I decided to use questionnaires in this setting based on literature where questionnaires have been used to elicit people's preferences for treatment (116,268,269). Likert type questionnaires have also been useful in reporting self-reported outcomes such as quality of life (272), mood and fatigue (273) in several neurological conditions including stroke. I also anticipated that

questionnaires would be easy and quick to apply and results would be easy to present. Questionnaires also asked the same questions from all participants.

Our questionnaires had a good response rate, indicating that family members and doctors found this as an acceptable method of providing their opinions and also, the areas explored were of potential importance to them.

Limitations

A small number of questionnaires were completed by doctors (n=9) and family members (n=24) from one hospital. The doctors were colleagues who worked in a single stroke service. Therefore, my results would not be generalizable to other settings.

The questionnaires were completed based on one meeting between the doctor and family member(s). In reality, the patients' medical condition may change over time and therefore, several discussions of prognosis and treatment options usually happen. Therefore, a questionnaire at one time point does not fully capture the situation.

While it appeared that the position family members were on the treatment decision spectrum (Chapter 4) had a bearing on their answers in questionnaires, questionnaires constrain responses, do not allow clarification of responses and therefore, do not capture the reasons behind why certain responses were provided.

In order to elicit useful responses from both family members and doctors, the design of the questionnaires were slightly different. This meant that I was not able to make any direct comparisons.

As I described in the beginning of this chapter, I was not able to involve patients in this part of my study. Therefore, these results are not transferable to patients who have capacity after major stroke.

5.7 Future considerations

Questionnaires may be applied to a larger number of participants in different settings. Repeat questionnaires could be considered at different points during the patient's hospital admission to capture changes in responses and treatment decisions.

We may have gained more insight by observing (and recording) the meeting between doctors and family members and interviewing both parties while appreciating that different individuals may have different views and recollections of what was discussed at the meeting. By audio or video recording the meeting, I would be able to revisit the consultation to understand what was discussed at the meeting and how decisions were made. (288,289) Subsequently, qualitative interviews with doctors would allow a better understanding of why they expressed certain views on treatments, why they may not have discussed certain treatments and if, and how they felt their views regarding treatments and communication may have influenced treatments that were agreed for the patient. Qualitative interviews with family members, exploring communication between doctors and themselves would have given us context to which responses were provided in the questionnaires.

Future studies should also endeavour to involve patients who have capacity after major stroke by using effective communication tools and strategies. I will discuss this in Chapter 9.

The evaluation of shared decision-making using validated tools e.g. CollaboRATE should also be considered. (290,291)

5.8 Summary

Although communication between doctors and family members in this small group of participants seemed largely satisfactory, there were certain areas (particularly with the communication of diagnosis and predictions of outcomes) where communication may be improved. Doctors and family members seemed to mostly agree on treatment decisions for the patient with

major stroke. While questionnaires had several strengths in this setting, their results are not generalizable based on their limitations.

5.9 Next steps

In my next chapter, I will report the opinions of family members on how communication may be improved between the doctor and themselves. I will focus on seeking their feedback on several aspects relating to communication of prognostic information and also on the use of communication aids to enhance communication between the doctor and themselves.

Chapter 6 Presentation of information to family members in the early period after major stroke

6.1 Acknowledgement of my contribution

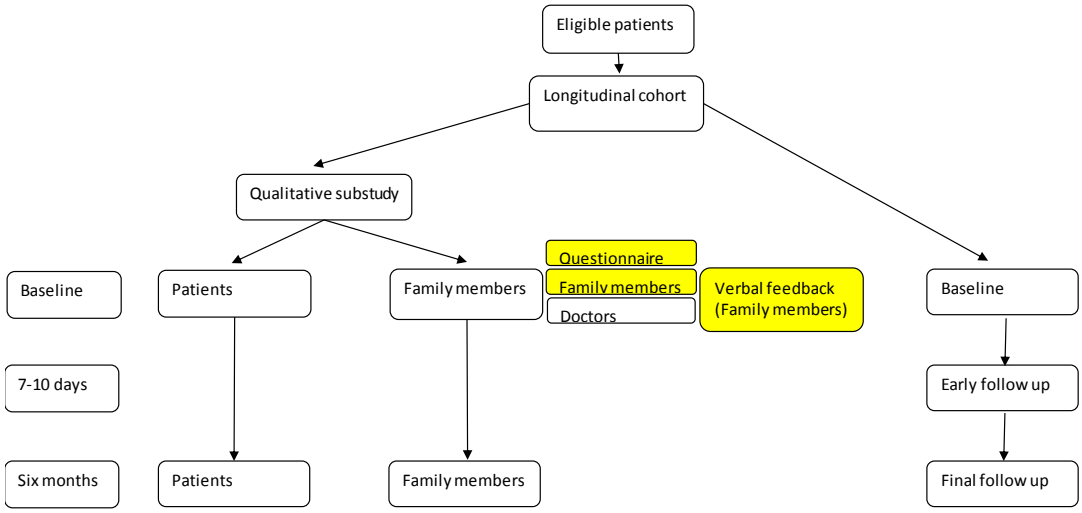
I analysed the relevant questions in the questionnaires I described in Chapter 5. I performed the feedback exercise reported in this chapter. I wrote this chapter and made changes following comments from my supervisors.

6.2 Introduction

My findings in Chapter 5 indicate that, in the context of major stroke, certain aspects of communication between doctors and family members may be improved. In this chapter, I report the opinions of family members of patients admitted with major stroke (and who lacked capacity) on how they feel communication between the doctor and them may be improved. I obtain their opinions on four areas (related to various aspects of being provided with prognostic information and on the use of communication aids) using two methods: a) A questionnaire (Described in Chapter 5) completed after family member initial qualitative interviews. b) A verbal feedback exercise after their initial qualitative interviews.

The flow diagram below (boxes coloured in yellow) indicates the part of my study this chapter relates to.

Figure 6.1 Study Schematic: Chapter 6



I summarise relevant literature below:

a) Format of presentation of prognostic information

In Chapter 1, I noted how prognostic information presented in different formats may be useful to facilitate shared decision-making by patients and their families. (103–108) However, much of this evidence is reported based on patients in the outpatient setting who are less medically unwell when compared to major stroke inpatients. In Chapter 4, I reported how family members found information regarding the patient's prognosis from doctors useful. Some had also said they wished they had been given information to better prepare for the possibility of the patient dying after major stroke. Knowledge of the best format in which information may be presented to family members could help doctors tailor their communication of information.

b) 'Accuracy' or 'correctness' of prognostic information

I define prognostic 'accuracy' as the probability that, when a statistical model is used to make predictions of an outcome, patients predicted to have the outcome will truly have that outcome, i.e. the positive predictive value (PPV) of a statistical model. In Chapter 1, I described how doctors strive for excellent prognostic accuracy to facilitate shared decision-making. (102)

However, achieving this may not be possible, and an alternative may be to communicate prognosis at the 'accuracy' or 'correctness' patients and families wished for.

c) Information on specific abilities after major stroke

In Chapter 1, I described how, in clinical trials, global scales of physical disability such as the mRs are used to report patient outcome after stroke. This does not take quality of life components into account. (292) In Chapter 2, I showed how patients varied with respect to their specific abilities and HRQoL within the same mRs level. (i.e. two patients with the same mRs may differ with respect to their abilities to walk, talk and also rated their quality of life differently). Communication of prognosis by specific abilities may be more helpful to patients and family members for their understanding and/or to facilitate shared decision-making.

d) Tools to enhance communication between doctors and family members

As reported in Chapters 1 and 5, the GMC encourages doctors to support discussions between them and patients or families by using written materials, visual aids and providing a written or audio record of the discussion and any decisions that were made. (44) This may be useful in the context of major stroke where many patients and families report feeling distressed and overwhelmed with the situation. (Chapters 3 and 4) Therefore, it is possible that they may not absorb much of the verbal information that is provided to them. (Chapters 3 and 4)

Similar to Chapter 5, this chapter is based on opinions from family members only. This is because patients were overwhelmed and distressed having received a diagnosis of major stroke. (Chapter 3) Hence, I was unable to engage them in feedback exercises.

6.3 Aims

To obtain the opinions of family members of patients admitted with major stroke (and who lacked capacity) on:

a) The format in which prognostic information should be presented to them
b) How accurate prognostic information should be
c) Whether information regarding specific abilities after stroke (as described in Chapter 2) [e.g. to be independent, to walk, to be continent, to live without major anxiety or depression, to live at home] would be helpful to them
d) If additional tools such as visual aids, audio recordings and written information may be useful to enhance communication between them and the doctor.

6.4 Methods

Family members (n=24) who took part in qualitative interviews (Chapter 4) and completed a brief questionnaire (Chapter 5) were invited to provide verbal feedback on (a) to (d) above. As I described in Chapter 5, I split the analysis of this questionnaire between two chapters.

6.4.1 Questionnaire

I described the questionnaire completed by family members in Chapter 5. The relevant questions/ statements to this chapter are:

a) Easiest format of presentation of prognostic information to understand
b) Hardest format of presentation of prognostic information to understand
c) Predictions are unhelpful in making decisions about treatments
d) I will be pleased to have an audio recording of the meeting
e) Written information will be helpful

Questions relating to the format of presentation of prognostic information (a and b) were ‘best of three’, where family members chose one answer from three options (graphs, pictures, ratios/words). We chose these formats based

on existing literature (Described in my discussion below) and expert opinion of stroke doctors in the hospital where recruitment took place. Questions c to e were Likert-type questions and participants indicated their response from a range of ‘strongly disagree’ to ‘strongly agree’. Since each question addressed different domains, a composite score was not calculated. All statements except (c) were hypothetical.

Due to the small number of questionnaires, I report my results descriptively and by using tables and figures.

6.4.2 Verbal feedback

I asked family members who took part in qualitative interviews and completed a questionnaire a series of more structured questions at the end of their initial interviews. All questions were hypothetical.

I detail these questions below:

a) Format in which prognostic information should be presented

I showed family members an example of the different formats in which prognostic information may be presented (words, pictures and bar chart) and asked them which was easiest for them to understand. I pre-warned them that some of these formats may be distressing to them and that they could refuse to view this information or provide their opinions. I specifically iterated that the information presented was not intended to be relevant to their situation. (Figure 6.2)

Figure 6.2 Example of formats in which prognostic information may be presented for 'able to walk at 6 months'

b) How accurate prognostic information should be

I asked how correct or accurate (probability that individuals predicted to have an outcome will truly end up with that outcome) they thought prognostic information should be to inform their understanding and/or facilitate decision-making. I asked them to offer their answers in percentages. I interpreted their answer as the PPV of a statistical model.

c) Their thoughts on information regarding specific abilities after major stroke

I asked family members what they thought about being given predictions of specific abilities (e.g. to walk, to talk, to eat) after a major stroke and if this may be helpful to their understanding and/or to facilitate decision-making.

d) Their views on additional tools to enhance communication such as visual aids, audio recordings and written information

I explained that the tools I was seeking their opinions about were intended to enhance verbal communication between doctors and themselves, rather than being used as a substitute.

I asked family members their opinions about doctors showing them a picture of the patient's brain scan to explain the extent of damage. I also asked their

opinions on pictures detailing how the stroke could have resulted in specific impairments or pictures showing specific abilities (e.g. being able to walk, or living at home). I also asked them for their opinion on being provided with an audio recording of the communication (of patient diagnosis, prognosis and treatment options) between the doctor and themselves. I asked if they would listen to this audio recording again, or share it with other people (family members or friends). I also asked if providing them with a written record of information (e.g. leaflet or printed copy of relevant diagnosis, prognosis and treatment options) would be useful to them.

I present their opinions using relevant quotes. Where possible, I have listed the number of family members providing their opinions in each of the categories within brackets.

I also reviewed the responses of individual family members in the questionnaires and verbal feedback exercise in the context of their position on the treatment decision spectrum (reported in Chapter 4).

6.5 Results

6.5.1 Analysis of questionnaires

As I reported in Chapter 5, all questionnaires (n=24) were returned. For the statements relevant to this chapter, 29 responses (out of a total possible of 120) were obtained. (Table 6.1)

Table 6.1 Relevant statements and results from questionnaire on information presentation

Statement on questionnaire	Total possible responses	Number of responses received	Detail
Easiest format of presentation of prognostic information to understand	24	2	One graphs, one picture

Hardest format of presentation of prognostic information to understand	24	2	One graphs, one picture
Predictions are unhelpful in making decisions about treatments	24	20	10 strongly disagreed 7 disagreed 2 agreed 1 strongly agreed
I will be pleased to have an audio-recording of the meeting	24	2	1 agreed 1 disagreed
Written information will be helpful	24	3	2 agreed 1 strongly agreed

6.5.2 Verbal feedback

a) The format in which prognostic information should be presented

I found that different family members expressed their preference for prognostic information to be presented in different formats. About a third (n=7) said that they wished this information presented to them in ratios or percentages, a further third (n=8) preferred pictorial representation, very few liked a bar chart (n=2) and the rest (n= 7) wished prognostic information to be communicated to them in ratios or percentages in words, without any visual representations.

i) Wish for information to be presented in different formats

'I think you have to make sure that materials are there for people…don't want to be bombarded with too many facts and figures but maybe want to have something to look at and like a graph or something like that [pointing to a picture], that represents it in a fairly simple way because you maybe got enough things going on in your mind.'

ii) A pictorial representation

'Yeah. It's really good. I think it was a bit of a shock, as well, though.. kind of, hit quite hard, but that hit home.'

. 'I think if I'd shown pictures with little diagrams on it like that I think I'd would be treated like an idiot. Just speak to me, you know.'

iii) Information in ratios

'I think ratios, you know, one in five, one in ten. Well, I would understand it better than looking at the pictures.'

b) How 'correct' prognostic information should be

More than half of the family members (n=13) reported that they did not think prognostic information could be 100% correct. When I asked these family members to offer a percentage level of prognostic accuracy, around half of them (n=6) reported that predictions that were around 50% correct would be sufficient to their understanding of the situation or to facilitate decision-making:

'I think fifty per cent would be fine. I mean, you can't say with 100 per cent certainty what's going to happen, so there's no point in expecting it'.

'I would think I would like it to be, like, 50 per cent accurate, at least, you know, before we can make decisions based on that'.

Another third of family members (n=8) described wishing for predictions that were 80% correct and above:

'I think 80 per cent is a good percentage or upwards. Anything less is basically giving you false hope. But 80 per cent is… it's more than half, so you know that it's not going to be totally like that, but you know there's going to be certain aspects that it will be like that, you know. Then you can make decisions.'

In contrast, a quarter of family members (n=6) described their wish for very 'correct' predictions (above 90%) to help their understanding of the situation:

'Ninety or a hundred per cent; so we need to be quite certain about what's going to happen in the future. Yeah, because it's people's lives you're talking about'.

c) Information regarding specific abilities after stroke

Some family members (n=7) reported that the prediction of specific abilities would be useful to their understanding of the situation, and might even guide decision-making.

'*Well, I think there are one or two things that are really most prominent in the decisions for me; incontinent and can't swallow, those are the two main things. I think she (referring to her mother) could put up with being immobile and maybe needing help with that but not even being able to enjoy food or…you know, that would be no use at all; it's not a quality of life, I wouldn't have thought, that she would want to endure'.*

d) If additional tools such as visual aids, audio recordings and written information may be useful to enhance communication between them and the doctor.

i) Visual aids

Many (n=19) family members reported that the doctor had shown them the brain scan of their family member (the patient) who was admitted with major stroke. Of these family members, over 80% of families (n=17) found viewing brain scans of the patient useful to understand the diagnosis and likely prognosis and reported that this assisted them in decision-making regarding treatments. Another five (who were not shown the brain scan of the patient) said that they would find viewing the brain scan useful to their understanding of the situation of likely poor prognosis.

'At first I felt as though …I wasn't pressing hard enough for treatment. But in actual fact when the young man showed me the scan and spoke about the likelihood of anything, it was clear there was really nothing more to be done. So I did feel as though I got a proper understanding of the prognosis.'

' Looking at the scan on the computer. That was dead helpful. It let me understand where the massive bleed has happened. Let me understand now why the neurosurgeons can't go in because of where it actually is and how

deep it is. …you know, when they're saying 'massive bleed', you don't know where. But seeing it actually on the computer like that, it did help me…'

Nearly two thirds of family members (n=15) described that they would find the use of pictures to explain how the stroke had resulted in specific impairments (e.g. inability to walk) helpful to understand the situation.

'The thing is, as well, none of our family have ever had a stroke. My mother's the first that's had a stroke. So we've got no idea about strokes at all. Rather than trying to explain something. You show them a picture, it's easier for you to……look at a picture and say, well, I can see that. Because where you are just now, you're not in a nice place. So your mind's not working right. But if somebody was showing you a picture, you would be able to easier relate…'

In contrast, few (n=2) family members suggested that viewing pictures might be too upsetting for them, especially at a time when they may be feeling overwhelmed with the situation.

'No; I think that would be quite frightening; wouldn't need to see that. … couldn't be bothered to look at that.'

ii) Audio recording

Roughly two thirds (n=14) of family members reported that they might find an audio recording of the consultation between the doctor and them useful. Most of these family members (n=12) said that they would listen to this again; mainly to clarify and ponder the information but also to consider questions they may not have raised at the time when they may have been feeling upset and overwhelmed:

'I think that would be an excellent idea because I was probably overly anxious about what had happened and how much I absorbed... I can't fully remember everything said. I had far too much else running through my mind. it would be good to go back over something. And also, my sister, we share the care of my mum, but she lives in [place deleted], so, you know, for me to try and repeat everything that Dr [name deleted] had said would be impossible'.

However, around a third of family members (n=8) felt that an audio recording would be unnecessary. These family members reported that they would

rather speak to the doctor if they wished for clarifications:

'*No, I wouldn't listen back to it. I think once I'd heard what I'd heard and ask what I'd wanted to ask; just an understanding, kindly face at a time when you're just looking at somebody in a bed who is going to die is probably much better than anything external, like audio'.*

iii) Written information

Around a third (n=7) reported they might find written information useful, as it would be a record of what was said at the consultation with the doctor at a time when they may not have fully considered all of the information as they were in shock from having received the diagnosis:

'It's extremely useful because it's enough of a shock to find that someone's had a stroke to then remember everything that the doctor has been saying to you. So to have written information with diagram of things like the brain and where the stroke has been and what parts of the brain affect which bits of the body I think is very useful.'

In contrast, around a half of family members (n=13) said they did not think written information would be of any help to them.

'I'm not in a state, I'm actually too tired to think straight, I think that reading stuff – won't take it in. Sitting down and reading something I would find quite daunting.'

6.5.2.1 Reviewing feedback provided by family members with respect to treatment decisions made

Family members' responses in the questionnaire and feedback that they provided seemed to be related to their position on the treatment decision spectrum (Chapter 4)

Responses in questionnaire

Those who strongly disagreed or disagreed with the statement on predictions being unhelpful were mostly family members who had felt that the patient would have chosen not to initiate life-extending treatments from the outset.

Verbal feedback

Many family members, who had felt that the patient would have chosen not to initiate life-extending treatments from the outset reported that predictions that were around 50% correct would be sufficient and they did not seem to have strong views on receiving information on specific abilities or using tools to enhance communication.

The family members who were in the middle of the treatment decision spectrum (i.e. who felt that the patient would have chosen to withdraw treatments over time), asked for predictions which were at least 80% correct to guide their understanding and/or facilitate decision-making. They reported that prediction of specific abilities would be helpful to their understanding of prognosis and/or to guide decision-making, and that tools such as audio recordings and written information would be useful to their understanding of diagnosis and prognosis.

Those family members at the other end of the treatment decision spectrum (i.e. who felt that the patient would have wished for all treatments to continue) did not express strong views on prognostic information or on tools to enhance communication.

Regardless of their position on the treatment decision spectrum, different family members reported preferring prognostic information to be presented in different formats. Viewing brain scans seemed to have a beneficial impact on peoples' understanding and in many cases, this allowed them to come to terms with poor prognosis and acceptance that life-extending treatments may not be appropriate for the patient.

6.6 Discussion

My results indicate that information would need to be tailored to suit different individuals. Below, I report literature relevant to my results.

Format of presenting prognostic information

In-keeping with existing literature which I described in Chapter 1, (109,110,112,114) I also found that different formats of presenting prognostic information may be appealing to different individuals. For instance, graphs and pictures, including bar charts, icon arrays and using people images, may be helpful to the understanding of some individuals. (110,293–295)However, others may find this distressing. Therefore, my results further support guidelines recommending information to be personalised depending on individual preferences. (29)

Information on specific abilities after major stroke given at different accuracies

Prediction of specific abilities after major stroke may be useful to some family members (specifically those in the middle of the treatment decision spectrum). . Predictions that are at least 80% accurate has been suggested by these family members to be useful to them to guide their understanding, and/or to facilitate decision-making.

However, the majority of family members who felt that the patient would have chosen not to initiate treatments from the outset (Chapter 4) reported that predictions which were 50% accurate may be enough for them to confirm their understanding of poor prognosis and support a treatment preference that had previously been expressed by the patient. Others wished for higher predictive accuracies to facilitate decision-making (i.e. 90% and above).

A statistical model which can provide predictions of specific abilities after major stroke at different accuracies may be useful for the communication of prognosis. I will describe the development and validation of new statistical models predicting various specific abilities after major stroke at PPVs chosen by family members (of 50%, 80% and 90%) in my next chapter. (Chapter 7)

Tools to enhance communication

In stroke, several visual aids (computerised and written) have been developed. (190) However, many of these have been tested in the outpatient setting, rather than in the early period after a major stroke.(294,296,297)

The difficulty of using tools to complement verbal communication in the early period after stroke is that decision-making is challenged by time limitations. The need to engage patients (if appropriate) and families and convey knowledge in the context of the shock and effects of stroke is challenging. (293) One tool that has been successfully used in the acute stroke setting is a computerised decision aid for stroke thrombolysis (COMPASS) tool. This contains visual representations of information and has been shown to improve the understanding of families and patients of the risks and benefits of thrombolysis. (293) My findings also indicate that visual representations of information (especially viewing brain scans) may be appealing to many family members. Therefore, a communication tool incorporating pictorial representations of information could be useful to some. I will describe this further in Chapter 9.

There is also a wide range of evidence supporting the use of other tools to enhance doctor-patient communication. As I reported in Chapters 1 and 5, the GMC encourages health professionals to support discussions between them and patients or families by using written materials, visual aids and also giving a written or audio record of the discussion and any decisions that were made. (44) There is a wide range of published literature in intensive care (276), paediatrics (277) and stroke (103) on the benefits of providing written information to people. The use of audio recordings to aid understanding and information recall has also been reported in many medical specialties including oncology, (279,280) paediatrics (281–283), cardiac surgery,(284,285) orthopaedic surgery (286) and primary care.(278) My findings indicate that some family members may find these tools useful.

The use of Likert type questionnaires

I found that statements relating to prognosis and communication aids were poorly completed in our questionnaire. This is in contrast to statements relevant to communication which were well completed (Chapter 5). This poor response rate could be due to a variety of reasons:

i) Since most family members had already accepted the likely poor prognosis of the patient (Chapter 4), the most plausible explanation would be that the questions were not seen as relevant by family members.
ii) Forcing an answer for statements that were either irrelevant, or required some thought, may have been unacceptable to family members
iii) Most statements were hypothetical; therefore, family members may have found it more difficult to provide answers to statements that had not been provided to them in 'real time' by the doctor

6.6.1 Limitations

The questionnaire and verbal feedback exercise did not capture the context in which the opinions were provided. No concrete conclusions can be drawn from the evaluation of (the very few) responses provided on the relevant statements in the questionnaire.

Most opinions (excluding viewing brain scans) were based on hypothetical scenarios. I may have obtained more considered and thoughtful responses if doctors had presented 'real time' information using visual aids, had used different formats of prognostic information to communicate prognosis, offered audio recordings or given written information to family members.

I had not anticipated that there may be a link between the position of family members on the treatment decision spectrum and the opinions on information presentation that they provided. In hindsight, qualitative interviews with family members would have been more appropriate.

We did not use a validated measure of evaluating shared decision-making between family members and doctors e.g. using CollaboRATE. (290)

As I described in Chapter 5, patients were not involved in this part of my study and therefore, my results are not transferable to patients who had capacity after major stroke.

6.7 Summary

Information would need to be tailored to each individual's preferences. The communication of specific abilities after major stroke may be useful to some family members to understand the consequences of major stroke and/or to facilitate shared decision-making. Tools to enhance communication (e.g. visual aids, audio recordings and written information) may be useful to some.

6.8 Next steps

In Chapter 2, I showed that patients admitted with major stroke varied with respect to their specific abilities. In this chapter, I reported that some family members found communication of specific abilities helpful to their understanding and/or to facilitate decision-making. I also reported that different individuals wished for prognostic information at different accuracies (which we defined as PPVs). Based on my findings, in my next chapter, I will describe the development and validation of new statistical models to predict some specific abilities after major stroke at PPVs chosen by family members.

Chapter 7 Predicting specific abilities after major stroke: development and validation of prognostic models

7.1 Publication status

I wrote this chapter following comments from my supervisors. I edited the chapter (in length and layout) to submit for publication. A paper from this chapter is under consideration with 'The International Journal of Stroke.'

7.2 Acknowledgement of my contribution

I developed the concept of model development and validation with my supervisors. We then involved our statistician to help develop statistical models to predict several specific abilities after major stroke.

I was involved in looking at trial datasets, deciding which datasets were appropriate for development of the models, then reviewing potential predictor variables and outcomes of interest, in deciding how and why to select patients from the trials to be included in our development cohort, in discussions on how predictor variables could be standardised when defined differently in different trials, in discussions on which predictor variables should be included in our models, and why and how models may be improved.

I then externally validated the developed models in our cohort of patients with major stroke (Described in chapter 2).

7.3 Introduction

In Chapter 2, I found that patients with major stroke varied with respect to their specific abilities. Therefore, I reported that describing prognosis by specific abilities may be appropriate. Qualitative interviews (Chapter 4) suggested that communication of prognosis was important to family members and in some cases, to facilitate shared decision-making. In Chapter 6, I reported that some family members would find information on specific abilities (e.g. to eat normally, to walk) after major stroke at varying PPVs

(50%, 80% and 90%) helpful. Based on these findings, in this chapter, I describe the development and validation of new models predicting some specific abilities after major stroke. I report the performance of the models at PPVs (50%, 80% and 90%) chosen by family members (Chapter 6).

We chose to develop and validate prognostic models for the following six specific abilities at six months after major stroke: i.e. to a) be independent, b) walk, c) talk without major problems, d) eat normally e) live without major anxiety or depression and f) live at home. We were not able to develop models to predict three other abilities we judged to be of importance to patients and family members (to be continent, to live without major cognitive problems and to live without severe pain) (Chapter 2). This was because the former two outcomes were not available in the development datasets we used. Due to time constraints, we were unable to develop and validate a model to predict the latter (to live without severe pain).

We chose to predict abilities rather than disabilities based on my findings (Chapter 3) which indicated that majority of patients looked for hope and positive information from doctors after major stroke. (119)

I reported in chapter 2 that different measures could be used to report the same specific ability (e.g. smRsq, BI and EQ5D to report ‘to walk’). However, in our development dataset (which I will describe below), the choice of using different measures was not available and therefore, we were restricted to the measures we had available to us. We dichotomised outcomes based on opinion of stroke professionals in the hospital where recruitment of our longitudinal cohort (chapter 2) took place. To agree a standardised approach towards defining specific abilities, we would ideally have conducted an online survey of health professionals. However, due to time constraints, this was not possible.

7.4 Methods

7.4.1 Model development

7.4.1.1 Description of the development dataset

We built a development dataset comprising selected patients who had participated in large randomised controlled trials (FOOD 1, 2 and 3, CLOTS 1, 2 and 3 and IST3) coordinated from our department in Edinburgh. (34,36,298)

We chose these trials because, between them, we knew they had baseline variables which are likely to be of predictive value (described below) and had the outcome variables of the specific abilities we were interested in predicting. The population, which were trial-based cohorts, had data collected prospectively, and therefore, of high quality. Furthermore, we had easy access to this data which was stored on the University of Edinburgh servers.

FOOD (Feed Or Ordinary Diet) was a multicentre international randomised trial evaluating feeding policies in patients admitted to hospital with a recent stroke. (36) A total of 5033 patients were enrolled in the three trials which evaluated different feeding policies between November 1996 and July 2003. While FOOD 1 recruited patients who could swallow, FOOD 2 and 3 recruited dysphagic patients within 7 days and 30 days after hospital admission respectively. Patients could be recruited into more than one FOOD trial.

CLOTS (Clots in Legs Or sTockings after Stroke) tested external compression devices (e.g. graduated compression stockings and intermittent pneumatic compression) for prevention of deep venous thrombosis in acute stroke patients. (34) A total of 8228 patients were recruited into three trials examining the effect of different compression devices versus standard care between March 2001 and September 2012. All eligible patients were immobile and recruited on days 0 to 3 of hospital admission.

IST3 (The third International Stroke Trial) assessed the benefits and harms of intravenous thrombolysis with recombinant tissue plasminogen activator within six hours of acute ischaemic stroke.(298) 3035 patients with ischaemic stroke were randomly allocated within six hours to intravenous alteplase plus standard care or standard care alone. Patients were recruited between May 2000 and July 2011.

The inclusion criteria and outcome measurements from each of these trials are shown in Table 7.1.

Table 7.1 Inclusion criteria and outcome measurements of each trial included in our development dataset

Criteria	FOOD 1 N=4023	FOOD 2 N=859	FOOD 3 N=321	CLOTS 1 N=2518	CLOTS 2 N=3014	CLOTS 3 N=2876	IST3 N=3035
Inclusion	Can swallow First or recurrent stroke (ischaemic or haemorrhagic)	Dysphagic First or recurrent stroke (ischaemic or haemorrhagic)	Dysphagic First or recurrent stroke (ischaemic or haemorrhagic)	Acute stroke Immobile Admitted within 1 week of stroke (ischaemic or haemorrhagic)	Acute stroke Immobile Admitted within 1 week of stroke(ischaemic or haemorrhagic)	Acute stroke Immobile Admitted within 3 days of stroke (ischaemic or haemorrhagic)	Acute ischaemic stroke Time of stroke onset known Treatment could be started within 6h of onset CT//MRI excluded haemorrhage or structural brain lesions
Timing to recruitment from hospital admission	Within 30 days	Within 7 days	Within 30 days	Within 3 days	Within 3 days	Within 3 days	Within 6 hours of stroke onset
Intervention	Normal hospital diet versus normal	Early enteral tube feeding versus avoid enteral tube	Enteral tube feeding via PEG versus NG	Routine care plus thigh length graduated compression	Thigh length stockings versus below knee stockings	Routine care, or routine care plus IPC for 30 days (or until	0.9mg/kg alteplase to max of 90mg versus control

	hospital diet and oral nutritional supplements	feeding for at least 1 week		stockings or routine care with avoidance of GCS		earlier discharge or walking independently)	
Exclusion	Subarachnoid haemorrhage Unlikely to benefit from trial intervention Already enrolled into same FOOD trial Significant swallowing problems	Subarachnoid haemorrhage Unlikely to benefit from trial intervention Already enrolled into same FOOD trial	Subarachnoid haemorrhage Unlikely to benefit from trial intervention Already enrolled into same FOOD trial	Subarachnoid haemorrhage Contraindications to Graduated compression stockings Diabetic and sensory neuropathy Peripheral vascular disease	Subarachnoid haemorrhage Contraindications to Graduated compression stockings Diabetic and sensory neuropathy Peripheral vascular disease	Less than age 16 Subarachnoid haemorrhage Contraindications to IPC Diabetic and sensory neuropathy Peripheral vascular disease	Contraindications to thrombolysis
Outcomes	Survival Oxford Handicap Scale (OHS) Place of residence	Survival OHS Place of residence	Survival OHS Place of residence	DVT/ PE within 30 days Medical complications of intervention At 6 months	DVT/ PE within 30 days Medical complications of intervention At 6 months	DVT/ PE within 30 days Medical complications of intervention At 6 months	OHS at 6 months (alive and independent, OHS 0-2) Within 7 days

	Method of feeding Quality of life (EuroQol) In hospital complications	Method of feeding Quality of life (EuroQol) In hospital complications	Method of feeding Quality of life (EuroQol) In hospital complications	Survival DVT/PE Use of anticoagulants OHS EQ5D-3L	Survival DVT/PE Use of anticoagulants OHS EQ5D-3L	Survival DVT/PE Use of anticoagulants OHS EQ5D-3L	Death Complications related to treatment or stroke
Timing to final outcomes	6 months	6 months	6 months	6 months	6 months	6 months	6 months

All the trials had different permissible timings to recruitment. We excluded predictive variables that were collected after 3 days as the resulting models might not be relevant to our aim of making early predictions when there are opportunities to influence decisions regarding life-extending treatments. (Described in Chapter 1) Therefore, we decided to include patients who were recruited between days 0 and 3 (inclusive) of hospital admission after stroke.

The proportions of patients from each trial (FOOD, CLOTS, IST3) who were recruited within 0-3, 4-7 and > 7 days of admission are shown in Table 7.2. There was a total of 16576 patients recruited into these trials. We included 13117 (79.1%) patients recruited into these trials in our development dataset (i.e. those recruited within days 0-3). Although patients may be recruited to more than one FOOD trial, patients who contributed to more than one FOOD trial were only included once within our development dataset.

Table 7.2 Proportions of patients in each trial based on timing from admission to recruitment

	0-3 Days		**4-7 Days**		**>7 Days**		**Missing**	**Total**
	n	%	n	%	n	%		n
FOOD	1854	36.8	1744	34.7	1434	28.5	1	5033
CLOTS	8228	96.7	275	3.2	5	0.1	1	8508
IST	3035	100.0	0	0.0	0	0.0	0	3035
ALL	13117	79.1	2019	12.2	1439	8.7	2	16576

7.4.1.2 Definition of outcomes

As described in Chapter 1, outcomes to be predicted should be clinically important and collected with good interrater reliability. (299–302) I chose to predict the probability of six specific abilities important for stroke patients, their family members and the providers of their health care: to be independent, to walk, to talk without major problems, to eat normally, to live without major anxiety or depression and to live at home. We had data on four of these specific abilities (to be independent, to walk, to live without major anxiety or depression and to live at home) from all of the trials. For predicting the ability to talk without major problems, data were only available from IST3 and for being able to eat normally, data were available from only

the FOOD trials. Table 7.3 shows the data available for model development for each specific ability.

Table 7.3 Data available, and used for developing models for each specific ability

Specific abilities at six months	Total number (n)	n excluded (Missing values)	n (%)used for model development
To be independent	13117	244	12873 (98.1)
To walk	13117	460	12657 (96.5)
To talk without major problems (IST3 only)	3035	414	2621 (86.4)
To eat normally (FOOD only)	1854	10	1844 (99.5)
To live without major anxiety or depression	13117	485	12632 (96.3)
To live at home	13117	415	12702 (96.8)

Outcomes can be predicted at fixed and clinically relevant points in time. (301) We predicted specific abilities at six months because all the major trials making up our development cohort consistently reported outcomes at six months.

We dichotomised our outcomes at six months based on judgement of stroke professionals in the hospital where recruitment of our validation cohort took place (Chapter 2). As described in Chapter 2, we report ‘good’ and ‘poor’ outcomes as a shorthand.

Table 7.4 shows the measures or scales used to measure specific abilities at six months, and the dichotomies we used. As described above, (and unlike in our longitudinal cohort which I described in Chapter 2, where several measures could have been used to define a specific ability), there was only one scale/measure that was available to us from the development dataset to report each specific ability.

Table 7.4 The measures/ scales used to report specific abilities at six months, and dichotomies used to define 'good' and 'poor' outcomes: development cohort

Specific abilities at 6 months	Measure/ Scale	Good outcome	Poor outcome
To be independent	OHS	0-2	3-6
To walk	EQ5D 3L	No problems Some Problems	Confined to bed Dead
To talk without major problems	Specific question* (IST3 only)	No major problems	Major problems Dead
To eat normally	Specific question* (FOOD only)	Normal	Nose tube Side tube Dead
To live without major anxiety or depression	EQ5D 3L	Not anxious/ depressed Moderately anxious/ depressed	Extremely anxious/ depressed Dead
To live at home	Specific question*	Own home Relatives home	Residential home Care home Hospital Dead

*options given and dichotomised as shown

7.4.1.3 Selection of predictor variables

Predictor variables entered into prognostic models must be easy to collect with good inter-rater reliability. (300–302) The number of variables used must be carefully controlled.(303) For example, too few variables may mean that important predictors are excluded (underfitting), whilst too many variables can result in overfitting (i.e. inclusion of apparently important predictors which are not actually independent predictors; equivalent to a Type 1 error) and paradoxical fitting (where, a variable with a positive association with the outcome is found to have a negative association

in the model e.g. older age might be found to increase the probability of survival whereas in reality, it might decrease it).

The risk of overfitting, underfitting and paradoxical fitting decreases as the Events Per Variable (EPV) increases, especially with EPVs over 10. (302,304–306) The EPV is the ratio of the number of outcome events in the dataset per variable entered. For a dichotomous variable, the EPV is based on the event with the smaller number of outcomes. For example, if we wish to find predictors of 'being independent' using a sample in which there are 60 patients who are independent and 100 who are dependent, we can study no more than 6 (=60/10) predictor variables. However, this rule has been questioned. (307)

There are multiple ways by which variables may be added: (i) A 'forward step-wise' approach (299,308) where the predictor variable that has the strongest (most statistically significant) association with outcome is identified and entered first, with then the variables not included in this one variable model re-analysed and entering the next variable which explains the largest amount of remaining variability. This process continues until none of the variables that have been left out of the model are associated with the outcome at some predefined level of statistical significance (usually probability of less than 0.05). At each step after a new variable has been added to the model, the variables already in the model are re-examined to establish whether they still have a significant association with the outcome (defined by a Wald statistic with a probability of less than 0.1). If the significance of the Wald statistic is greater than or equal to 0.1, then that variable is removed from the model. This process continues until all variables in the model are significant. (ii) A 'backward' approach where all the identified variables are initially introduced and then variables are withdrawn one by one, till the overall prediction does not deteriorate. (309) In a stable model (i) and (ii) should give the same results. If the results obtained are different, then there may be an inter-relationship between some variables and the model would be considered unstable. (iii) Variables are forced into the model because they have been shown to be good predictors of certain outcomes in other contexts.

We identified nine potential predictive variables that were common to all the trials making up our development dataset. These were the six simple variables (SSV)

[age, pre-stroke functional status, living alone pre-stroke, being able to walk unaided post stroke, lift both arms off the bed post stroke and have a normal verbal Glasgow Coma Score post stroke], gender, being diabetic and being overweight*. As I reported in Chapter 1, SSVs have been widely studied. I will describe this in detail below. We tested the addition of extra variables (gender, being diabetic and being overweight) to the SSVs using a 'backward' approach. We found that the addition of extra variables to SSV did not change the AUCs (Area under the receiver operating curve) of our models.

*(Note: The question: 'Is overweight?' was asked in different ways in the different trials, so to make a comparison, we combined their responses. (In CLOTS, 'Is overweight' was a yes/no answer. In FOOD, 'Is obese' was a yes/no answer. In IST3, Male>90kg or female >80kg were considered overweight).

SSV

The SSV models were developed from a community based cohort of stroke patients (Oxford Community Stroke Project) who presented up to 30 days post stroke. (91) The three models predict survival at 30 days, independent survival at 6 and 12 months following stroke, and ability to live at home at 6 and 12 months after stroke. Each of these models have incorporated the SSVs but have different coefficients as they predict different outcomes. The model predicting independent survival at six months has been validated in those presenting within 2 days of stroke (100) and in the hyper-acute stroke phase (101) for stratification in randomised trials. (24) SSVs have also been used to adjust for case mix when comparing the quality of hospital based stroke services (310) and in data collection for national audit purposes. (98) While five of the six simple variables are strong predictors of independent survival (100), the variable 'living alone pre-stroke' was originally incorporated in the models to predict whether someone would be alive and living at home at six months and a year after stroke (311) and has been shown in studies to not be predictive of death (311) or of independent survival. (312) The SSV model has been shown to have similar discrimination to more complex models including the 11 item NIHSS and age model (313) and other predictive systems including additional variables e.g. urinary continence. (91)

We used SSVs only as the predictor variables in our models. This was because, a) As reported above, the discrimination of the models with or without the addition of extra variables to the SSV were the same b) we were interested in predicting specific abilities after stroke which relied on the patient surviving and the SSVs have been shown to be a good predictor for survival (91) c) The SSV model includes three variables (living alone pre-stroke, ability to walk after stroke and normal verbal response on GCS score after stroke) which are closely related to three of the specific abilities we wished to predict at six months (to live at home, to walk and to talk without major problems) d) As reported above, the SSV has been validated for use (in clinical trials) in the acute and hyper-acute stroke settings and we wished to make early predictions after stroke (101) d) the variables are clinically relevant and easily collected (93) and e) these variables were common to all trials making up our development cohort and our validation cohort (described below).

7.4.1.4 Data quality

Analysis was conducted on the final versions of the trial datasets, following any cleaning determined necessary by the trial teams. Missing values were recorded. We checked six month outcomes for consistency e.g. If a patient or proxy had indicated 'confined to bed' in response to the EQ5D-3L dimension on mobility, then they should not have OHS 0-2. We excluded any misclassifications.

7.4.1.5 Statistical techniques

We used multivariate logistic regression to develop all our models using SSV. We used SAS 9.4 (a statistical package developed by the SAS institute, 2013).

7.4.1.6 Checking our models

We examined what happened to the models when we made assumptions based on baseline variables e.g. If a patient could walk at baseline, then we assumed he/she would still be able to walk at six months. We found this to have no effect on the AUCs of our models.

7.4.2 Validation

Validation is the process of evaluating the performance of a model.(299) Two methods are used: internal validation and external validation.

In internal validation, part or all of the dataset on which the model was developed is used to test model performance. However, testing a model on the dataset that it was developed from usually produces an optimistic view of the model's performance. This is because biases in patient selection or data collection are not accounted for.(300)

External validation is required before a model may be assessed fit for use in clinical practice.(304) External validation means assessing the performance of a model when applied to an independent dataset. This independent dataset is one that should ideally be collected by different investigators in a different location at a different time to the development dataset.

The two aspects of looking at a model's performance are discrimination and calibration. Discrimination is the ability of the model to separate individuals who develop the outcome of interest from those who do not. (303,314) It is quantified by calculating the area under the receiver operating characteristic curve (AUC) of sensitivity versus 1 minus specificity.(100) An area of 1 implies a test with perfect discrimination whilst an area of 0.5 implies that the model's predictions are no better than chance. I report the 95% confidence intervals of the AUCs.

I assessed the calibration of the model. This is an assessment of whether predicted probabilities in groups of patients having an outcome were the same, higher or lower than those observed. (303,314) I plotted calibration curves of the proportion of patients in our validation cohort who actually had a good outcome against the proportion predicted by the model (in tenths of predicted probability of a good outcome). A model is well calibrated if the points on the graph follow a 45 degree line from the origin (i.e. the predicted and observed probabilities are the same). The vertical distance between the points and the diagonal indicates how optimistic or pessimistic the predictions are.

Based on my results from Chapter 6, I also performed cross tabulations of predicted versus actual outcomes for each outcome at varying PPVs (50%, 80%,90%). This allowed me to estimate the proportion of the patients who could be given a prediction of having a specific ability at each of these PPVs.

We assessed internal validation by reporting discrimination of our models in the whole development dataset. I externally validated our models in an independent cohort of patients with major stroke. (Described in chapter 2) I used Stata 15 (Timberlake, 2017) for external validation.

7.4.2.1 Dataset for external validation

I described the recruitment and follow-up of our longitudinal cohort of patients with major stroke (n=403) in detail in Chapter 2. Briefly, I recruited patients from a tertiary teaching hospital in the United Kingdom between 10th May 2017 and 25th May 2018 between days 0 and 10 after stroke. I followed up patients to around six months to assess their specific abilities. Only one patient was lost to follow up.

The measures/scales and dichotomies that I used to allow comparisons to be made between our development and validation cohorts is shown in Table 7.5. There were some differences in measures/scales used between our development and validation cohort. For example, while the trials in our development cohort all used OHS to report functional outcome (to be independent), I used mRs measured by the smRsq. However, these scales (OHS and mRs) are very similar and therefore, we considered them to be the same. (11,149)

Table 7.5 Measures/scales and dichotomies to define specific abilities, comparing development and validation cohorts.

	Development cohort			**Validation cohort**		
Specific abilities at 6 months	**Measure/ Scale**	**Good outcome**	**Poor outcome**	**Measure/Scale**	**Good outcome**	**Poor outcome**
To be independent	OHS	0-2	3-6	mRs (via smRsq)	0-2	3-6
To walk	EQ5D 3L	No problems Some Problems	Confined to bed or Dead	EQ5D 5L	No problems Slight problems Moderate problems	Severe problems Unable or Dead
To talk without major problems	Specific question*	No major problems	Major problems or Dead	Specific question*	No dysphasia Mild to moderate dysphasia	Severe dysphasia, Mute or Dead
To eat normally	Specific question*	Normal	Nose tube Side tube Or Dead	Specific question*	Normal Oral modified	Nasogastric tube Percutaneous gastrostomy Radiologically inserted gastrostomy or Dead

To live without major anxiety or depression	EQ5D 3L	Not anxious/ depressed Moderately anxious/ depressed	Extremely anxious/ depressed or Dead	EQ5D 5L	Not anxious/ depressed Slightly anxious/ depressed Moderately anxious/depressed	Severely anxious/ depressed Extremely anxious/depressed or Dead
To live at home	Specific question*	Own home Relatives home	Residential home Care home Hospital or Dead	Specific question*	Own home Relatives home	Residential home Care home Hospital or Dead

*Question asked with options given, responses dichotomised to ‘good’ and ‘poor’ outcome

7.5 Results

The characteristics and specific abilities at six months of all 13117 patients in our development cohort on whom models were developed and 403 patients in our validation cohort on whom the models were externally validated are given in Table 7.6.

The mean age of patients in our validation cohort was around 3 years older than our development cohort (77.5 and 74.7 respectively). Fewer patients in our validation cohort were independent before stroke (76.4% versus 92.6%). At six months, fewer in our validation cohort were independent (14.9% versus 29.0%), able to walk (48.1% versus 59.1%) and able to live at home (54.1% versus 59.3%). (Table 7.6) Note: all percentages are rounded to 1 decimal place and the number who died have been reported separately.

Table 7.6 Baseline characteristics and specific abilities at six months of patients in each trial (FOOD, CLOTS, IST3) and in combination to form our development cohort and our validation cohort.

Variables	**Trials**			**Development cohort** **n= 13117**	**Validation cohort** **n= 403**
	FOOD **n=1854**	**IST3** **N=3035**	**CLOTS** **N=8228**		
Six simple variables (91)					
Age; mean (standard deviation)	72.7 (12.5)	77.3 (12.2)	74.2 (12.1)	74.7 (12.3)	77.5 (11.8)
Independent before stroke, n (%)	1663 (89.7)	3018 (99.4)	7468 (90.8)	12149 (92.6)	308 (76.4)
Living alone before stroke	518 (27.9)	1129 (37.2)	2809 (34.1)	4456 (34.0)	158 (39.2)
Lift arms after stroke	847 (45.6)	1351 (44.5)	3247 (39.5)	5445 (41.5)	152 (37.8)
Able to walk after stroke	377 (20.3)	487 (16.0)	0 (0.0)	864 (6.6)	28 (6.9)

Normal verbal score of Glasgow Coma Scale	1199 (64.7)	1615 (53.2)	5455 (66.3)	8269 (63.0)	248 (61.5)
Other characteristics					
Gender					
Male	970 (52.3)	1465 (48.3)	4031 (49.0)	6466 (49.3)	179 (44.4)
Female	884 (47.7)	1570 (51.7)	4197 (51.0)	6651 (50.7)	224 (55.6)
Specific abilities at six months (measure/ scale)					
Disability (OHS or mRs)					
0	158(8.5)	254(8.4)	280(3.4)	692 (5.3)	8 (2.0)
1	268(14.5)	429(14.1)	626(7.6)	1323 (10.1)	45 (11.2)
2	283(15.3)	405(13.3)	1104(13.4)	1792 (13.7)	7(1.7)
3	339(18.3)	428(14.1)	1716(20.9)	2483 (18.9)	149 (37.0)
4	189(10.2)	255(8.4)	950(11.5)	1394 (10.6)	46 (11.4)
5	224(12.1)	449(14.8)	1417(17.2)	2090 (15.9)	36 (8.9)
6	384(20.7)	815(26.9)	1900(23.1)	3099 (23.6)	111 (27.5)

Missing	9 (0.5)	0(0.0)	235(2.9)	244 (1.9)	1 (0.3)
To be independent (mRs/OHS)					
mRs/ OHS 0-2	709 (38.2)	1088 (35.8)	2010 (24.4)	3807 (29.0)	60 (14.9)
mRs/ OHS 3-6	1136 (61.3)	1947 (64.2)	5983 (72.7)	9066 (69.1)	342 (84.9)
Missing	9 (0.5)	0 (0.0)	235 (2.9)	244 (1.9)	1 (0.2)
To walk (EQ5D)					
No problems/ some (slight/ moderate) problems	1274 (68.7)	1797(59.2)	4684(56.9)	7755 (59.1)	194 (48.1)
Severe problems/ unable	187 (10.1)	286 (9.4)	1330 (16.2)	1803 (13.7)	97 (24.1)
Dead	384 (20.7)	815 (26.9)	1900 (23.1)	3099 (23.6)	111 (27.5)
Missing	9 (0.5)	137 (4.5)	314 (3.8)	460 (3.5)	1 (0.3)
To talk without major problems				**N=3035 (IST3 ONLY)**	
No major problems (No dysphasia/ mild to moderate dysphasia)	NA	1332 (43.9)	NA	1332 (43.9)	278 (69.0)

Major problems (Severe dysphasia, Mute)	NA	474 (15.6)	NA	474 (15.6)	13 (3.3)
Dead	NA	815 (26.9)	NA	815 (26.9)	111 (27.5)
Missing	NA	414 (13.6)	NA	414 (13.6)	1 (0.3)
To eat normally				**N=1854 (FOOD ONLY)**	
Normal/ oral modified	1409 (76.0)	NA	NA	1409 (76.0)	286 (71.0)
Tube (side/ nose/ percutaneous)	51 (2.8)	NA	NA	51 (2.8)	4 (1.0)
Dead	384 (20.7)	NA	NA	384 (20.7)	111 (27.5)
Missing	10 (0.5)	NA	NA	10 (0.5)	2 (0.6)
To live without major anxiety or depression (EQ5D)				**N=13117 (ALL)**	
None/ some (slight/ moderate)	1312 (70.8)	1869 (61.6)	5499 (66.8)	8680 (66.2)	252(62.5)
Severe/ extreme	144 (7.8)	190 (6.3)	519 (6.3)	853 (6.5)	39(9.6)

Dead	384 (20.7)	815 (26.9)	1900 (23.1)	3099 (23.6)	111 (27.5)
Missing	14 (0.8)	161 (5.3)	310 (3.8)	485 (3.7)	1 (0.3)
To be able to live at home					
Own home/ relatives home	1222 (65.9)	1757 (57.9)	4798 (58.3)	7777 (59.3)	218 (54.1)
Hospital/ care home/ residential	239 (12.9)	366 (12.1)	1221 (14.8)	1826 (13.9)	72 (17.9)
Dead	384 (20.7)	815 (26.9)	1900 (23.1)	3099 (23.6)	111 (27.5)
Unknown/ other uncategorised*	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
Missing	9 (0.5)	97 (3.2)	309 (3.8)	415 (3.2)	1 (0.3)

*n=1 in validation cohort discharged back to prison

7.5.1 Developed models

The parameter coefficients, odds ratios (OR) and corresponding 95% confidence intervals (CI) for each predictor variable are shown in Table 7.7.

The OR gives the strength of the relationship between the predictor variable and outcome of interest. For example, for the model predicting 'to be independent', a patient who was able to walk after their stroke had a 4.13x increased odds of being independent at six months when compared to a patient who was not able to walk after their stroke. Age has been modelled as a continuous variable: the odds ratios presented are the odds per one year increase in age. The 95% CI indicates whether the relationship between the predictor variable and outcome of interest is statistically significant. If the CI does not cross or include 1.0, then the relationship is significant. For example, for the variable 'able to walk after stroke' in the model predicting 'to be independent', 95% CI does not cross 1.0, indicating that the relationship between 'able to walk after stroke' and independence is statistically significant.

Positive parameter coefficients imply that patients are more likely to have a 'good' outcome and a negative parameter implies that patients are less likely to have a 'good' outcome. For predicting independence, all predictor variables excluding age had a positive parameter coefficient. So, younger patients were more likely to be independent.

Table 7.7 Coefficients, odds ratios and 95% CI for each predictor variable predicting specific abilities at six months.

Logistic regression model for :	Parameter coefficient (SE)	Odds ratio (95% CI)
To be independent		
Constant	-0.82(0.19)	
Independent before stroke	1.28(0.12)	3.61(2.83-4.60)

Living alone	0.10(0.05)	1.10(1.00-1.21)
Normal Glasgow Coma Scale verbal score	0.80(0.05)	2.22(2.00-2.46)
Able to lift arms	1.41(0.05)	4.11(3.75-4.50)
Able to walk	1.42(0.09)	4.13(3.47-4.91)
Age	-0.04(0.002)	0.97(0.96-0.97)
To walk		
Constant	3.61 (0.19)	
Independent before stroke	0.77 (0.08)	2.17 (1.85-2.55)
Living alone	-0.07 (0.05)	0.93 (0.85-1.02)
Normal Glasgow Coma Scale verbal score	0.93 (0.04)	2.53 (2.32-2.76)
Able to lift arms	1.43 (0.05)	4.19 (3.81- 4.60)
Able to walk	1.12 (0.14)	3.06 (2.34-4.00)
Age	-0.07 (0.002)	0.94 (0.93-0.94)
To talk without major problems		
Constant	-12.23(367.9)	
Independent before stroke	13.33(36.9)	>999.999(<0.001->999.99)
Living alone	0.02(0.09)	1.02(0.85-1.23)
Normal Glasgow Coma Scale verbal score	1.43(0.09)	4.16(3.48-4.98)
Able to lift arms	0.98(0.09)	2.66(2.19-3.22)
Able to walk	0.64(0.15)	1.90(1.42-2.53)
Age	-0.03(0.004)	0.97(0.96-0.98)

To eat normally		
Constant	3.97(0.54)	
Independent before stroke	0.39(0.18)	1.48(1.04-2.12)
Living alone	-0.05(0.14)	0.95(0.72-1.26)
Normal Glasgow Coma Scale verbal score	1.18(0.13)	3.25(2.52-4.19)
Able to lift arms	0.92(0.15)	2.52(1.88-3.37)
Able to walk	0.95(0.27)	2.58(1.53-4.34)
Age	-0.06(0.01)	0.95(0.93-0.96)
To live without major anxiety or depression		
Constant	2.51(0.18)	
Independent before stroke	0.45(0.07)	1.58(1.36-1.82)
Living alone	-0.03(0.04)	0.97(0.89-1.06)
Normal Glasgow Coma Scale verbal score	0.76(0.04)	2.14(1.96-2.32)
Able to lift arms	0.76(0.05)	2.14(1.95-2.34)
Able to walk	0.65(0.12)	1.92(1.53-2.41)
Age	-0.04(0.00)	0.96(0.96-0.97)
To live at home		
Constant	4.35 (0.19)	
Independent before stroke	0.80(0.08)	2.22(1.90-2.60)
Living alone	-0.50(0.04)	0.61(0.56-0.67)
Normal Glasgow Coma Scale verbal score	0.89(0.04)	2.43(2.23-2.65)

Able to lift arms	1.02(0.05)	2.78(2.53-3.04)
Able to walk	1.04(0.12)	2.83(2.22-3.60)
Age	-0.071(0.002)	0.93(0.93-0.94)

7.5.2 Internal validation

The AUCs for the models were good. (AUCs 0.72 -0.81) (Table 7.8)

Table 7.8 Internal validation: Area under the curve (AUCs) of models in development dataset

Model for specific ability	AUC* (95% CI)
To be independent	0.79 (0.78-0.80)
To walk	0.81 (0.80-0.81)
To talk without major problems	0.79 (0.77-0.81)
To eat normally	0.81 (0.78-0.83)
To live without major anxiety or depression	0.72 (0.71-0.73)
To live at home	0.80 (0.79- 0.81)

*Area under the curve

7.5.3 External validation

7.5.3.1 Discrimination

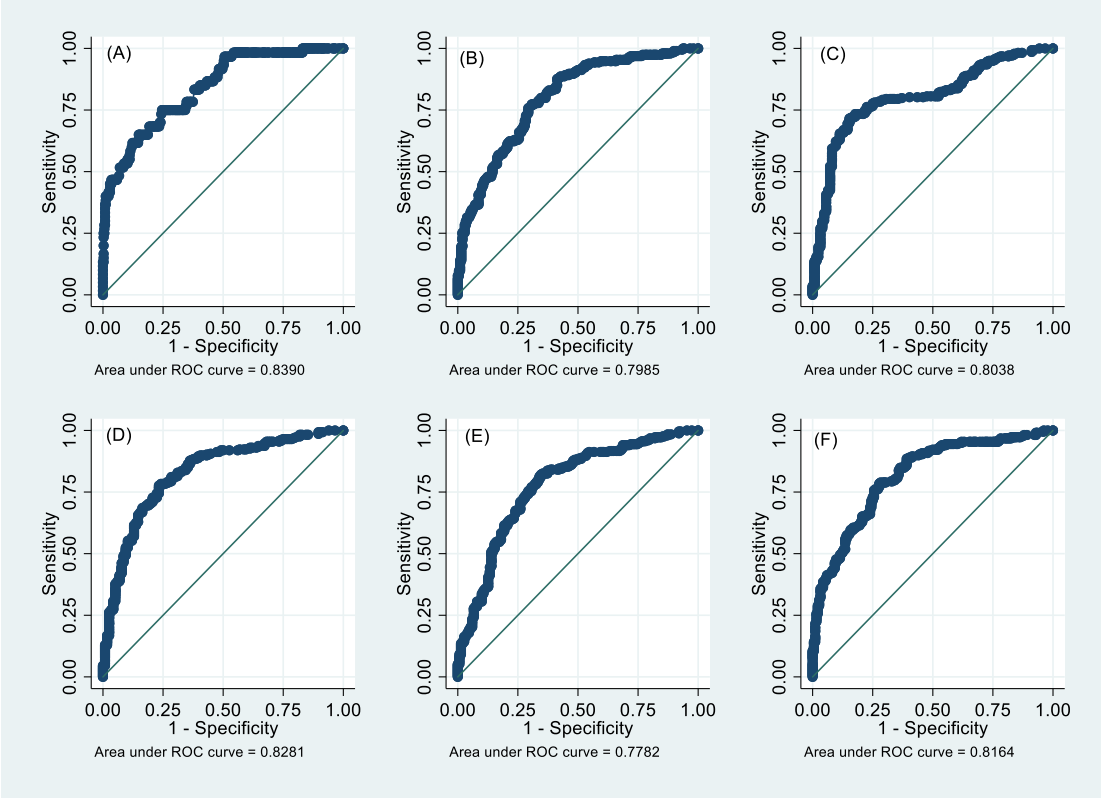
The Area under the curves (AUCs) of our models are shown in Table 7.9.

Our models had AUCs 0.78 to 0.84. However, the 95% CI were wide. Figure 7.1 shows the corresponding ROC curves.

Table 7.9 Area under the curves (AUCs) of externally validated models

Specific abilities	Area under the curve (AUC) (95%CI)
To be independent	0.84 (0.79 to 0.89)
To walk	0.80 (0.76 to 0.84)
To talk without major problems	0.80 (0.76 to 0.85)
To eat normally	0.83 (0.79 to 0.87)
To live without major anxiety or depression	0.78 (0.73 to 0.83)
To live at home	0.82 (0.78 to 0.86)

Figure 7.1 ROC curves for specific abilities at six months (external validation): (A) To be independent (B) To walk (C) To talk without major problems (D) To eat normally(E) To live without major anxiety or depression (F) To live at home



7.5.3.2 Calibration

The calibration curves for each specific ability are shown in Figure 7.2

Four out of our six models for specific abilities (to walk (B), to eat normally (D), to live without major anxiety or depression (E) and to live at home (F)) were well calibrated. The model for 'to be independent' (A) was optimistic in predicting the outcome, but especially so in the middle of the range of predicted probabilities of good outcome (i.e. 0.3 to 0.6).The model for 'to talk without major problems' was pessimistic, especially in the lower predicted probabilities of a good outcome. Although it looks as though the first two tenths have the same predicted probability of a good outcome (but different observed outcomes), the predicted probabilities of the first two tenths are different. (Table 7.10)

Figure 7.2 Calibration curves for specific abilities (A) to be independent (B) to walk (C) to talk without major problems (D) to eat normally (E) to live without major anxiety or depression (F) to live at home (Red lines represent each patient with (1) or without (0) the outcome

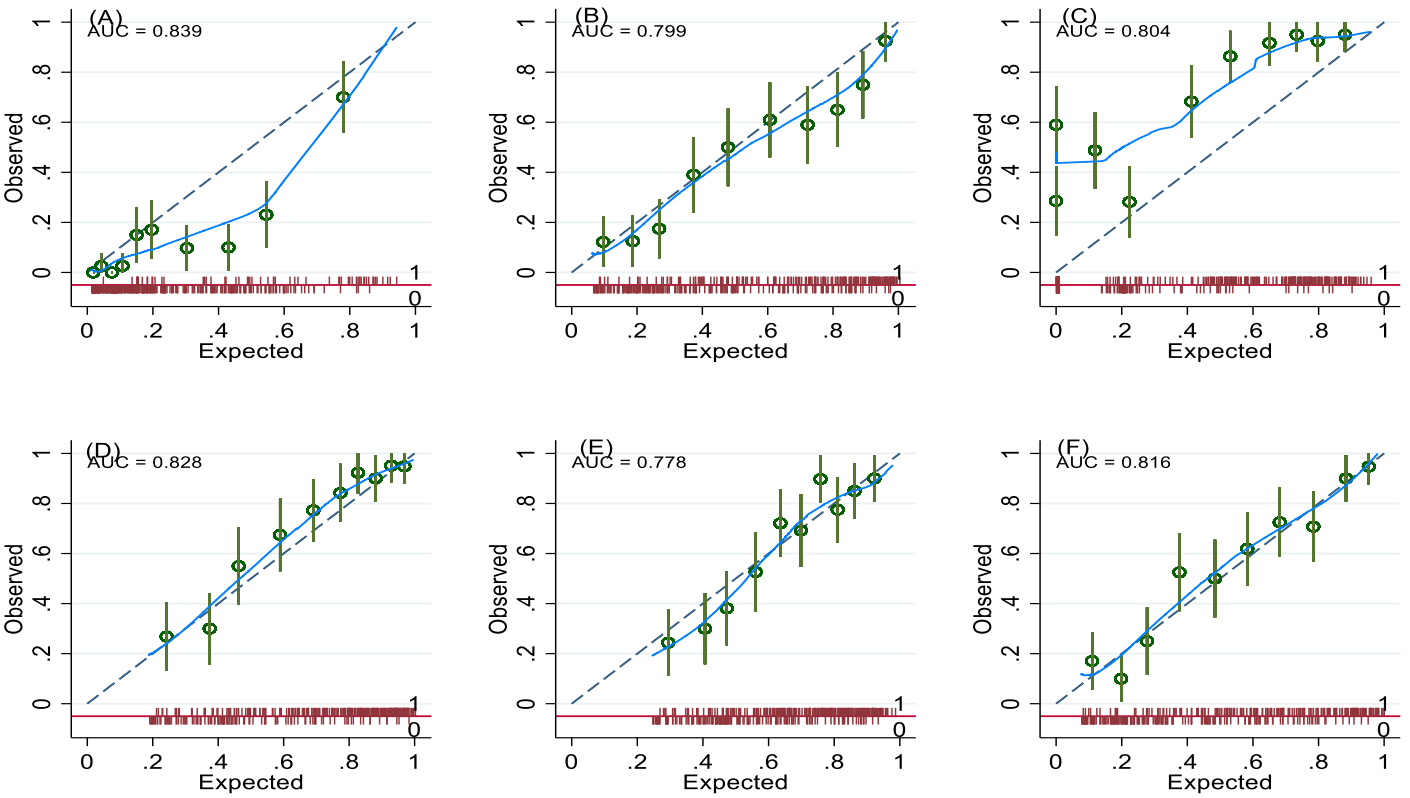


Table 7.10 Predicted probability of a good outcome for first two tenths for the model 'to talk without major problems'.

Specific ability	Tenth	Predicted probability of a good outcome Mean (SD)	Predicted probability of a good outcome Median (total range)
To talk without major problems	1st	$3.42x10^{-7}$ ($5.72x10^{-8}$)	$3.21x10^{-7}$ ($2.72x10^{-7}$ to $4.54x10^{-7}$)
	2nd	$1.20\ x10^{-6}$ ($6.16x10^{-7}$)	$1.17x10^{-6}$ ($4.68x10^{-7}$ to $2.71x10^{-6}$)

7.5.4 Performance of models at PPVs 50%, 80% and 90%

Based on my findings in Chapter 6, here, I report the performance of our developed and validated models at varying PPVs (50%, 80%, 90%). (Table 7.11)

Table 7.11 Performance of models at varying PPVs.

Specific Ability		Positive predictive values (PPV)		
		50%	80%	90%
To be Independent	Cut-point	0.307	0.51	0.72
	Sensitivity	53.3	40.0	15.0
	Specificity	90.9	98.5	99.7
	NPV	91.7	90.4	87.0
	Correctly classified	85.3	89.8	87.1
To walk	Cut-point	0.12	0.745	0.80

	Sensitivity	99.5	41.2	27.3
	Specificity	6.7	90.4	97.1
	NPV	93.3	62.3	58.9
	Correctly classified	51.5	66.7	63.4
To talk without major problems	Cut point*	NA	0.545	0.73
	Sensitivity	100	80.2	72.3
	Specificity	0	56.5	82.3
	NPV	0	56.0	57.0
	Correctly classified	69.2	72.9	75.4
To eat normally	Cut point**	NA	0.425	0.79
	Sensitivity	100	92.0	70.3
	Specificity	0	44.0	81.0
	NPV	0	68.9	52.5
	Correctly classified	71.1	78.1	73.4
To live without major anxiety or depression	Cut point***	NA	0.57	0.884
	Sensitivity	100	81.0	15.9
	Specificity	0	66.0	97.3
	NPV	0	67.4	40.8
	Correctly classified	62.7	75.4	46.3
To live at home	Cut-point	NA	0.65	0.824
	Sensitivity	100	60.6	38.5
	Specificity	0.0	82.1	95.1

	NPV	NA	63.7	56.6
	Correctly classified	54.2	70.4	64.4

*worse PPV possible is 69.2% **Worse PPV possible is 71.1% ***worse PPV possible is 62.7%

The numbers and percentages of patients who could be given a prediction of a good outcome at six months after major stroke (i.e. having a specific ability) at these PPVs are in Table 7.12 to Table 7.29.

For example, at PPV 50% for predicting independence (Table 7.12), in our validation cohort, we could inform 63/402 (15.7%) patients that they had a 50:50 chance of being independent at six months. This model had a specificity of 90.9% but a sensitivity of 53.3%. (Table 7.11) At PPV 80% for predicting independence (Table 7.13), we could inform 29/402 (7.2%) patients that they had an 80% chance of being independent at six months. This model had a specificity of 98.5% but a sensitivity of 40.0%. At PPV 90% for predicting independence (Table 7.14), we could inform 10/402 (2.5%) patients that they had a 90% chance of being independent at six months. This model had a specificity of 99.7% but a sensitivity of 15.0%.

Table 7.30 summarises the numbers and percentages of patients/families who could be given a prediction of a good outcome of a specific ability at varying PPVs.

For each specific ability, the proportion of patients and their families in our validation cohort who could be given a prediction at a PPV varied. For example, at 80% PPV, 29/402 (7.2%) patients/families could be informed that they had an 80% chance of being independent but 327/402 (81.5%) patients/families could be informed that they had an 80% chance of being able to eat normally. Also, fewer patients/families could be given a prediction of a specific ability at higher PPVs. For example, for predicting the ‘ability to walk’, at 90% PPV, 59/402 (14.7%) patients/families could be informed that they had a 90% chance of being able to walk at six months. However, at 50%

PPV, 387/402 (96.3%) patients/families could be informed that they had a 50% chance of being able to walk at six months.

For some specific abilities (to talk without major problems, to eat normally, to live without major anxiety/depression and to live at home), I could not report the models performances at 50% PPV. The lowest PPV possible (where sensitivity of the model is 100% and specificity is 0%) is shown in Table 7.11.

Table 7.12 Number of patients/families who could be given a prediction of 'to be independent' at six months at positive predictive value of 50%

To be independent	**Actual outcome**		
Predicted	**Good**	**Poor**	**Total**
Good	32	31	63
Poor	28	311	339
Total	60	342	402

Table 7.13 Number of patients/families who could be given a prediction of 'to be independent' at six months at positive predictive value of 80%

To be independent	**Actual outcome**		
Predicted	**Good**	**Poor**	**Total**
Good	24	5	29
Poor	36	337	373
Total	60	342	402

Table 7.14 Number of patients/families who could be given a prediction of 'to be independent' at six months at positive predictive value of 90%

To be independent	**Actual outcome**		
Predicted	**Good**	**Poor**	**Total**
Good	9	1	10
Poor	51	341	392
Total	60	342	402

Table 7.15 Number of patients/families who could be given a prediction of 'to walk' at six months at positive predictive value of 50%

To walk	**Actual**		
Predicted	Good	Poor	Total
Good	193	194	387
Poor	1	14	15
Total	194	208	402

Table 7.16 Number of patients/families who could be given a prediction of 'to walk' at six months at positive predictive value of 80%

To walk	**Actual**		
Predicted	Good	Poor	Total
Good	80	20	100
Poor	114	188	302
Total	194	208	402

Table 7.17 Number of patients/families who could be given a prediction of 'to walk' at six months at positive predictive value of 90%

To walk	**Actual**		
Predicted	Good	Poor	Total
Good	53	6	59
Poor	141	202	343
Total	194	208	402

Table 7.18 Number of patients/families who could be given a prediction of 'to talk without major problems' at six months at positive predictive value of 69.15% (lowest possible PPV)

Talk without major problems	**Actual outcome**		
Predicted	**Good**	**Poor**	**Total**
Good	278	124	402
Poor	0	0	0
Total	278	124	402

Table 7.19 Number of patients/families who could be given a prediction of 'to talk without major problems' at six months at positive predictive value of 80%

Talk without major problems	**Actual outcome**		
Predicted	**Good**	**Poor**	**Total**
Good	223	54	277
Poor	55	70	125
Total	278	124	402

Table 7.20 Number of patients/families who could be given a prediction of 'to talk without major problems' at six months at positive predictive value of 90%

Talk without major problems	**Actual outcome**		
Predicted	**Good**	**Poor**	**Total**
Good	201	22	223
Poor	77	102	179
Total	278	124	402

Table 7.21 Number of patients/families who could be given a prediction of 'to eat normally' at six months at positive predictive value of 71.1% (lowest possible PPV)

To eat normally	**Actual outcome**		
Predicted	**Good**	**Poor**	**Total**
Good	286	115	401
Poor	0	0	0
Total	286	115	401

Table 7.22 Number of patients/families who could be given a prediction of 'to eat normally' at six months at positive predictive value of 80%

To eat normally at six months	**Actual outcome**		
Predicted	**Good**	**Poor**	**Total**
Good	263	64	327
Poor	23	51	74
Total	286	115	401

Table 7.23 Number of patients/families who could be given a prediction of 'to eat normally' at six months at positive predictive value of 90%

To eat normally at six months	Actual outcome		
Predicted	**Good**	**Poor**	**Total**
Good	201	21	222
Poor	85	94	179
Total	286	115	401

Table 7.24 Number of patients/families who could be given a prediction of 'to live without major anxiety/depression' at six months at positive predictive value of 62.7% (lowest possible PPV)

Live without major anxiety/depression	Actual outcome		
Predicted	**Good**	**Poor**	**Total**
Good	252	150	402
Poor	0	0	0
Total	252	150	402

Table 7.25 Number of patients/families who could be given a prediction of 'to live without major anxiety/depression' at six months at positive predictive value of 80%

Live without major anxiety/depression	Actual outcome		
Predicted	**Good**	**Poor**	**Total**
Good	204	51	255
Poor	48	99	147
Total	252	150	402

Table 7.26 Number of patients/families who could be given a prediction of 'to live without major anxiety/depression' at six months at positive predictive value of 90%

Live without major anxiety/depression	**Actual outcome**		
Predicted	**Good**	**Poor**	**Total**
Good	40	4	44
Poor	212	146	358
Total	252	150	402

Table 7.27 Number of patients/families who could be given a prediction of 'to live at home' at six months at positive predictive value of 50% (closest possible is 54.2%)

To live at home	**Actual**		
Predicted	Good	Poor	Total
Good	218	184	402
Poor	0	0	0
Total	218	184	402

Table 7.28 Number of patients/families who could be given a prediction of 'to live at home' at six months at positive predictive value of 80%

To live at home	**Actual**		
Predicted	Good	Poor	Total
Good	132	33	165
Poor	86	151	237
Total	218	184	402

Table 7.29 Number of patients/families who could be given a prediction of 'to live at home' at six months at positive predictive value of 90%

To live at home	**Actual**		
Predicted	Good	Poor	Total
Good	84	9	93
Poor	134	175	309
Total	218	184	402

Table 7.30 Summary of the number and percentages of patients who could be given a prediction of having a specific ability at six months at different PPVs.

N=402 except *n=401	**PPV**					
	50%		**80%**		**90%**	
Specific ability at six months	**N**	**%**	**N**	**%**	**N**	**%**
To be independent	63	15.7	29	7.2	10	2.5
To walk	387	96.3	100	24.9	59	14.7
To talk without major problems	402	100	277	68.9	223	55.5
To eat normally*	401	100	327	81.5	222	55.4
To live without major anxiety/depression	402	100	255	63.4	44	10.9
To live at home	402	100	165	41.0	93	23.1

7.6 Discussion

7.6.1 Summary of main results

We have developed and externally validated statistical models to predict six specific abilities after major stroke and reported their performance at PPVs chosen by family members of patients with major stroke. In an independent cohort of patients with major stroke, all six models had good discrimination, and four out of six models calibrated well (models predicting 'to walk', to eat normally', 'to live without major anxiety or depression' and 'to live at home').

There is a trade-off between being able to provide patients and families with predictions which have a high probability of being correct and the number of patients/ families able to receive these predictions.

7.6.2 Strengths

The models were developed based on variables (SSV) that are easy to collect with good inter-rater reliability (93,100) and most are good predictors of survival.(100) The development cohort had patients with a wide range of characteristics (based on individual inclusion criteria for the different trials), of varying stroke severities and very large numbers of patients (n=13117). Since our development cohort was obtained from patients in large trials, data collection had a standardized approach, was collected by many persons over time with minimal losses to follow up.(23,36,298,315) There was no overlap of investigators or patients between the development and validation cohorts. Models developed using patients recruited into trials between days 0-3 performed well in an independent cohort where patients were recruited between days 0-10, suggesting that the models are flexible.

7.6.3 Limitations

Our development cohort was not designed for the purpose of predicting specific abilities after stroke. Therefore, certain baseline variables which may have been better predictors of certain specific abilities (e.g. previous history of anxiety or depression as a predictor for anxiety or depression at six months) were not available.

The relatively poor discriminatory power (compared to our other models) of the model predicting anxiety and depression may be because these two different diagnoses have different predictors and hence predicting them in combination is difficult. Anxiety may be more evident in younger patients (316) and those with milder strokes (317), whereas depression may be more likely in older patients (318,319) and those with greater functional dependence as a result of a major stroke.(319–321) Therefore, predicting anxiety and depression separately using different predictive variables may be

more likely to correctly identify those who would not have major problems with either at six months. We were unable to do this as this outcome in our development cohort was reported based on the EQ5D where anxiety and depression are considered as one entity.

Relative to our development dataset, our validation cohort of 403 patients was small, hence the estimates of AUC and their 95% CI were wide. Ideally, I would have recruited a larger cohort of patients with major stroke in order to achieve tighter CI around the estimates. However, I was limited by the length of my fellowship. The validation cohort was also recruited from a single site.

Different measures/scales were used to measure specific abilities at six months in the development and validation cohorts. As I described, for example, while the trials used the Oxford Handicap Scale (OHS) to report patient functional status, I used the modified Rankin scale (mRs) measured by the simplified modified Rankin questionnaire (smRsq) in my validation cohort. Ideally, I would have used the same measures/scales to report outcomes in our validation cohort as that used in our development cohort.

As I described in Chapter 2, using different measures/ scales to report an outcome would give us different results. I showed in Chapter 2 how using smRsq, BI and EQ5D-5L to report 'to walk' at six months gave us slightly different results. Ideally, we would have used a measure/scale that reports outcomes more consistently (e.g. smRsq rather than BI or EQ5D to report 'to walk'). However, in our development dataset, we did not have this choice and were restricted to using assessments that were consistently reported by the trials (EQ5D to report 'to walk' in this case).

The cut-offs we chose for dichotomising 'good' and 'poor' outcomes were based on judgements of stroke professionals and we acknowledge that different individuals would have different perceptions of 'good' and 'poor' outcomes. Using different cut-offs would give us different results.

The different casemix of patients within our development cohort and between our development and validation cohorts could account for the modest performance of our models. Our development cohort consisted of patients with very different inclusion and exclusion criteria being recruited into the three different groups of trials (FOOD, CLOTS and IST3). Our validation cohort was an observational cohort of patients with major stroke, who, in comparison to patients in our development cohort (where patients with less major strokes were not excluded), generally had poorer outcomes with respect to some abilities (e.g. being independent) at six months.

These differences could account for our model predicting 'to be independent' being optimistic. However, the reason for the predictions being optimistic in the middle of the range of predicted probabilities of a good outcome is unclear.

Although the model predicting 'able to talk without major problems' had reasonable discrimination (AUC 0.80), the confidence intervals were wide (0.76-0.85). The predictions from this model were particularly pessimistic in the lower range of predicted probability of good outcome. This could be related to the differences in characteristics between patients recruited into IST3 and our validation cohort. Of note, the first two tenths of predicted probabilities of a good outcome were both close to zero, though the groups had different observed outcomes. A plausible explanation for this could be related to the coefficient and confidence interval for the predictor variable 'Independent before stroke'. As shown in Table 7.7, the coefficient for this predictor variable was large (13.3) and confidence interval was very wide. This indicates that being independent before stroke had a large weighting on speech outcome, with those dependent before stroke having a very low likelihood of having a good outcome for speech after stroke. 99.4% of patients in our development cohort (participants in IST3 trial) were independent before stroke compared with 76.4% in our validation cohort. Therefore, 95 patients (23.6%) were dependent before stroke in our validation cohort. According to our model, these patients have a very low

likelihood of a good outcome with respect to their speech. However, in-keeping with my findings in Chapter 2 where I reported that patients in the same mRs level could have different specific abilities, this model shows that patients who were 'dependent' may still have different observed specific abilities ('to talk without major problems' in this case).

Although the models predicting 'able to eat normally' and 'to live without major anxiety/ depression' both discriminated and calibrated well in the validation cohort, it is possible that much of this may be attributable to the models' abilities to predict survival rather than these specific abilities. As shown in Table 7.6, there was a relatively larger proportion of patients who had died when compared to having major problems with eating normally or living with major anxiety/ depression. I will explore this in Chapter 8.

7.6.4 Predictions at different PPVs

There is a trade-off between the PPV and the proportion of patients who can be given a prediction at that PPV. There is uncertainty about how well the family members who suggested these 'accuracies' understood the question in the feedback exercise. (Chapter 6) Once some of our models have been further evaluated (particularly those which calibrated well in our cohort of major stroke patients), it is possible that predictions from these models may be used to improve understanding of prognosis and facilitate shared decision-making regarding treatments. As I reported in Chapter 6, predictions at a PPV of 50% may be sufficient for family members who had already accepted poor patient prognosis and where the patient's treatment preference on not initiating life-extending treatments was known. Predictions at 80% and 90% PPVs may be useful for family members where patient preferences were not clear at the outset. Since patients and some family members looked for hope and positive information (Chapters 3 and 4), it is also possible that, when predictions are given at a time when these individuals may be receptive to such information, the knowledge that the patient may have a 50%, 80% or 90% probability of having a specific ability (i.e. a 'good' outcome) at six months may offer them the hope they were

looking for and even help them prepare for the consequences of major stroke. As I described in Chapter 2, there is variation within each mRs level of patient's specific abilities; and therefore, the possibility of having a specific ability at six months (e.g. being able to speak) may be enough for some patients and families to consider patient preferences for life-extending treatments.

Our models are able to provide predictions at accuracies that are quantifiable (i.e. 50%, 80% or 90%). Therefore, they would be able to provide more consistent predictions between different doctors. If predictions from our models are found to be at least as good as a senior stroke physician's professional judgement, doctors (especially those more junior) may be able to use these models as a 'sense check' of their judgement of the patient's prognosis before approaching patients or family members to discuss prognosis. This requires our models to be evaluated further.

7.7 Conclusions

We have developed and externally validated six prognostic models to predict specific abilities six months after major stroke. All the models had good discrimination in an independent cohort of patients with major stroke and four out of six models calibrated well. At PPVs chosen by family members, there is a trade-off between the PPV and the proportion of patients/families who can be given a prediction at that PPV. Further evaluation of models which calibrated well (i.e. models predicting specific abilities to walk, to eat normally, to live without major anxiety or depression and to live at home) is required before they may be used to provide prognostic information to family members in the context of a major stroke. This may include further external validation in larger independent cohorts of patients with major stroke and assessing if predictions from the models are at least as good as those of experienced stroke physicians.

7.8 Implications for future work

There is also potential to evaluate, and perhaps enhance, the performance of these models. For example we could:

a) Examine how much of the models discriminatory power is derived from their prediction of survival versus the prediction of the patient's specific ability. All our models have been developed to predict survival and a specific ability (e.g. survival and to talk without major problems). In order to assess how much of the model's discrimination is attributable to its ability to predict survival versus the specific ability, we would need to examine the performance of models developed and validated in cohorts where only surviving patients are included.

b) Explore if adding some additional baseline variables and data on progress (e.g. patient treatment and complications in the early period after stroke, change in functional abilities) may improve predictions.
I will explore these possibilities in Chapter 8.

Chapter 8 Exploring how predictions of specific abilities after major stroke may be improved

8.1 Acknowledgement of contributions

I performed all the analysis contained in this chapter. I wrote this chapter and made changes following comments from my supervisors.

8.2 Introduction

Following on from my findings in Chapter 7, in this chapter, I will:

a) Examine the ability of our models (Described in Chapter 7) to predict specific abilities at six months after major stroke in cohorts of survivors to establish how much our models are predicting a specific ability as distinct from survival.
b) Explore in models developed from our longitudinal cohort (described in Chapter 2) if the addition of some variables to SSV may improve predictions of some specific abilities at six months.
   For example, the addition of the following baseline variables (described in Chapter 2) to predict the following specific abilities:
   i) Charlson comorbidity index and independence
   ii) Marital status and 'to live without major anxiety/ depression'
   iii) Current pet ownership and ' to live without major anxiety/depression'
   iv) Gender and 'to live without major anxiety/depression'
   v) Urinary continence and 'to live at home'.

   The addition of variables on patient progress to predict independence at six months. For example,

   vi) Patient complications and treatments by early follow up
   vii) Change in BI between baseline and early follow up, reflecting change in patient functional status

I will describe my reasoning, methodology, analysis and results within each section below.

8.2.1 The ability of our models (Described in Chapter 7) to predict specific abilities as distinct to survival

8.2.1.1 Reasoning:

As I described in Chapter 7, it is possible that, for some models, much of the discrimination of our models were attributable to the model's ability to predict survival rather than the specific ability. Therefore, to assess this, I will describe how we developed and validated models predicting specific abilities including only surviving patients (at six months) in both our development and validation cohorts.

8.2.1.2 Method:

We tried to remove all patients who had died by six months from both our development and validation cohorts. However, for some specific abilities (to be independent, to walk, to live at home), in our development cohort, between 70 and 75 patients had completed their follow up assessments before their six month follow up date but had died by six months. These patients were not excluded. For ease of reporting, I describe our development cohort in this chapter as that containing surviving patients only at six months (n=10018). We anticipate that the inclusion of 70-75 extra patients may not greatly affect our results.

We then repeated the process described in Chapter 7 of developing and validating models; i.e. we used SSV to develop models from large trial data (FOOD, CLOTS, IST3) to predict six specific abilities at six months after major stroke using multivariable logistic regression. I externally validated the models in our cohort of patients with major stroke who had survived to six months (n=291). (Described in Chapter 2)

8.2.1.3 Analysis:

I will report the parameter coefficients, odds ratios and 95% CI of each predictor variable in these models. I will report the discrimination and calibration of these models.

Table 8.1 summarises the data available for developing models for each specific ability in survivors, compared to that for all patients.

Table 8.1 Data available, and used for developing models for each specific ability from large trial data

Specific abilities at six months	Total n	Total n (surviving patients)	n excluded (Missing values)	n used for model development (all patients- Chapter 7)	n used for model development (surviving patients)
To be independent	13117	10018	244	12873	9846*
To walk	13117	10018	460	12657	9629**
To talk without major problems (IST3 only)	3035	2220	414	2621	1806
To eat normally (FOOD only)	1854	1470	10	1844	1460
To live without major anxiety or depression	13117	10018	485	12554	9533
To live at home	13117	10018	415	12702	9677***

*72 extra patients **71 extra observations***74 extra observations

The measures/scales and dichotomies that I will use to allow comparisons to be made between our development and validation cohorts are shown in Table 8.2. I reported this in Chapter 7. The difference here is that those patients who had died by six months in both our development and validation cohorts have been excluded from our dichotomy of ‘poor’ outcome. (With the exception of 70-75 patients for some specific abilities as described above)

Table 8.2 Measures/scales and dichotomies; comparing development and validation cohorts of surviving patients at six months only

	Development cohort			**Validation cohort**		
Specific abilities	**Measure/Scale**	**Good outcome**	**Poor outcome**	**Measure/Scale**	**Good outcome**	**Poor outcome**
To be independent	OHS	0-2	3-5	smRsq	0-2	3-5
To be able to walk	EQ5D 3L	No problems Some Problems	Confined to bed	EQ5D 5L	No problems Slight problems Moderate problems	Severe problems Unable
To talk without major problems	Specific question*	No major problems	Major problems	Specific question*	No dysphasia Mild to moderate dysphasia	Severe dysphasia, Mute
To eat normally	Specific question*	Normal	Nose tube Side tube	Specific question*	Normal Oral modified	Nasogastric tube Percutaneous gastrostomy Radiologically inserted gastrostomy

To live without major anxiety or depression	EQ5D 3L	Not anxious/ depressed Moderately anxious/ depressed	Extremely anxious/ depressed	EQ5D 5L	Not anxious/ depressed Slightly anxious/ depressed Moderately anxious/depressed	Severely anxious/ depressed Extremely anxious/depressed
To live at home	Specific question*	Own home Relatives home	Residential home Care home Hospital	Specific question*	Own home Relatives home	Residential home Care home Hospital

*Question asked, options given and dichotomised to good and poor outcome

8.2.1.4 Results:

The specific abilities of surviving patients in our development (n=10018) and validation cohorts (n=291) are shown in Table 8.3. As shown, once patients who had died by six months were excluded from our development and validation datasets, for some specific abilities, the number of outcome events was very low. For example, only 51 (3.5%) were tube fed (based on surviving patients from FOOD trials).

Table 8.3 Specific abilities at six months of surviving patients in development and validation cohorts.

Specific abilities at six months (scale/ measure)	**Development cohort** **n= 10018 (100%)**	**Validation cohort** **n= 291 (100%)**
Disability **(OHS or mRs)**		
0	692 (6.9)	8 (2.7)
1	1323 (13.2)	45 (15.5)
2	1792 (17.9)	7 (2.4)
3	2483 (24.8)	149 (51.2)
4	1394 (13.9)	46 (15.8)
5	2090 (20.9)	36 (12.4)
Missing	244 (2.4)	1 (0.3)
Being independent (mRs/OHS)		
mRs/ OHS 0-2	3807 (38.0)	60 (20.6)

mRs/ OHS 3-5	5967 (59.6)	231 (79.4)
Missing	244 (2.4)	1 (0.3)
Able to walk (EQ5D)		
No problems/ some (slight/ moderate) problems	7755 (77.4)	194 (66.7)
Severe problems/ unable	1803 (18.0)	97 (33.3)
Missing	460 (4.6)	1 (0.3)
To talk without major problems	**N=2220 (survivors from IST3 only)**	
No major problems (No dysphasia/ mild to moderate dysphasia)	1332 (60.0)	278 (95.5)
Major problems (Severe dysphasia, Mute)	474 (21.4)	13 (4.5)
Missing	414 (18.6)	1 (0.3)

To eat normally	**N=1470 (survivors from FOOD only)**	
Normal/ oral modified	1409 (95.9)	286 (98.2)
Tube (side/ nose/ percutaneous)	51 (3.5)	4 (1.4)
Missing	10 (0.7)	2 (0.7)
To live without major anxiety or depression (EQ5D)	**N=10018 (All survivors)**	
None/ some (slight/ moderate)	8680 (86.6)	252(86.6)
Severe/ extreme	853 (8.5)	39(13.4)
Missing	485 (4.8)	1 (0.3)
To live at home		
Own home/ relatives home	7777 (77.6)	218 (74.9)
Hospital/ care home/ residential	1826 (18.2)	72 (24.7)
Unknown/ other uncategorised*	0 (0.0)	1 (0.3)
Missing	415 (4.1)	1 (0.3)

*discharged to prison

The models developed from our cohort of surviving patients are described in Table 8.4. I have also listed the parameter coefficients and ORs of the models we developed including all patients (reported in Chapter 7). For some models, certain predictor variables had higher ORs when only surviving patients were included in model development. For example, for the model predicting 'to walk', the ORs for the predictor variables 'able to lift arms' and 'able to walk after stroke' were higher than the corresponding ORs for these predictor variables when all patients were included in model development.

Table 8.4 Coefficients and odds ratios (95% CI): models predicting specific abilities at six months, comparing models developed using all patients with models developed using surviving patients only

Logistic regression model for:	**Parameter coefficient (SE)**	**Odds ratio (95% CI)**	**Parameter coefficient (SE)**	**Odds ratio (95% CI)**
	All patients (Chapter 7)		Surviving patients	
To be independent				
Constant	-0.82(0.19)		-1.05(0.20)	
Independent before stroke	1.28(0.12)	3.61(2.83-4.60)	1.22(0.13)	3.39(2.64-4.36)
Living alone	0.10(0.05)	1.10(1.00-1.21)	0.14(0.05)	1.15(1.04-1.26)
Normal Glasgow Coma Scale verbal score	0.80(0.05)	2.22(2.00-2.46)	0.61(0.05)	1.85(1.66-2.06)
Able to lift arms	1.41(0.05)	4.11(3.75-4.50)	1.33(0.05)	3.78(3.44-4.15)
Able to walk	1.42(0.09)	4.13(3.47-4.91)	1.41(0.10)	4.10(3.40-4.95)
Age	-0.04(0.002)	0.97(0.96-0.97)	-0.03(0.00)	0.98(0.97-0.98)

To walk				
Constant	3.61 (0.19)		3.59 (0.25)	
Independent before stroke	0.77 (0.08)	2.17 (1.85-2.55)	0.81(0.11)	2.25(1.83-2.77)
Living alone	-0.07 (0.05)	0.93 (0.85-1.02)	-0.07(0.06)	0.93(0.82-1.05)
Normal Glasgow Coma Scale verbal score	0.93 (0.04)	2.53 (2.32-2.76)	0.71(0.06)	2.04(1.82-2.29)
Able to lift arms	1.43 (0.05)	4.19 (3.81- 4.60)	1.82(0.07)	6.20(5.38-7.14)
Able to walk	1.12 (0.14)	3.06 (2.34-4.00)	1.44(0.25)	4.22(2.57-6.96)
Age	-0.07 (0.002)	0.94 (0.93-0.94)	-0.05(0.00)	0.95(0.94-0.95)
To talk without major problems				
Constant	-12.23(367.9)		-11.72(378.6)	
Independent before stroke	13.33(36.9)	>999.999(<0.001->999.99)	11.59 (378.6)	>999.99 (<0.001->999.99)
Living alone	0.02(0.09)	1.02(0.85-1.23)	0.05(0.13)	1.06(0.82-1.35)

Normal Glasgow Coma Scale verbal score	1.43(0.09)	4.16(3.48-4.98)	1.82(0.12)	6.16(4.84-7.84)
Able to lift arms	0.98(0.09)	2.66(2.19-3.22)	0.53(0.13)	1.69(1.31-2.18)
Able to walk	0.64(0.15)	1.90(1.42-2.53)	0.42(0.18)	1.53(1.07-2.18)
Age	-0.03(0.004)	0.97(0.96-0.98)	-0.00(0.00)	1.00(0.99-1.01)
To eat normally				
Constant	3.97(0.54)		4.25(1.23)	
Independent before stroke	0.39(0.18)	1.48(1.04-2.12)	0.46(0.38)	1.58(0.75-3.36)
Living alone	-0.05(0.14)	0.95(0.72-1.26)	0.56(0.40)	1.75(0.80-3.81)
Normal Glasgow Coma Scale verbal score	1.18(0.13)	3.25(2.52-4.19)	2.14(0.40)	8.51(3.88-18.68)
Able to lift arms	0.92(0.15)	2.52(1.88-3.37)	1.57(0.50)	4.80(1.81-12.76)
Able to walk	0.95(0.27)	2.58(1.53-4.34)	1.38(1.05)	3.98(0.51-31.19)
Age	-0.06(0.01)	0.95(0.93-0.96)	-0.04(0.01)	0.96(0.93-0.99)

To live without major anxiety or depression				
Constant	2.51(0.18)		0.94(0.27)	
Independent before stroke	0.45(0.07)	1.58(1.36-1.82)	0.27(0.15)	1.31(0.98-1.74)
Living alone	-0.03(0.04)	0.97(0.89-1.06)	0.016(0.08)	1.02(0.87-1.19)
Normal Glasgow Coma Scale verbal score	0.76(0.04)	2.14(1.96-2.32)	0.177(0.08)	1.19(1.02-1.39)
Able to lift arms	0.76(0.05)	2.14(1.95-2.34)	0.47(0.08)	1.60(1.37-1.87)
Able to walk	0.65(0.12)	1.92(1.53-2.41)	0.29(0.16)	1.34(0.97-1.84)
Age	-0.04(0.00)	0.96(0.96-0.97)	0.01(0.003)	1.01(1.01-1.02)
To live at home				
Constant	4.35 (0.19)		4.98 (0.26)	
Independent before stroke	0.80(0.08)	2.22(1.90-2.60)	0.81 (0.10)	2.24(1.84-2.73)
Living alone	-0.50(0.04)	0.61(0.56-0.67)	-0.78(0.06)	0.46(0.41-0.51)

Normal Glasgow Coma Scale verbal score	0.89(0.04)	2.43(2.23-2.65)	0.62(0.06)	1.87(1.67-2.10)
Able to lift arms	1.02(0.05)	2.78(2.53-3.04)	0.99(0.06)	2.70(2.39-3.05)
Able to walk	1.04(0.12)	2.83(2.22-3.60)	1.05(0.18)	2.86(2.02-4.04)
Age	-0.071(0.002)	0.93(0.93-0.94)	-0.06(0.00)	0.94(0.93-0.94)

8.2.1.4.1 Internal validation

The Area under the Curves (AUCs) for our developed models are shown. (Table 8.5) The AUCs of the models were slightly lower when only surviving patients were included in model development when compared to all patients being included (Reported in Chapter 7). The exception was the model predicting 'to eat normally' though the CI was wide.

Table 8.5 Internal validation: Area under the Curves (AUCs) of models in development dataset (surviving patients only)

Model predicting specific ability:	**Area under the Curve (AUC) (95% CI)**	
	All patients (Chapter 7)	Surviving patients
To be independent	0.79 (0.78-0.80)	0.76 (0.75-0.76)
To walk	0.81 (0.80-0.81)	0.80 (0.79-0.81)
To talk without major problems	0.79 (0.77-0.81)	0.76(0.73-0.79)
To eat normally	0.81 (0.78-0.83)	0.88 (0.83-0.92)
To live without major anxiety or depression	0.72 (0.71-0.73)	0.59 (0.57-0.61)
To live at home	0.80 (0.79- 0.81)	0.78 (0.77-0.79)

8.2.1.4.2 External validation

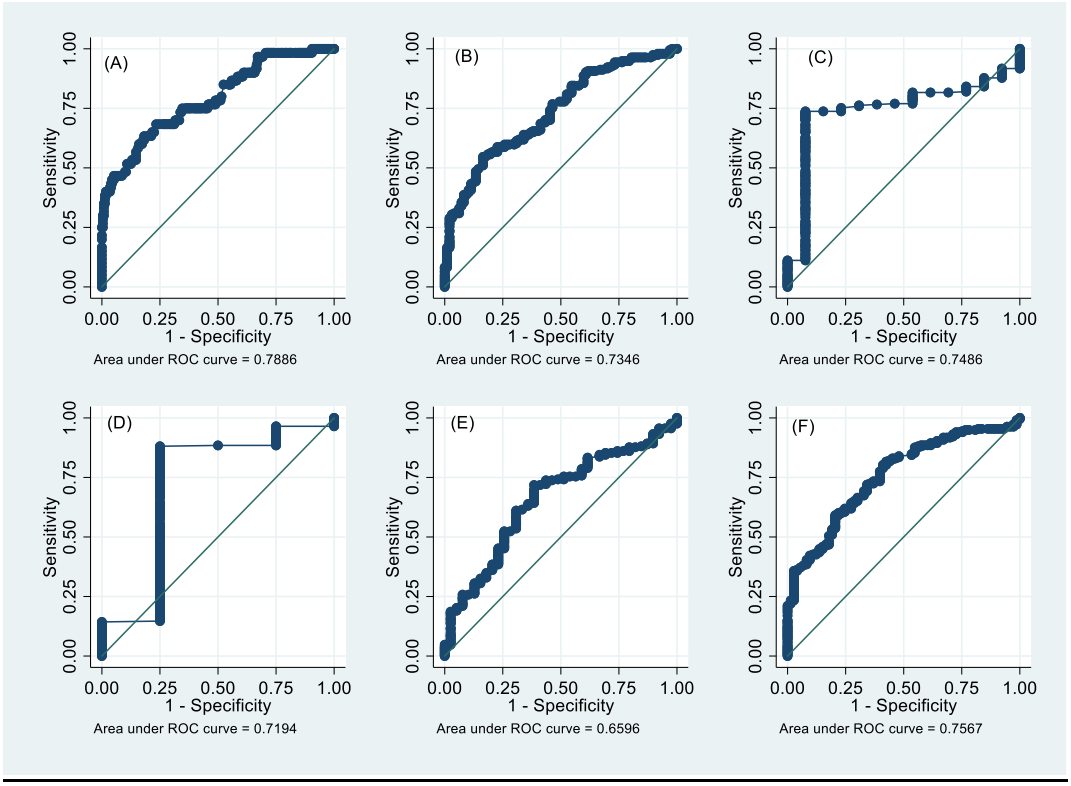
8.2.1.4.2.1 Discrimination

The AUCs of the models are shown in Table 8.6. All six models had poorer discriminative ability when compared to the models (which included all patients) I described in Chapter 7. Figure 8.1 shows the ROC curves of the models developed and validated using surviving patients at six months.

Table 8.6 Area under the Curve (AUCs) of externally validated models, surviving patients at six months

Specific abilities at 6 months	**Area under the Curve (AUC) (95%CI)**	
	All patients (Chapter 7)	Surviving patients
To be independent	0.84 (0.79 to 0.89)	0.79 (0.72-0.86)
To walk	0.80 (0.76 to 0.84)	0.73 (0.68-0.79)
To talk without major problems	0.80 (0.76 to 0.85)	0.75 (0.63-0.86)
To eat normally	0.83 (0.78 to 0.87)	0.72(0.34-1.0)
To live without major anxiety or depression	0.78 (0.73 to 0.83)	0.66 (0.57-0.75)
To live at home	0.82 (0.78 to 0.86)	0.76 (0.70-0.82)

Figure 8.1 Receiver Operating Curves (ROC) curves for specific abilities at six months where only surviving patients were included from the development and validation cohorts: (A) to be independent (B) to walk (C) to talk without major problems (D) to eat normally (E) to live without major anxiety or depression (F) to live at home

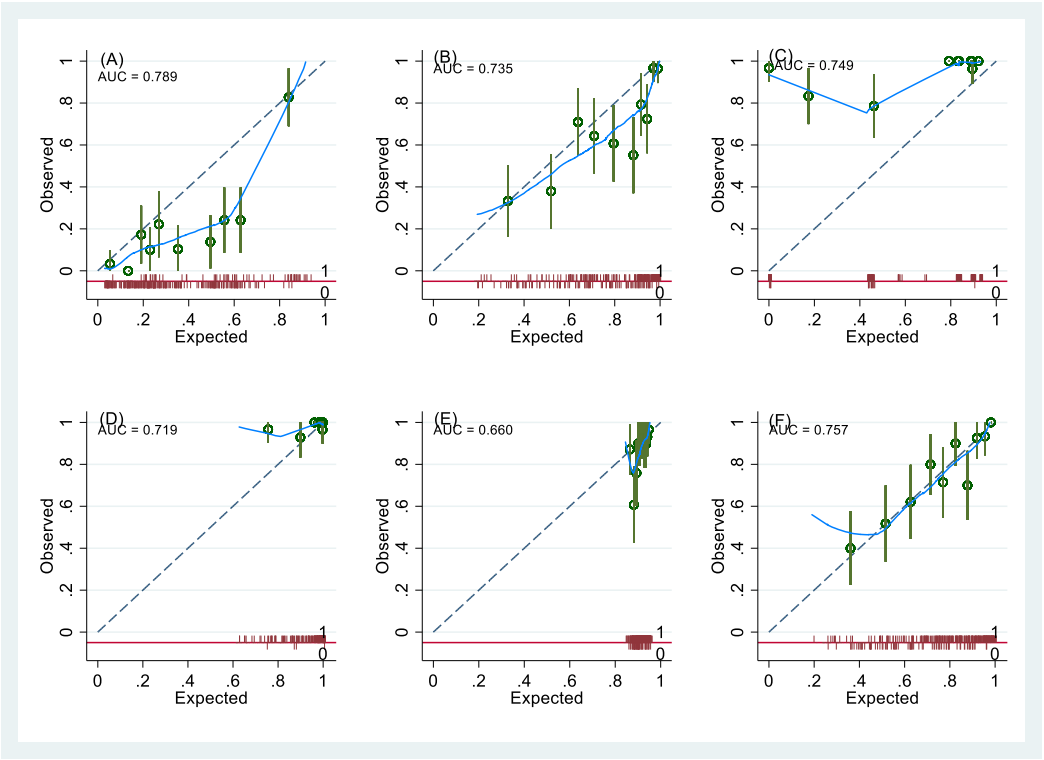


8.2.1.4.2.2 Calibration

The calibration curves of our validated models predicting each specific ability are shown in Figure 8.2.

Apart from the model predicting ‘to live at home’ at six months, the rest of the models calibrated poorly. The model for ‘being independent’ (A) was optimistic in predicting the outcome, but especially so in the middle of the range of predicted probabilities of good outcome. The model for ‘to walk’ (B) was slightly optimistic, especially so at the higher predicted probabilities of a good outcome. The model for ‘to talk without major problems’ was pessimistic, especially in the lower predicted probabilities of a good outcome. Both the models for ‘eat normally ’ and ‘living without major anxiety or depression’ were optimistic, predicting all surviving patients in our validation cohort to have a high predicted probability of a good outcome.

Figure 8.2 External validation: calibration curves for (A) To be independent (B) To walk (C) To talk without major problems (D) To eat normally (E) To live without major anxiety or depression (F) To live at home; where only surviving patients were included in both development and validation cohorts



*The red lines represent each individual patient with (1) or without (0) the outcome

Based on the poor calibration of these models, I will not report their performance at PPVs chosen by family members (Chapter 6) as these models are unlikely to be of any use in clinical practice due to their poor performance.

8.2.1.5 Summary of results

When only surviving patients from our development and validation cohorts were included in model development and validation, all our models discriminated and calibrated less well than our models developed and validated including all patients.

8.2.2 Addition of variables to improve predictions of specific abilities at six months

8.2.2.1 Reasoning:

Some baseline variables that I collected (listed in Chapter 2) have been shown in existing literature (not restricted to stroke) to be potential predictors of specific abilities. I described these in Chapter 2 and have summarised below. Therefore, these might be included to improve prognostic models.

For instance,

i) Higher Charlson score is associated with poorer functional outcome at six months after stroke. (127)
ii) Being married is associated with lower odds of depression after stroke. (123,124)
iii) Pet ownership is associated with better psychological outcomes. (125,126)
iv) Being male is associated with increased odds of depression after stroke, while being female is associated with increased odds of anxiety after stroke. (122)
v) Urinary incontinence is associated with higher rate of institutionalisation two years after stroke. (132)

Furthermore, complications and treatments in the early period after a major stroke may also affect patient outcome: patients who have had a major stroke can be very unwell in the early period and therefore mortality can be high and treatments used in the early period after a major stroke (e.g. enteral tube feeding and intermittent pneumatic compression) may prolong patient survival, but with significant disability (As described in Chapter 1). Therefore, including extra variables in my prognostic model (of complications and treatments, and change in patient functional status in the early period after major stroke) may improve the prediction of 'being independent' at six months.

Although literature may have found associations between baseline variables and outcome at longer time periods (e.g. two years after stroke), since we only had data available at six months after stroke, we were only able to test if these variables may improve predictions at six months after stroke.

8.2.2.2 Our hypotheses (for outcomes at six months after major stroke):

(I) Lower Charlson score may be associated with better functional outcomes (i.e. 'being independent')

(II) Being married may be associated with lower odds of anxiety/depression

(III) Pet ownership before stroke may be associated with lower odds of anxiety/depression

(IV) Being female may be associated with lower odds of anxiety/depression

(V) Being continent of urine at baseline may be associated with being able to live at home

(VI) Adding data on patient progress (complications and treatments) may improve prediction of 'to be independent'.

(VII) Adding data on change in patient functional status in the early period after stroke may improve prediction of 'to be independent'.

8.2.2.3 Method:

Using our longitudinal cohort of patients with major stroke (n=402 (one loss to follow up at six months), described in chapter 2), I will develop models to predict three specific abilities listed above (to be independent, to live without major anxiety/depression, to live at home) using multivariable logistic regression. I will use SSV as my predictor variables. I will assess if the addition of any of the variables (listed above) improved my models. I will perform the likelihood ratio test (LRT) (the goodness of fit of two competing models based on the ratio of their likelihoods). To compare two models using the LRT, the base model (or less general model) is nested inside the more general model and the base model can be obtained by constraining some of

the parameters of the more general model. The base model represents the null hypothesis, whereas the more general model represents the alternative hypothesis. I will take $p<0.05$ as the statistical significance level of the test. Low values of the likelihood ratio means that the observed result was much less likely to occur under the null hypothesis as compared to the alternative, and therefore rejects the null hypothesis. High values of the statistic means that the observed outcome was nearly as likely to occur under the null hypothesis as the alternative, and so the null hypothesis cannot be rejected.

My null hypothesis is that a model with SSV as predictor variables predicts the outcome of interest at six months. My alternative hypothesis is that a model with addition of other variables would give better predictions. A likelihood ratio, $p< 0.05$ would reject my null hypothesis.

I will use Stata SE 15 for all analysis.

As I reported in Chapter 7, it may be better to predict anxiety and depression separately as these two different diagnoses have different predictors. However, this is not possible as this outcome in our cohort is based on participants completing the EQ5D-5L, where anxiety and depression are regarded as one entity.

In my longitudinal cohort (described in Chapter 2), I collected two variables detailing patient complications- i.e. infection and stroke recurrence. For the latter, only 12 patients in my cohort had a recurrence of stroke in the early period and therefore this variable is not included due to the low EPV rate. I also collected several variables detailing treatments received by the patient (enteral tube feeding, parenteral fluids, antibiotics, IPC, catheter, escalation beyond ward level care and neurosurgery). Of these treatments, only three patients in our cohort were escalated beyond ward level care and none had neurosurgery. Therefore, I did not include these in the modelling process.

I also collected BI at baseline and at early follow up (Chapter 2). I took a change in BI between these two time points to reflect a change in patient

functional status. I excluded those patients who had died by early follow up (n=17).

8.2.2.4 Results:

My base model with SSV only as predictor variables, predicting 'to be independent' (mRs 0-2) is shown below. Although some individual variables do not reach statistical significance in our cohort, we know from literature (reported in Chapter 7) that SSVs are strong predictors of independence and survival. Therefore, all SSVs have been included.

Table 8.7 SSV to predict independence using our longitudinal cohort, n=402

'To be independent at six months'	**Odds ratio (OR)**	**Standard Error (SE)**	**p**	**95% Confidence interval (CI)**
SSV 'alone'	1.08	0.38	0.81	0.55-2.15
SSV 'independent'	8.89	7.20	0.07	0.89-53.48
SSV 'orientated'	7.98	5.35	0.002	2.14-29.74
SSV 'lift arms'	1.29	0.48	0.49	0.63-2.65
SSV 'walk'	15.98	9.28	<0.0001	5.12-49.85
Age	0.96	0.01	0.002	0.93-0.98
Constant	0.08	0.14	0.12	0.003-1.94

*SSV=Six Simple Variables

i) Addition of Charlson comorbidity index score to SSV to predict independence at six months after major stroke

Adding Charlson comorbidity index score as a continuous variable to SSV did not significantly improve predictions. (OR 0.80, 0.62-1.04), LRT 0.09

ii) Addition of variables (gender, marital status, pet ownership) to SSV to predict 'to live without major anxiety/ depression' at six months after major stroke.

In univariate analysis, unadjusted for SSV, gender (p=0.12) and marital status (p=0.35) were not significantly associated with the outcome. Pet ownership was significantly associated with the outcome. (p=0.03)

The model for predicting 'to live without major anxiety/depression' with SSV as baseline variables is shown below:

Table 8.8 SSV to predict 'to live without major anxiety/depression' at six months using our longitudinal cohort, n=402

'To live without major anxiety/depression at six months'	**Odds ratio (OR)**	**Standard Error (SE)**	**p**	**95% Confidence interval (CI)**
SSV 'alone'	1.17	0.30	0.55	0.70-1.95
SSV 'independent'	1.23	0.38	0.50	0.67-2.24
SSV 'orientated'	4.87	1.26	<0.0001	2.94-8.07
SSV 'lift arms'	2.28	0.66	0.004	1.30-4.02
SSV 'walk'	3.32	2.69	0.14	0.68-16.23
Age	0.98	0.01	0.12	0.96-1.00
Constant	1.66	1.66	0.61	0.23-11.83

*SSV= Six Simple Variables

The addition of gender (to our base model with SSV only) as a variable did not improve predictions. (OR 1.21 (0.74-1.98), LRT 0.45)

The addition of marital status (to our base model with SSV only) did not improve predictions. LRT 0.43. OR and 95% CI for each level within 'marital status' with 'single' set as the base is shown in Table 8.9.

Table 8.9 Marital status and anxiety/depression at six months, adjusted for SSV

Marital status	Odds ratio (OR)	Standard error (SE)	p	95% CI
Single	1 (base)			
Married	2.45	1.17	0.06	0.96-6.27
Lives with partner	5.95	5.95	0.07	0.84-42.21
Widowed	2.01	0.90	0.12	0.83- 4.85
Separated	2.02	2.11	0.50	0.26-15.64
Divorced	1.13	0.74	0.86	0.31-4.10
Unknown	0.89	1.13	0.93	0.07-10.67
Constant	1.06	1.19	0.96	0.12-9.51

*SSV= Six Simple Variables

Although there appeared to be an association in univariate analysis, addition of 'pet ownership' to our base model did not significantly improve predictions. LRT 0.20. The OR and 95% CI are shown in Table 8.10.

Table 8.10 Pet ownership and to live without major anxiety/depression at six months, adjusted for SSV

Pet ownership (recorded at baseline)	Odds ratio (OR)	Standard error (SE)	p	95% CI
None	1 (base)			
Current	1.96	0.75	0.08	0.92- 4.16
In the previous 12 months, but not currently	1.02	0.34	0.94	0.54-1.95
Constant	1.04	1.08	0.97	0.14-7.94

*SSV= Six Simple Variables

iii) Addition of 'Urinary continence' as a variable (single item from BI) to SSV to predict 'to live at home' at six months after major stroke

The model for predicting 'to live at home' with SSV as baseline variables is shown below:

'To live at home at six months'	Odds ratio (OR)	Standard Error (SE)	p	95% Confidence interval (CI)
SSV 'alone'	0.63	0.17	0.08	0.37-1.06
SSV 'independent'	2.17	0.70	0.02	1.15-4.09
SSV 'orientated'	4.76	1.27	<0.0001	2.82-8.04
SSV 'lift arms'	3.00	0.83	<0.0001	1.72-5.16
SSV 'walk'	4.39	3.71	0.08	0.84-22.98
Age	0.96	0.01	0.002	0.94-0.99
Constant	3.62	3.71	0.210	0.48-27.00

*SSV= Six Simple Variables

The addition of urinary continence as a variable to our base model (with SSV only) significantly improved prediction of 'to live at home' six months after major stroke. (OR 1.10 (1.04-1.18), LRT 0.003

(iv) Addition of data detailing patient treatments and complications by early follow up to predict 'to be independent' at six months after major stroke

I described our model predicting 'to be independent' at six months after major stroke above.

Addition of complications (i.e. infection) to our base model containing SSV only does not significantly improve predictions. (OR 0.62 (0.27-1.44), LRT 0.26)

Addition of treatments (intermittent pneumatic compression, antibiotics, fluids, enteral tube feeding and catheter) individually to our model containing SSV only also did not significantly improve predictions. (LRT 0.27) Individual OR and 95% CI of each treatment is shown below:

Table 8.11 Addition of treatments to SSV mode to predict 'to be independent'; OR and 95% CI

To be independent at six months	Odds ratio (OR)	Standard error (SE)	p	95% CI
IPC	0.71	0.31	0.43	0.30-1.67
Parenteral fluids	0.84	0.35	0.67	0.37-1.90
Antibiotics	0.75	0.34	0.52	0.31-1.82
Enteral tube feeding	0.30	0.25	0.15	0.06-1.53
Catheter	0.84	0.45	0.75	0.30-2.40
Constant	0.15	0.25	0.25	0.006-3.77

*SSV= Six Simple Variables

iv) Addition of change in functional status to predict 'to be independent' at six months after major stroke

I generated a new variable which reflected the change in BI scores between baseline and early follow up (i.e. for each individual patient, BI at early follow up minus baseline BI; so negative values indicate deterioration in patient functional status and positive values indicate improvement in patient functional status) (Table 8.12). Our base model with SSV only predicting 'to be independent' at six months is shown in Table 8.13. n=385 was available for model development as 17 patients had died by early follow up and therefore, did not have a BI score. Addition of a change in early patient functional status (Reflected by change in BI) improves prediction of 'to be independent' at six months. (OR 1.05 (1.03-1.07)) LRT <0.001

Table 8.12 Change in Barthel Index (BI) between baseline and early follow up excluding those who had died by early follow up, n=385

Change in Barthel Index between baseline and early follow up	n	%
-35	3	0.78
-30	2	0.52
-20	11	2.86
-15	6	1.56
-10	16	4.16
-5	34	8.83
0	65	16.88
5	58	15.06
10	39	10.13
15	30	7.79
20	35	9.09
25	21	5.45
30	18	4.68
35	14	3.64
40	12	3.12
45	5	1.30
50	3	0.78
55	3	0.78
60	4	1.04
65	5	1.30
70	1	0.26

Total	385	100

Table 8.13 SSV to predict 'to be independent' at six months with surviving patients at early follow up only, n=385

'To be independent at six months'	**Odds ratio (OR)**	**Standard Error (SE)**	**p**	**95% Confidence interval (CI)**
SSV 'alone'	1.07	0.37	0.84	0.54-2.12
SSV 'independent'	7.05	7.38	0.06	0.91-54.85
SSV 'orientated'	7.27	4.92	0.003	1.94-27.36
SSV 'lift arms'	1.27	0.47	0.51	0.62-2.63
SSV 'walk'	15.78	9.13	<0.001	5.08-49.02
Age	0.96	0.01	0.003	0.93-0.99
Constant	0.09	0.14	0.13	0.004-2.04

*SSV= Six Simple Variables

8.2.2.5 Summary of results

When adjusted for SSV, the variable 'urinary continence' appeared to significantly improve prediction of 'to live at home' six months after major stroke. Addition of change in patient functional status (calculated by a change in BI scores) in the early period after stroke also improved prediction of 'to be independent' at six months after major stroke.

8.3 Discussion

8.3.1.1 Summary of results from this chapter

Based on models developed from large trial data and validated in our cohort:

Models developed and validated in cohorts including surviving patients only had poorer discrimination and calibration when compared to models developed and validated on all patients. The discriminative ability of some models e.g. those predicting 'to eat normally 'and to live without major anxiety/depression' maybe related to their ability in predicting survival rather than the specific ability.

Based on models developed from our cohort:

When models developed from our longitudinal cohort (Described in Chapter 2) were adjusted for SSV, only the addition of the variable 'Urinary continence' appeared to significantly improve prediction of 'to live at home' and addition of data on change in patient functional status by BI improved prediction of 'to be independent' at six months after major stroke.

Including surviving patients only in development and external validation of prognostic models predicting specific abilities at six months after major stroke.

When compared to the models we developed and validated using all patients (reported in Chapter 7), the discriminative ability and calibration of models developed and validated using cohorts of surviving patients only was poorer. These models are unlikely to be of use in clinical practice. This is because it would not be possible to predict specific abilities in patients who have not survived. Furthermore, once those who had died by six months had been excluded, the EPV to predict some specific abilities (e.g. 'to eat normally') was low.

As described in Chapter 7, once the models which calibrated well have been evaluated further, it is possible that doctors may be able to use these models to provide predictions of survival and a specific ability in a one-step process. However, with the models I have described in this chapter, a two-step process would be required to provide predictions: i.e. survival and specific abilities are predicted separately. When we consider doctors communicating

prognosis to patients and families, using a one-step process and saying ‘you have a x% chance of being able to walk’ is clearer and raises less uncertainty than communicating the likelihood of survival and then the likelihood of achieving a specific ability (e.g. ‘You have an x% chance of surviving, and if you survive, y% chance of being able to walk).

Variables which may improve predictions

Despite literature reporting associations between some variables and specific abilities after stroke, when adjusted for SSV, only two variables seemed to significantly improve prediction of two specific abilities at six months after major stroke. These were urinary continence predicting ‘to live at home’ and change in functional status predicting ‘to be independent’.

Therefore, as previously reported (91), SSV appears to predict outcomes as well as models with additional baseline variables. However, one may consider adding in and testing data on patient functional change to future models. This may also mean that predictions made later (days 7-10, rather than 0-3 after stroke) could be useful for shared decision-making regarding treatments, especially when some patients and family members may not be ready to participate in decision-making in the early period after major stroke.

8.4 Limitations

- Although some individual variables in SSV were not statistically significant in our cohort, we included all SSV based on existing literature which has shown that SSVs are good predictors of independent survival
- Models developed from our cohort are based on relatively (relative to models we developed in Chapter 7) fewer patients and therefore do not have the required power to draw conclusions from. Ideally, variables should be tested in larger cohorts
- We were not able to externally validate these models, hence they do not currently have any clinical use- this was simply intended as an exploration of variables to improve predictions from future models

8.5 Conclusions

Models developed and validated using cohorts of surviving patients performed poorly and are not useful in clinical practice. The simplest models using SSV as predictor variables performed as well as models with additional variables, though addition of some variables e.g. data on functional progress and urinary continence may improve predictions of 'to be independent' and 'to live at home' respectively. Future models may consider further evaluating the addition of variables in predicting specific abilities.

8.6 Next steps

Based on my findings in this thesis so far, I report that we need to optimise communication of information to patients and families in a way that is individualised, useful to their purposes, easily communicated and understood. In my final chapter (Chapter 9), I summarise my findings and describe a future intervention to improve communication between doctors, patients and family members in the context of major stroke.

Chapter 9 Conclusions

9.1 Summary of results

Through mixed methods research, I have explored various aspects relating to shared decision-making regarding treatments in major stroke. This includes: a) the characteristics and progress of patients admitted with major stroke including their specific abilities and HRQoL, b) the experiences, views and needs of patients with capacity and family members where patients lacked capacity over time, c) communication between doctors and family members in the period where treatment decisions were being made, d) opinions of family members on various aspects relating to communication of diagnostic and prognostic information, e) development and external validation of new prognostic models to provide predictions of specific abilities at six months after major stroke f) potential ways in which prognostic models may be improved.

I have found that:

- Many patients are significantly physically disabled at six months after major stroke. However, they vary with respect to their specific abilities (e.g. to walk, to talk) and HRQoL despite being in the same disability level defined by mRs. (Chapter 2)
- In the early period after major stroke, patients reported feeling in shock and in distress and looking for hope from doctors. They were not ready to participate in shared decision-making regarding treatments. However, at six months, they said they wished they had been given realistic information. Many patients had unmet psychological and support needs. (Chapter 3)
- Treatment decisions involving family members where the patient lacked capacity appeared to be influenced by the patient's pre-stroke state of health and preferences they may have expressed before their stroke. Family members looked for prognostic information from doctors for different purposes i.e. to discuss known patient

preferences to not initiate treatments, to help facilitate treatment decisions, maintain hope that the patient would survive and recover or to prepare for the possibility that the patient may die and uncertainties of this process. (Chapter 4)

- There were areas where communication of diagnosis and prognosis may be improved between doctors and family members (Chapter 5)
- Some family members may wish information on specific abilities after major stroke to understand impact of stroke and/or facilitate their involvement in decision-making. However, different individuals wished for information in different formats and predictive accuracies. The use of visual aids, especially viewing of brain scans, was helpful to many to understand the impact of major stroke and/or be involved in decision-making. (Chapter 6)
- We can formally predict four specific abilities at six months after major stroke. The prognostic models we have developed and validated will require further evaluation. In the future, we hope that they may be used by doctors as a sense check of their judgement of the patient's prognosis and in communicating prognostic information to provide patients and families with the hope they may require, to understand the situation of major stroke better or even to facilitate shared decision-making regarding treatments. (Chapter 7)
- Using SSV as predictor variables predicts specific abilities as well as models with additional variables. However, addition of data on change in patient functional status in the early period after major stroke may improve prediction of 'to be independent' at six months. (Chapters 8)

In Chapter 1, I outlined several areas relevant to major stroke and shared decision-making regarding treatments. I would like to finish my thesis by considering how my findings have contributed towards these areas and may have clinical implications.

9.2 Impact of major stroke

In Chapter 1, I reported how patients who have had a major stroke face two possibilities: death or survival with disability. I also reported how, in the UK, stroke is a major cause of mortality and morbidity, with over a third of stroke survivors living with severe disability and many dependent on formal or informal care for their daily activities. (9,14–16) Data suggests that one-year mortality for TACS is around 60-70% with most people being significantly disabled at a year. The one year mortality is around 15-23% for PACS and POCS and 10-15% for LACS. (322,323) In my longitudinal cohort, (Chapter 2), I reported how over a quarter (27.5%) of patients I recruited had died and 20.3% were significantly disabled (mRs 4 and 5) at six months. The difference between the mortality and morbidity of my cohort in comparison to published data is likely due to our definition of major stroke and follow up of outcomes to six months rather than a year.

9.3 Patient management in keeping with their preferences

While guidelines (30,324) recommend that patients are involved in decision-making, as I reported in Chapter 3, I found that patients were shocked and distressed as a result of their diagnosis and were therefore, not ready or able to voice their preferences in the early period after major stroke. This has been reported in other medical settings including intensive care and cardiology. (65,325)

While studies have reported higher satisfaction and treatment compliance when patients are involved in decision-making, (61,62,326) there is also evidence to suggest that in some cases, patients may wish to negotiate how much and when they would like to know about their prognosis. (327–329)

Below I report my four main findings with respect to shared decision-making involving patients with capacity after major stroke.

Timing of shared decision-making

Guidelines focus on early information provision to patients to guide patient management. But the right timing when patients with major stroke may be receptive to information and be involved in decision-making would vary between individuals.

However, in the context of major stroke, as I reported in Chapter 1, some treatment decisions need to be taken early. (330) Decisions to withhold treatments such as IPC (35) and enteral tube feeding (24) can typically not be changed later and may influence patient outcome i.e. either death from withholding these treatments or survival with disability and a chronic stage of recovery with continuing these treatments. These decisions are often made at a time when there is large degree of uncertainty. (331)

Where patients are not ready to participate in decision-making and treatment decisions need to be made, doctors often seek patient preferences from family members(as I reported in Chapter 4) and consider the patient's 'best interests'. One has to consider how these approaches may sit with the notion of patient autonomy, especially when we cannot be certain that family members are voicing patient preferences rather than their own and doctors interpretation of what may be in the patient's 'best interests' may not necessarily be what the patient may want.

Looking for hope

As I described in Chapter 3, patients looked for hope and positive information in the early period after major stroke. For doctors to communicate hope while being realistic can be challenging. (53) The need for optimism and hope to be sustained in the process of honestly delivering bad news (e.g. a limited life expectancy) is an ideal expressed by both patients and doctors. (332–334) However, providing realistic information which may cause further distress and withholding potentially truthful information which may then give false hope raises a conundrum between two ethical principles: non-maleficence and autonomy. Therefore, there is a delicate balance between fostering realistic

hope and unethically creating unrealistic expectations (e.g. of achieving independence). (334,335)

Furthermore, hope is a broad concept that can hold different meanings for different individuals. (333) Existing work especially in oncology, on how patients may define hope report that some individuals may find hope by knowing that things can go well, others may find hope by knowing that there is a good chance that things may go well even if things have gone wrong, some may find hope by knowing that they have a good chance, if not better, as the next person of having the best outcome and finally, some others may find hope by knowing that they can still enjoy a good quality of life even if there is uncertainty with regards to their life expectancy. (333,336)

While there is a lack of research on how doctors communicate hope while trying to maintain realism, (336) some communication strategies have been studied and reported in literature, especially in oncology (333,337) and intensive care (255,256), which may be transferable to the major stroke setting. For example, delivering honest medical information sensitively, communicating continued support and providing information about choices including that of treatments seemed to maintain hope. (337,338) Specific behaviours by the doctor such as knowing about the patient's condition, using occasional humour and reassurance that their symptoms may be controlled also seemed to maintain hope. (333)

The hope-information paradox

I reported this phenomenon in Chapter 3. This is where the information preferences of patients were not consistent over time and six months later, many wished that they had been given realistic information earlier on after major stroke to help them prepare for the physical and psychological impact of major stroke.

This mismatch in information preferences over time has also been reported in the palliative care setting. (339)

While there may not be perfect solutions to addressing this paradox, some strategies have been studied. For example, communication strategies which maintain hope but deliver honesty (described above and in Chapter 3) may be helpful. (333,337) The concept of parallel planning may also be relevant. This is where two 'plans' run in parallel which allows for the unpredictability in the course of the condition; for example, for a patient with major stroke who may wish to return home, Plan A may be to return home with a care package and Plan B may be to go to a care home. The communication of multiple plans maintains hope by acknowledging the patient's wishes and preferences while providing information on alternatives (which may be more realistic) to plan for the future. Communicating the 'best case scenario' and 'worse case scenario' and 'Hope for the best but plan for the worst' also aim to maintain hope but provide an alternative plan for a possible more realistic consequence. (220,339) Relatedly, cultivating adaptive coping strategies while communicating prognosis may also be useful and could mitigate the distress some patients may experience when learning about their potential lack of recovery after major stroke. (329)

In stroke, where prognosis is often uncertain, the communication of prognostic uncertainty would be useful to manage patient information needs and expectations. I will detail this in Section 9.5.

Ongoing unmet needs

I found that many patients described feeling upset and distressed at six months and therefore, had ongoing emotional and support needs. My findings agree with existing literature in stroke which have shown that even years after a stroke, patients describe various physical limitations and perhaps relatedly, psychological and support needs which contribute towards a suboptimal quality of life. (73,201) My findings re-iterate the need to assess and provide support to patients with major stroke, including but not limited to,

coming to terms with loss, depression, grief and changes in life participation. (73,340–342)

My work is not intended to find perfect solutions to these challenges. However, acknowledging the above areas and related challenges and considering recommendations I have provided (above and in individual chapters) based on evidence from other settings may allow doctors to support patients with major stroke better.

9.4 Involvement of family members in decision-making where the patient lacked capacity

Another area I referred to in Chapter 1 was the involvement of proxies (often family members) in decision-making regarding treatments where the patient lacked capacity. In my study, this is limited to the appropriateness of life extending treatments in patients who were severely ill after major stroke.

As described in Chapter 4, my findings confirm existing literature that family members consider patient preferences and pre-stroke state of health when being involved in shared decision-making (76,243) and some family members may find this process upsetting and challenging. (223,225,226)

The emotional needs of family members, both in the early period and later on, after a major stroke has also been described in another longitudinal qualitative study. (73) The grieving process of family members after the loss of their loved one is also important to acknowledge and understand to allow individuals to be referred for further support.(73,201,231,343)

As described in Chapter 4, we identified a treatment decision spectrum based on the patients' state of health prior to the stroke and any stated preferences which appeared to influence family members' information and support needs. While we accept that people may not respond in predictable ways, the knowledge that treatment decisions lie on a spectrum may allow doctors to prepare for discussions regarding prognosis with family members. I will discuss communication strategies in the section 9.5.

9.5 Communication between doctors and family members where the patient lacked capacity after major stroke

While feedback on communication between doctors and family members was largely positive, I found some instances where this may have been improved (Chapter 5).

Doctors may find it useful to use a framework to guide them through decision-making that is both ethical and evidence based. (344) Briefly, the recommended four step approach would involve: a) A focus on the condition (i.e. stroke): the estimation of prognosis, treatment gains and burdens b) A focus on the individual: the values and preferences of the patient c) A focus on the healthcare team: situational awareness of what may be appropriate or futile for the individual d) A focus on the doctor-patient relationship: the goals of care in-keeping with patient values. (344)

Effective communication would be key in shared decision-making. I have described strategies on communicating hope and honesty in Chapter 3 and in Section 9.3. Having a structure in communication; for example, using the REDMAP (Ready, Expect, Diagnosis, Matters, Actions, Plan) strategy (345), serious illness conversation guide (346) or using the DECIDE (Define the decision, Explain the situation, Consider available options, Invite views, Decide together, Evaluate the decision) model (347) may be helpful for doctors when involving patients or family members in shared decision-making.

Well studied illness trajectories of cancer (short decline), heart failure (episodic decline), dementia and frailty (prolonged decline) (348–350) allow patients, families and healthcare professionals to understand and prepare for how function may decline and advance to death. However, these trajectories are not suitable for those who have had a stroke, where patients and families are largely unprepared and face a trajectory that often results in early death or a more uncertain prognosis that may resemble the chronic disease trajectory with prolonged dwindling. (331) Understanding this pattern and using strategies to communicate uncertainty and the range of possible

outcomes are important. There is evidence from studies in oncology to suggest that family members wish to know that it was possible that the patient was sick enough to die, communication of uncertainty increases satisfaction of care, leaves room for hope, increases trust in doctors and allows for preparation that the patient may not survive. (252,335,339,351) Similar to the hope-information paradox I described in Section 9.3, family members who resist knowing that the patient was sick enough to die have also reported a retrospective understanding that they would have benefited from prognostic information and that death was a possibility. (339)

However, doctors may find the communication of uncertainty difficult (53) and are often poor at initiating discussions about end of life care. (338,339) Being explicit about this uncertainty (338) and using affective sensitive language would be helpful.(352) Using strategies (described above) such as communicating ‘Best case worse case scenarios’ and ‘Hope for the best but plan for the worst’ also increase prognostic awareness while alluding to uncertainty. (220)

I was unable to draw any definite conclusions on the influence of doctors’ views or communication on the treatments agreed for the patient. This was related to my study design (questionnaires) which did not explore the contexts in which answers were provided and small sample size.

While communication training for doctors may be helpful to familiarise and support doctors in various communication strategies,(353) feedback from patients and family members are important for continually improving communication and professional development. A validated tool such as CollaboRATE, a brief patient reported measure, may be useful to evaluate shared decision-making. (290,291)

9.6 Presentation of prognostic information

In Chapter 1, I described how information may be presented to patients and families to aid understanding and decision-making. In Chapter 6, I reported how the preferences for presentation of information varied between different individuals. I also found that many family members found viewing brain scans of the patient useful to their understanding of the patient's poor prognosis and therefore, it is likely that the treatment would not be successful.

The understanding of prognosis and treatment goals is influenced by many factors. As I described in Chapter 4, previous experiences, emotions and information from other sources (e.g. friends and family) may influence how people understand risk of accepting or declining certain treatments. While there is evidence advocating the use of pictographs to increase understanding, (354) presenting information in natural frequencies rather than percentages, and absolute risk reduction rather than relative (355) and communicating using quantitative information rather than qualitative, as I reported, different individuals asked for different ways for information to be presented to them.

Therefore, doctors are recommended to use balanced framing (to convey both loss and gain messages) when explaining benefits and harms to people. It may also be helpful to provide the same information in both simple frequencies and in percentages and presenting both absolute and relative risk reductions of treatment for individuals to make an informed decision. Using pictographs and graphs may be useful. (293,356)

Two main limitations of my work are: 1) my findings were based on methodology (questionnaires and verbal feedback) which did not capture the contexts in which opinions were provided, and were based on hypothetical scenarios rather than real time information. 2) The lack of patient feedback on information presentation. This was because patients were too distressed and unable to engage in a shared decision-making process in the early period after a major stroke (as described in Chapter 3).

Future research should focus on obtaining patient feedback at a different time point in their post- stroke journey and consider the use of communication aids to try and maximise patient involvement. This may involve the use of simple aids such as alphabet boards, communication charts and books or more complex aids such as the E-Tran Frame (a specialised chart) and a communication passport that the person could use to communicate their likes and dislikes to others. Electronic aids such as Voice Output Communication Aids to play messages aloud, symbol sets e.g. talking mats where sets of picture symbols represent a range of vocabulary and subject matter and smartphone apps where symbols may be picked and text or sound added to them may also be useful for some patients with aphasia.(357,358)

9.7 Prediction of outcomes after major stroke

As I have described in several areas in my thesis, prognostic information may be useful to patients and families to aid their understanding of the impact of major stroke or be involved in shared decision-making. (91)

To communicate the range of possible outcomes after a major stroke, and the uncertainty associated with this, doctors need to have an idea of the possible trajectory and be able to make predictions based on individual patient characteristics. Guidelines recommend the use of prediction models to complement clinical judgement when making prognostic estimates. (26)

Further to what I have described above, I describe two main areas from my work relevant to prognostic information after major stroke.

Describing prognosis by specific abilities

As I reported in Chapter 2, patients in the same disability level varied with respect to their specific abilities. Based on this finding and feedback from family members (reported in Chapter 6), I report that describing, and communicating prognosis expressed in terms of specific abilities may be more appropriate rather than using terms such as dependency or disability

(based on patient outcome scales such as mRs) which may have varied meanings to people. However, in the presence of different measures and cut-offs to define each specific ability, a standardised approach would need to be agreed. Dichotomising outcomes to 'good' and 'poor' based on how outcomes are reported in trials may not reflect individual preferences and therefore, further co-production work with adequate patient involvement would be required.

Prediction of specific abilities at six months after major stroke

In Chapter 7 I described the development and external validation of new prognostic models to predict specific abilities after major stroke. I showed that we could predict some specific abilities (to walk, to eat normally, to live without major anxiety/depression and to live at home) at six months after major stroke reasonably well. I reported models performances at accuracies (PPV 50%, 80%, 90%) chosen by family members (n=24). (Chapter 4)

As I reported in Chapter 1, although there are existing prognostic models which predict specific abilities after stroke e.g. mobility, recovery of arm function and depression, many have limited use due to lack of external validation.(94–97)

My models would require further evaluation as I described in Chapter 7. In the future, they may have some uses to doctors, patients and family members.

For instance,

If the models are found to be as good as an experienced stroke physician's estimate of prognosis, doctors may use these models as a 'sense-check' of their judgement of the patient's prognosis before approaching patients or family members to discuss the patient's likely prognosis. This would reduce variation in communication of information between different doctors.

Patients may find the information sufficient to provide them with hope. It is possible that the knowledge of a possible chance (e.g. 50%, 80% or 90%) of having a specific ability at six months may offer them hope. By providing patients a quantifiable chance of an outcome, doctors may be able to balance their communication of hope with being realistic.

Family members may find predictions helpful to understand the impact of major stroke, discuss patient preferences and participate in shared decision-making or maintain hope that the patient may survive the major stroke.

9.8 Strengths and limitations

Within each chapter (1 to 8), I detailed the strengths and limitations of my work relevant to that chapter. Below, I describe some broader strengths and limitations of my work.

9.8.1 Strengths

By using a combination of research methodologies, my work has provided both a broad and deep understanding of various aspects relating to treatment decision-making after major stroke. The insights I gained into patients' and families' experiences and needs could not have been obtained from a purely quantitative study.

9.8.2 Limitations

A major limitation of my work is generalisability; the study was performed in a single site and patients with minor stroke were excluded. The latter was due to my inclusion criteria and aim of my study. Those who opted into qualitative interviews may also have been patients or family members who felt they were more able to discuss their experiences. Furthermore, conclusions and recommendations from these interviews were based on self-reporting by participants rather than by direct observations.

Time constraints of my fellowship meant that both the qualitative and quantitative aspects of my study were performed concurrently. Therefore, some theories or hypothesis were developed based on expert opinion (of

stroke professionals in the hospital where recruitment took place) before the start of the study (e.g. likely importance of predicting patient specific abilities after major stroke) rather than emerging from my data. In hindsight, if I were not restricted by the duration of my fellowship, I would have performed the qualitative aspect of my research first and used this to inform my quantitative work.

9.9 Personal reflection

In the last three years, I have developed skills in different research methodologies. I have learnt that qualitative and quantitative methodologies can complement each other and result in stronger evidence when interventions are being developed to promote patient care. I have learnt to appreciate that narrative can add meaning and context to numbers while numbers can be used to add precision to words and narrative.

As a clinical doctor, I initially thought that qualitative interviewing would be simple as I communicate with patients and family members on a daily basis and have obtained positive formal and informal feedback of my communication skills over the last ten years. However, as I progressed in my learning, I grew to realise that conducting qualitative interviews was very challenging.

The change in my role from a doctor to a researcher meant that I could not, and also was no longer expected, to provide information, test results or management plans. My role had changed to one where I listened, explored experiences and needs and in many instances, provided a shoulder to cry on. Furthermore, I had to ensure that my pre-conceived views as a doctor did not influence the interpretation of my data or the way I conducted the interviews. This meant that I paid extra attention to my verbal and non-verbal communication, trying to ensure that I was not influencing the narrative participants were giving me. I had not previously anticipated how emotional it may be to gain such in-depth insight into people's lives and experiences; and

by keeping a reflexive diary, I was able to reflect on my experiences on a regular basis.

Through my quantitative work, I have developed data management and statistical analysis skills. I feel more comfortable working with numbers and using statistical programs to perform basic analyses.

Performing a mixed methods study required a lot of organisation on my part. As I have described, I single handed-ly recruited over 400 patients into a cohort study while performing qualitative interviews, administering questionnaires, doing data entry and checking and analysing my data. I did find this quite overwhelming at times, but ensured that I kept on top of my tasks by setting daily achievable goals. The encouragement and support I obtained from my supervisors was immensely helpful. I can say for sure that this period of research has improved my prioritisation and organisational skills.

Writing is something that I have always found challenging. Therefore, to take on a mixed methods study where the style of reporting quantitative and qualitative data are so different was a daunting task. I have not found this easy, and appreciate the guidance, support and patience my supervisors have endured through my programme of work.

9.10 Future related research

Several further areas of research arise from this thesis. I have summarised these below:

1. Future work should find a way of standardising the definitions of each specific ability. An online survey to health professionals looking after patients with major stroke may be an appropriate first step. Co-production work with people who have had a stroke and their family members to understand their definition of ‘good’ and ‘poor’ outcomes would also be useful.

2. Future qualitative research could consider investigating the views and needs of stroke patients and family members from different socio-economic and ethnic minority backgrounds who may have different experiences, information and support needs. Interviews with patient-family member pairs (where the patient has retained capacity after major stroke) may also provide insight into the similarities and/or differences in their experiences.
3. Work needs to focus on the psychological needs of patients and family members. This may involve further qualitative interviews or focus groups with patients (at an appropriate time) and family members to elicit how best their needs may be met in hospital and the community. Once this is identified, opinions of health economists and NHS health service managers would need to be sought on how best current services may be adapted or expanded to facilitate patient and family member needs.
4. Qualitative interviews with doctors who look after patients with major stroke could give us important insight into the challenges they face in involving patients and family members in decision-making and how they currently cope with these challenges. This could allow development of strategies to support doctors in undertaking challenging discussions.
5. By observing communication between doctors and patients/ family members and performing interviews with both parties based on the provision of real time information, we would gain more useful information on how some treatment decisions were made and how communication may be improved between them.
6. Future prognostic models may be developed with specific predictors (e.g. prior history of anxiety/depression to predict anxiety/depression at six months after major stroke) and consider predicting anxiety and depression separately. Models may also consider adding data on change in patient functional status.

7. The models we have developed may be externally validated in larger cohorts of patients with major stroke and evaluated against predictions made by experienced stroke physicians.

9.11 A brief summary and future plans

Shared decision-making in the early period after major stroke can be challenging especially when many patients may not be able to engage in this process early on, patients and family members may look for hope and certainty at a time when prognosis is uncertain and the clinical condition of the patient may change rapidly. While there are no easy answers or a perfect approach to shared decision-making in major stroke, my work has highlighted some challenges and we have provided some recommendations to facilitate this process. The key is effective communication especially that of prognostic uncertainty, and of reassessment of decisions based on the patient's clinical condition.

Based on the results from this study and the review of existing literature, we propose the development of a communication tool to improve information provision to patients and families. This tool would contain information in different formats to suit different individuals. For example, the presentation of diagnosis of stroke in pictures (including brain scans) and words, the presentation of prognostic information in words, ratios, percentages and pictographs, the communication of uncertainty with prompts of structure for doctors and that of treatment choices, focusing on patient preferences.

With the advice and help from IT experts, we have developed a prototype of this communication tool to deliver tailored information to patients and families called 'Tailored talks'. To further develop this tool, we would require input from patients and family members and use co-production techniques. To do so, we have received a grant from the Lothian Health Board Endowment fund.

Once developed, the tool would need to be evaluated in a trial. Outcomes measured may include patient and family member satisfaction with

communication and achieving outcomes in keeping with their preferences. Measuring these outcomes may require a variety of techniques including HRQoL assessments, focus groups and further qualitative interviews. Over the next year, I will play an active role in the development of this tool and later, apply for post-doctoral fellowships to evaluate this tool.

9.12 A final note

My research has explored various aspects relating to shared decision-making regarding treatments in major stroke. I have highlighted several implications for clinical practice and indicated areas for future research. An intervention that may optimise information provision to patients and families is the use of a communication tool to deliver tailored information that is easily communicated and understood. As I described, over the next year, I will focus on developing and refining this tool.

References

1. World Health Organisation. Cerebrovascular disorders: a clinical and research classification. 1978. p. 1–84.

2. Feigin VL, Roth GA, Naghavi M, Parmar P, Krishnamurthi R, Chugh S, et al. Global burden of stroke and risk factors in 188 countries, during 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet Neurol [Internet]. 2016;15(9):913–24. Available from: http://dx.doi.org/10.1016/S1474-4422(16)30073-4

3. Anderson CS. The global burden of stroke : persistent and disabling The global burden of neurological disorders. Lancet Neurol [Internet]. 2019;18(5):417–8. Available from: http://dx.doi.org/10.1016/S1474-4422(19)30030-4

4. Stroke Association. State of the Nation Stroke Statistics [Internet]. 2018 [cited 2019 Nov 15]. Available from: https://www.stroke.org.uk/system/files/sotn_2018.pdf

5. Information Services Division. Quality and outcomes framework: Prevalence, achievement, payment and exceptions data for Scotland. NHS Scotland. 2063.

6. Welsh Government. Statistical first release: general medical services contract: Quality and Outcomes Framework Statistics for Wales. 2018.

7. Feigin VL, Norrving B, Mensah GA. Global Burden of Stroke. Circ Res. 2017;120(3):439–48.

8. Mensah GA, Norrving B, Feigin VL. The Global Burden of Stroke. Neuroepidemiology. 2015;45(3):143–5.

9. Saka Ö, Mcguire A, Wolfe C. Cost of stroke in the United Kingdom. Age Ageing. 2009;38(1):27–32.

10. Van Swieten JC, Koudstaal PJ, Visser MC, Schouten H, Van Gijn J.

Interobserver agreement for the assessment of handicap in stroke patients. Stroke. 1988 May;19(5):604–7.

11. Thompson DD, Murray GD, Sudlow CLM, Dennis M, Whiteley WN. Comparison of statistical and clinical predictions of functional outcome after ischemic stroke. PLoS One [Internet]. 2014;9(10):e110189. Available from: http://www.scopus.com/inward/record.url?eid=2-s2.0-84907842493&partnerID=tZOtx3y1

12. Quinn TJ, Langhorne P, Stott DJ. Barthel index for stroke trials: Development, properties, and application. Stroke. 2011;42(4):1146–51.

13. Sulter G, Steen C, De Keyser J. Use of the Barthel index and modified Rankin scale in acute stroke trials. Stroke. 1999;30(8):1538–41.

14. Townsend, N. W., K.; Bhatnagar, P.; Smolina, K.; Nichols, M.; Leal, J.; Luengo-Fernandez, R.; Rayner M. No Title. In: Coronary heart disease Statistics 2012 edition: British Heart Foundation, London. 2012. p. 107.

15. Evers SMAA, Struijs JN, Ament AJHA, Van Genugten MLL, Jager JC, Van Den Bos GAM. International comparison of stroke cost studies. Stroke. 2004;35(5):1209–15.

16. Patel A, Berdunov V, King D, Quayyum Z, Wittenberg R, Knapp M. Current, future and avoidable costs of stroke in the UK. 2017;12. Available from: https://www.stroke.org.uk/sites/default/files/costs_of_stroke_in_the_uk_report_-executive_summary_part_2.pdf

17. The Intercollegiate Stroke working Party. National clinical guideline for stroke [Internet]. Royal College of Physicians. 2012. Available from: https://www.rcplondon.ac.uk/sites/default/files/national-clinical-guidelines-for-stroke-fourth-edition.pdf

18. NAO Report (HC 291 2009-2010): Department of Health: Progress in improving stroke care (Full Report) - 0910291.pdf [Internet]. [cited 2015

Dec 24]. Available from: https://www.nao.org.uk/wp-content/uploads/2010/02/0910291.pdf

19. Chang P, Prabhakaran S. Recent advances in the management of acute ischemic stroke. F1000 Res. 2018;6:484.

20. King's College. Sentinel Stroke National Audit Programme (SSNAP) Clinical audit. 2019.

21. Campbell BC V, Muir K, Demchuk AM, Bracard S, Davalos A, Guillemin F, et al. Rapid Alteplase Administration Improves Functional Outcomes in Patients With Stroke due to Large Vessel Occlusions. Stroke. 2019;50:645–51.

22. Goyal M, Menon BK, van Zwam WH, Dippel DWJ, Mitchell PJ, Demchuk AM, et al. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. Lancet (London, England). 2016;387(10029):1723–31.

23. Dennis M, Sandercock P, Graham C, Forbes J. The Clots in Legs or sTockings after Stroke (CLOTS) 3 trial: A randomised controlled trial to determine whether or not intermittent pneumatic compression reduces the risk of post-stroke deep vein thrombosis and to estimate its cost-effectiveness. Vol. 19, Health Technology Assessment. 2015.

24. Dennis M, Lewis S, Cranswick G, Forbes J. FOOD: A multicentre randomized trial evaluating feeding policies in patients admitted to hospital with a recent stroke. Health Technol Assess (Rockv). 2006;10:1–91.

25. Yang M-H, Lin H-Y, Fu J, Roodrajeetsing G, Shi S-L, Xiao S-W. Decompressive hemicraniectomy in patients with malignant middle cerebral artery infarction: A systematic review and meta-analysis. Surgeon [Internet]. 2015 Aug [cited 2015 Dec 24];13(4):230–40.

Available from: http://www.sciencedirect.com/science/article/pii/S1479666X15000037

26. Holloway RG, Arnold RM, Creutzfeldt CJ, Lewis EF, Lutz BJ, McCann RM, et al. Palliative and End-of-Life Care in Stroke: A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association. Stroke [Internet]. 2014;45:1887–916. Available from: http://stroke.ahajournals.org/content/early/2014/03/27/STR.0000000000000015.abstract

27. Stroke Unit Trialists' collaboration. Organised inpatient (stroke unit) care for stroke (Review). Cochrane Database Syst Rev. 2013;(9):CD000197.

28. Hankey GJ, Warlow CP. Treatment and secondary prevention of stroke: Evidence, costs, and effects on individuals and populations. Lancet. 1999;354(9188):1457–63.

29. General Medical Council. Attitudes towards consent and decision making. 2018.

30. Chief Medical Officer. Realistic Medicine: Scottish Government [Internet]. 2014. Available from: https://www.gov.scot/publications/chief-medical-officers-annual-report-2014-15/

31. Slot KB, Berge E, Dorman P, Lewis S, Dennis M, Sandercock P. Impact of functional status at six months on long term survival in patients with ischaemic stroke: prospective cohort studies. Br Med J. 2008;1–7.

32. Alexander P, Heels-Ansdell D, Siemieniuk R, Bhatnagar N, Chang Y, Fei Y, et al. Hemicraniectomy versus medical treatment with large MCA infarct: A review and meta-analysis. BMJ Open. 2016;6(11):e014390.

33. Dennis M, Graham C, Smith J, Forbes J, Sandercock P. Which stroke patients gain most from intermittent pneumatic compression: further analyses of the CLOTS 3 trial. Int J Stroke [Internet]. 2015;10:103–7. Available from: http://doi.wiley.com/10.1111/ijs.12598

34. Dennis M, Sandercock P, Reid J, Graham C, Murray G, Venables G, et al. The effect of graduated compression stockings on long-term outcomes after stroke: The CLOTS trials 1 and 2. Stroke. 2013;44:1075–9.

35. Dennis M, Sandercock P, Reid J, Graham C, Forbes J, Murray G. Effectiveness of intermittent pneumatic compression in reduction of risk of deep vein thrombosis in patients who have had a stroke (CLOTS 3): a multicentre randomised controlled trial. Lancet. 2013;382:516–24.

36. Dennis M, Lewis S, Cranswick G, Forbes J. FOOD: a multicentre randomised trial evaluating feeding policies in patients admitted to hospital with a recent stroke. Health Technol Assess. 2006;10(2):1–120.

37. Berzon R, Hays RD, Shumaker SA. International use, application and performance of health-related quality of life instruments. Qual Life Res. 1993 Dec;2(6):367–8.

38. Brooks R, Group E. EuroQol : the current state of play *. 1996;37:53–72.

39. Szende Williams A. A. Measuring Self-Reported Population Health, An International Perspective based on EQ-5D. Demogr Res [Internet]. 2004; Available from: https://euroqol.org/wp-content/uploads/2016/10/Measuring_Self-Reported_Population_Health_-_An_International_Perspective_based_on_EQ-5D.pdf%0Ahttps://euroqol.org/wp-content/uploads/2016/10/Measuring_Self-

Reported_Population_Health_-_An_International_Perspe

40. Chaisinanunkul N, Adeoye O, Lewis RJ, Grotta JC, Broderick J, Jovin TG, et al. Adopting a Patient-Centered Approach to Primary Outcome Analysis of Acute Stroke Trials Using a Utility-Weighted Modified Rankin Scale. Stroke. 2015;46(8):2238–43.

41. Ali M, MacIsaac R, Quinn TJ, Bath PM, Veenstra DL, Xu Y, et al. Dependency and health utilities in stroke: Data to inform cost-effectiveness analyses. Eur Stroke J. 2017;2(1):70–6.

42. Broderick JP, Adeoye O, Elm J. Evolution of the Modified Rankin Scale and Its Use in Future Stroke Trials. Stroke. 2017;48:2007–12.

43. Rivero-Arias O, Ouellet M, Gray A, Wolstenholme J, Rothwell PM, Luengo-Fernandez R. Mapping the modified rankin scale (mRS) measurement into the generic EuroQol (EQ-5D) health outcome. Med Decis Mak. 2010;30(3):341–54.

44. General Medical Council. Treatment and care towards the end of life: good practice in decision making. Gen Med Counc [Internet]. 2010;1–85. Available from: https://www.gmc-uk.org/-/media/documents/treatment-and-care-towards-the-end-of-life---english-1015_pdf-48902105.pdf%0Ahttps://www.gmc-uk.org/Treatment_and_care_towards_the_end_of_life___English_1015.pdf_48902105.pdf%0Ahttp://www.gmc-uk.org/static/document

45. Holloway RG, Arnold RM, Creutzfeldt CJ, Lewis EF, Lutz BJ, McCann RM, et al. Palliative and end-of-life care in stroke: A statement for healthcare professionals from the American heart association/american stroke association. Stroke. 2014;45(6):1887–916.

46. Creaney R. What Works to Support and Promote Shared Decision Making: A synthesis of recent evidence What Works to Support and Promote Shared Decision Making: A synthesis of recent evidence.

2019.

47. National Institute for Health and Care. National Institute for Health and Care Excellence. Addendum to Clinical Guideline CG92, Reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients admitted to hospital (Chapter 24- stroke patients). 2015.

48. NICE. Venous thromboembolism in over16s : reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism. 2019.

49. Visvanathan A, Dennis M, Mead G, Whiteley WN, Lawton J, Doubal FN. Shared decision making after severe stroke—How can we improve patient and family involvement in treatment decisions? Int J Stroke. 2017;12(9):920–2.

50. Torke AM, Alexander GC, Lantos J. Substituted judgment: The limitations of autonomy in surrogate decision making. J Gen Intern Med. 2008;23(9):1514–7.

51. Fagerlin A, Ditto PH, Danks JH, Houts RM, Smucker WD. Projection in surrogate decisions about life-sustaining medical treatments. Health Psychol. 2001;20(3):166–75.

52. Majesko A, Hong SY, Weissfeld L, White DB. Identifying family members who may struggle in the role of surrogate decision maker. Crit Care Med. 2012;40(8):2281–6.

53. Doubal F, Cowey E, Bailey F, Murray SA, Borthwick S, Somerville M, et al. The key challenges of discussing end-of-life stroke care with patients and families: A mixed-methods electronic survey of hospital and community healthcare professionals. J R Coll Physicians Edinb. 2018;48(3):217–24.

54. Epner DE, Baile WF. Patient-centered care: The key to cultural competence. Ann Oncol. 2012;23(SUPPL.3):33–42.

55. Schouten BC, Meeuwesen L. Cultural differences in medical communication: A review of the literature. Patient Educ Couns. 2006;64(1–3):21–34.

56. Brennan PF, Strombom I. Improving Health Care by Understanding Patient Preferences: The Role of Computer Technology. J Am Med Inform Assoc [Internet]. 1998;5(3):257–62. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC61299/%5Cnhttp://www.ncbi.nlm.nih.gov/pmc/articles/PMC61299/pdf/0050257.pdf

57. Creutzfeldt CJ, Holloway RG. Treatment decisions after severe stroke: Uncertainty and Biases. Stroke. 2012;43(12):3405–8.

58. Elwyn G, Frosch DL, Kobrin S. Implementing shared decision-making: Consider all the consequences. Implement Sci [Internet]. 2016;11(1). Available from: http://dx.doi.org/10.1186/s13012-016-0480-9

59. Frosch DL, Kaplan RM. Shared decision making in clinical medicine: Past research and future directions. Am J Prev Med. 1999;17(4):285–94.

60. Guadagnoli E, Ward P. Patient participation in decision-making. Soc Sci Med [Internet]. 1998;47(3):329–39. Available from: http://www.opticsinfobase.org/abstract.cfm?uri=SOLED-2012-JM1A.1

61. Swift J, Callahan J. The Impact of Client Treatment preferences on outcome: a meta analysis. J Clin Psychol. 2009;65:368–81.

62. Wilson L, Loucks A, Bui C, Gipson G, Zhong L, Schwartzburg A, et al. Patient centered decision making: Use of conjoint analysis to determine risk-benefit trade-offs for preference sensitive treatment choices. J Neurol Sci [Internet]. 2014;344(1–2):80–7. Available from: http://dx.doi.org/10.1016/j.jns.2014.06.030

63. Mead GE, O'Keeffe ST, Jack CI, Maestri-Banks AM, Playfer JR LM. What factors influence patient preferences regarding cardiopulmonary

resuscitation? J R Coll Physicians L [Internet]. 1995;29(4):295–8. Available from: https://www.ncbi.nlm.nih.gov/pubmed/7473323

64. Wilson T, Miller J, Teare S, Penman C, Pearson W, Marlett NJ, et al. Patient perspectives on engagement in decision-making in early management of non-ST elevation acute coronary syndrome: A qualitative study. BMC Med Inform Decis Mak. 2017;17(1):1–7.

65. Zussman R. Sociological Perspectives on Medical Ethics and Decision-Making. Annu Rev Sociol [Internet]. 1997 Aug 1;23(1):171–90. Available from: https://doi.org/10.1146/annurev.soc.23.1.171

66. Friedrichs A, Spies M, Härter M, Buchholz A. Patient preferences and shared decision making in the treatment of substance use disorders: A systematic review of the literature. PLoS One. 2016;11(1):1–18.

67. Sprangers MAG, Schwartz CE. Integrating Response Shift Into Health Related Quality of Life Research a Theorical Model.Pdf. Soc Sci Med. 1999;48:1507–15.

68. Patrick DL, Pearlman RA, Starks HE, Cain KC, Cole WG, Uhlmann RF. Validation of preferences for life-sustaining treatment: implications for advance care planning. Ann Intern Med. 1997 Oct;127(7):509–17.

69. Pearlman RA, Cain KC, Starks H, Cole WG, Uhlmann RF, Patrick DL. Preferences for life-sustaining treatments in advance care planning and surrogate decision making. J Palliat Med. 2000;3(1):37–48.

70. Post PN, Stiggelbout AM, Wakker PP. The Utility of Health States After Stroke : A Systematic Review of the Literature. Stroke [Internet]. 2001 Jun 1 [cited 2015 Dec 24];32(6):1425–9. Available from: http://stroke.ahajournals.org/content/32/6/1425.long

71. Holloway RG, Benesch CG, Burgin WS, Zentner JB. Prognosis and decision making in severe stroke. JAMA. 2005 Aug;294(6):725–33.

72. Sarnowski B Von, Guerra WK, Kohlmann T, Moock J, Khaw A V, Kessler C, et al. Long-term health-related quality of life after decompressive hemicraniectomy in stroke patients with life-threatening space-occupying brain edema. Clin Neurol Neurosurg. 2012;114(6):627–33.

73. Kendall M, Cowey E, Mead G, Barber M, McAlpine C, Stott DJ, et al. Outcomes, experiences and palliative care in major stroke: A multicentre, mixed-method, longitudinal study. Cmaj. 2018;190(9):E238–46.

74. Scottish Parliament. Adults with Incapacity (Scotland) Act 2000: General Information. Scottish Parliam [Internet]. 2000;(April):1–115. Available from: http://www.scotland.gov.uk/Publications/2006/03/07

75. British Medical Association. Best interests decision making for adults who lack capacity toolkit [Internet]. A toolkit for doctors working in England and Wales. 2005 [cited 2020 May 15]. p. 1–38. Available from: https://www.bma.org.uk/advice-and-support/ethics/adults-who-lack-capacity/best-interests-decision-making-for-adults-who-lack-capacity-toolkit

76. Arnold RM, Kellum J. Moral justifications for surrogate decision making in the intensive care unit: implications and limitations. Crit Care Med. 2003;31:S347-53.

77. Brudney D. Choosing for another: beyond autonomy and best interests. 2009.

78. Tonelli MR. Substituted judgment in medical practice: evidentiary standards on a sliding scale. J Law Med Ethics. 1997;25(1):2,22-29.

79. Shalowitz DI, Garrett-Mayer E, Wendler D. The accuracy of surrogate decision makers: a systematic review. Arch Intern Med. 2006;166(5):493–7.

80. Sachs GA, Stocking CB, Stern R, Cox DM, Hougham G, Sachs RS. Ethical aspects of dementia research: informed consent and proxy consent. Clin Res. 1994 Oct;42(3):403–12.

81. Bryant J, Skolarus LE, Smith B, Adelman EE, Meurer WJ. The accuracy of surrogate decision makers: Informed consent in hypothetical acute stroke scenarios. BMC Emerg Med. 2013;13(1).

82. Hare J, Pratt C, Nelson C. Agreement between patients and their self-selected surrogates on difficult medical decisions. Arch Intern Med. 1992;152(5):1049–54.

83. Uhlmann RF, Pearlman RA, Cain KC. Physicians' and spouses' predictions of elderly patients' resuscitation preferences. J Gerontol. 1988 Sep;43(5):M115-21.

84. Anderson WG, Arnold RM, Angus DC, Bryce CL. Passive decision-making preference is associated with anxiety and depression in relatives of patients in the intensive care unit. J Crit Care [Internet]. 2009;24(2):249–54. Available from: http://dx.doi.org/10.1016/j.jcrc.2007.12.010

85. Heyland DK, Cook DJ, Rocker GM, Dodek PM, Kutsogiannis DJ, Peters S, et al. Decision-making in the ICU : perspectives of the substitute decision-maker. Intensive Care Med. 2003;29:75–82.

86. Johnson SK, Bautista CA, Hong SY, Weissfeld L, White DB. An Empirical Study of Surrogates ' Preferred Level of Control over Value-laden Life Support Decisions in Intensive Care Units. Am J Respir Crit Care Med. 20011;183:915–20.

87. Sehgal A, Galbraith A, Chesney M, Schoenfeld P, Charles G, Lo B. How strictly do dialysis patients want their advance directives followed? JAMA. 1992 Jan;267(1):59–63.

88. Meeker MA. Family surrogate decision making at the end of life:

Seeing them through with care and respect. Qual Health Res. 2004;14(2):204–25.

89. Coulter MA. The needs of family members of patients in intensive care units. Intensive Care Nurs. 1989;5(1):4–10.

90. Wilkinson P. A qualitative study to establish the self-perceived needs of family members of patients in a general intensive care unit. Intensive Crit Care Nurs. 1995;11(2):77–86.

91. Counsell C, Dennis M, Mcdowall M. Predicting functional outcome in acute stroke: comparison of a simple six variable model with other predictive systems and informal clinical prediction. J Neurol Neurosurg Psychiatry. 2004;75:401–5.

92. Counsell C, Dennis M. Systematic review of prognostic models in patients with acute stroke. Cerebrovasc Dis. 2001;12(3):159–70.

93. Teale EA, Forster A, Munyombwe T, Young JB. A systematic review of case-mix adjustment models for stroke. Clin Rehabil. 2012;26:771–86.

94. Smith MC, Barber PA, Stinear CM. The TWIST Algorithm Predicts Time to Walking Independently After Stroke. Neurorehabil Neural Repair. 2017;31(10–11):955–64.

95. Kwah LK, Herbert RD. Prediction of walking and arm recovery after stroke: A critical review. Brain Sci. 2016;6(4).

96. Liu R, Yue Y, Jiang H, Lu J, Wu A, Geng D, et al. A risk prediction model for post-stroke depression in Chinese stroke survivors based on clinical and socio-psychological features. Oncotarget. 2017;8(38):62891–9.

97. De Man-Van Ginkel JM, Hafsteinsdóttir TB, Lindeman E, Ettema RGA, Grobbee DE, Schuurmans MJ. In-hospital risk prediction for post-stroke depression: Development and validation of the Post-Stroke

Depression Prediction Scale. Stroke. 2013;44(9):2441–5.

98. Mary Macleod, M E Turner, M H Barber, P Langhorne, H Dodds MSD. Scottish stroke care audit: can we use routine data to investigate optimal care of stroke patients? [Internet]. International Journal of Stroke. 2012 [cited 2019 Aug 25]. p. 1–64. Available from: https://abdn.pure.elsevier.com/en/publications/scottish-stroke-care-audit-can-we-use-routine-data-to-investigate-2

99. The FOOD Trial Collaboration. Performance of a Statistical Model to Predict Stroke Outcome in the Context of a Large , Simple , Randomized , Controlled Trial of Feeding. Stroke. 2003;34:127–33.

100. Counsell C, Dennis M, McDowall M, Warlow C. Predicting outcome after acute and subacute stroke: Development and validation of new prognostic models. Stroke. 2002;33:1041–7.

101. Reid J, Gubitz G, Dai D, Reidy Y, Christian C, Counsell C, et al. External validation of a six simple variable model of stroke outcome and verification in hyper-acute stroke. J Neurol Neurosurg Psychiatry. 2007;78:1390–1.

102. Quinn TJ, Drozdowska BA. News & Views future of prognosis research: Stroke prediction and the future of prognosis research [Internet]. Nature Reviews Neurology. Springer US; 2019. Available from: http://dx.doi.org/10.1038/s41582-019-0181-5

103. Eames S, Hoffmann T, Worrall L, Read S. Patient Education and Counseling Delivery styles and formats for different stroke information topics : Patient and carer preferences. Patient Educ Couns [Internet]. 2011;84(2):e18–23. Available from: http://dx.doi.org/10.1016/j.pec.2010.07.007

104. Dolan JG, Iadarola S. BMC Medical Informatics and Risk communication formats for low probability events : an exploratory study

of patient preferences. BMC Med Inform Decis Mak. 2008;8(14):1–9.

105. Edwards A, Elwyn G, Mulley A. Clinical review Explaining risks : turning numerical data into meaningful pictures. Br Med J. 2002;324:827–30.

106. Paling J. Strategies to help patients understand risks. Br Med J. 2003;327:745–8.

107. Holmes-rovner M. International Patient Decision Aid Standards (IPDAS): beyond decision aids to usual design of patient education materials. Vol. 10, Health Expectations. 2007.

108. Timmermans D, Molewijk B, Stiggelbout A, Kievit J. Different formats for communicating surgical risks to patients and the effect on choice of treatment. Patient Educ Couns. 2004;54:255–63.

109. Ancker JS, Senathirajah Y, Kukafka R SJ. Design Features of Graphs in Health Risk Communication : A Systematic Review. Am J Med Inf Assoc. 2006;13:608–18.

110. Lipkus IM, Hollands JG. The Visual Communication of Risk. Monogr Natl Cancer Inst. 1999;25:149–63.

111. Wills CE, Holmes-rovner M. Patient comprehension of information for shared treatment decision making : state of the art and future directions. 2003;50:285–90.

112. Trevena LJ, Hons M, Davey HM, Hons B, Hons MPH, Barratt A, et al. A systematic review on communicating with patients about evidence. J Eval Clin Pract. 2006;13–23.

113. Waters EA, Weinstein ND, Colditz GA, Emmons K. Formats for improving risk communication in medical tradeoff decisions. J Health Commun. 2006 Mar;11(2):167–82.

114. Feldman-stewart DEB, Kocovski N, Mcconnell BA, Brundage MD,

Mackillop WJ. Perception of Quantitative Information for Treatment Decisions. Med Decis Mak. 2000;20:228–38.

115. Sheridan SL, Michael P. A Randomized Comparison of Patients ' Understanding of Number Needed to Treat and Other Common Risk. J Gen Intern Med. 2003;18:884–92.

116. Gramelspacher GP, Zhou X, Hanna MP, Tierney WM. Preferences of Physicians and Their Patients for End-of-Life Care. J Gen Intern Med. 1997;12:346–51.

117. World Health Organisation. World Health Organization: Definition of disability [Internet]. WHO online. 2019 [cited 2019 Dec 3]. Available from: https://www.who.int/topics/disabilities/en/

118. Quinn TJ, Dawson J, Walters MR, Lees KR. Exploring the reliability of the modified Rankin scale. Stroke. 2009;40(3):762–6.

119. Visvanathan A, Mead G, Dennis M, Whiteley W, Doubal F, Lawton J. Maintaining hope after a disabling stroke: A longitudinal qualitative study of patients' experiences, views, information needs and approaches towards making treatment decisions. PLoS One. 2019;14:e0222500.

120. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: Guidelines for reporting observational studies. Int J Surg. 2014;12(12):1495–9.

121. Tunstall-Pedoe H et al. The World Health Organization MONICA project (Monitoring trends and determinants in cardiovascular disease): a major international collabortation. J Clin Epidemiol. 1988;41(2):105–14.

122. Schultz SK, Castillo CS, Kosier JT, Robinson RG. Generalized anxiety and depression. Assessment over 2 years after stroke. Am J Geriatr

Psychiatry. 1997;5(3):229–37.

123. Burvill P, Johnson G, Jamrozik K, Anderson C, Stewart-Wynne E. RISK FACTORS FOR POST-STROKE DEPRESSION. Int J Geriatr Psychiatry. 1997;12:219–26.

124. Park EY, Kim JH. An analysis of depressive symptoms in stroke survivors: Verification of a moderating effect of demographic characteristics. BMC Psychiatry. 2017;17(1):1–7.

125. Herzog H. The impact of pets on human health and psychological well-being: Fact, fiction, or hypothesis? Curr Dir Psychol Sci. 2011;20(4):236–9.

126. Friedmann E, Katcher AH, Lynch JJ, Thomas SA. Animal Companions and One-Year Survival of Patients After Discharge From a Coronary Care Unit-ment of Cardiology, provided cardiological interpretation and logistic support. Tearsheet requests to. Public Health Rep [Internet]. 1980;95(4):307–12. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1422527/pdf/pubhealthrep00128-0003.pdf

127. Fidel L, Carlos J, Cuenca P, Diego J, Zamorano P, Naranjo IC. Charlson Comorbidity Index in Ischemic Stroke and Intracerebral Hemorrhage as Predictor of Mortality and Functional Outcome after 6 Months. J Stroke Cerebrovasc Dis. 2013;22(7):214–8.

128. Bamford J, Sandercock P, Dennis M, Burn J, Warlow C. Classification and natural history of clinically identifiable subtypes of cerebral infarction. Lancet (London, England). 1991;337(8756):1521–6.

129. Weir CJ, Bradford APJ, Lees KR. The prognostic value of the components of the Glasgow Coma Scale following acute stroke. QJM. 2003;96(1):67–74.

130. Weir NU, Counsell CE, McDowall M, Gunkel A, Dennis MS. Reliability

of the variables in a new set of models that predict outcome after stroke. J Neurol Neurosurg Psychiatry. 2003;74(4):447–51.

131. Teale E, Young J, Dennis M, Sheldon T. Predicting patient-reported stroke outcomes: a validation of the six simple variable prognostic model. Cerebrovasc Dis Extra. 2013;3(1):97–102.

132. Patel M, Coshall C, Rudd AG, Wolfe CDA. Natural history and effects on 2 year outcomes of urinary incontinence after stroke. Stroke. 2001;32:122–7.

133. Bruno A, Akinwuntan AE, Lin C, Close B, Davis K, Baute V, et al. Simplified modified rankin scale questionnaire: Reproducibility over the telephone and validation with quality of life. Stroke. 2011;42:2276–9.

134. Brazier J, Connell J, Papaioannou D, Mukuria C, Mulhern B, Peasgood T, et al. A systematic review, psychometric analysis and qualitative assessment of generic preference-based measures of health in mental health populations and the estimation of mapping functions from widely used specific measures. Health Technol Assess (Rockv). 2014;18(34):1–188.

135. Longworth L, Yang Y, Young T, Mulhern B, Hernández Alava M, Mukuria C, et al. Use of generic and condition-specific measures of health-related quality of life in NICE decision-making: A systematic review, statistical modelling and survey. Health Technol Assess (Rockv). 2014;18(9):1–224.

136. Brazier J, Roberts J, Tsuchiya A, Busschbach J. A comparison of the EQ-5D and SF-6D across seven patient groups. Health Econ. 2004;13(9):873–84.

137. Golicki D, Niewada M, Buczek J, Karlin A, Kobayashi A, Janssen MF, et al. Validity of EQ-5D-5L in stroke. Qual life Res. 2015;24:845–50.

138. Quinn TJ, Elliott E, Langhorne P. Topical Review Cognitive and Mood

Assessment Tools for Use in Stroke. Stroke. 2018;49:483–90.

139. O'Sullivan D, O'Regan NA, Timmons S. Validity and Reliability of the 6-Item Cognitive Impairment Test for Screening Cognitive Impairment: A Review. Dement Geriatr Cogn Disord. 2016;42(1–2):42–9.

140. Brooke P, Bullock R. Validation of a 6 item cognitive impairment test with a view to primary care usage. Int J Geriatr Psychiatry. 1999;14(11):936–40.

141. Goring H, Baldwin R, Marriott A, Pratt H, Roberts C. Validation of short screening tests for depression and cognitive impairment in older medically ill inpatients. Int J Geriatr Psychiatry. 2004;19:465–71.

142. Villareal DT, Grant E, Miller JP, Storandt M, McKeel DW, Morris JC. Clinical outcomes of possible versus probable Alzheimer's disease. Neurology. 2003;61(5):661—667.

143. The National Institute of Neurological Disorders and Stroke. NIH Stroke Scale [Internet]. 2003. Available from: https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Preventing-Stroke/Stroke-Scales-and-Related-Information

144. Uyttenboogaart M, Stewart RE, Vroomen PCAJ, De Keyser J, Luijckx GJ. Optimizing cutoff scores for the Barthel Index and the modified Rankin Scale for defining outcome in acute stroke trials. Stroke. 2005;36(9):1984–7.

145. Yamaguchi T, Sano K, Takakura K, Saito I, Shinohara Y, Asano T, et al. Ebselen in acute ischemic stroke: a placebo-controlled, double-blind clinical trial. Ebselen Study Group. Stroke. 1998;29(1):12–7.

146. West JS. The 6CIT Dementia Test: How the test works.

147. Euroqol. EuroQOL Crosswalk calculator [Internet]. 2019 [cited 2018 Aug 3]. Available from: https://euroqol.org/eq-5d-instruments/eq-5d-5l-

about/valuation-standard-value-sets/crosswalk-index-value-calculator/

148. Harrison JK, McArthur KS, Quinn TJ. Assessment scales in stroke: Clinimetric and clinical considerations. Clin Interv Aging. 2013;8:201–11.

149. Quinn TJ, Dawson J, Walters MR, Lees KR. Reliability of the modified rankin scale: A systematic review. Stroke. 2009;40:3393–5.

150. Wilson JTL, Hareendran A, Hendry A, Potter J, Bone I, Muir KW. Reliability of the modified Rankin Scale across multiple raters: Benefits of a structured interview. Stroke. 2005;36(4):777–81.

151. Quinn TJ, Lees KR, Hardemark HG, Dawson J, Walters MR. Initial experience of a digital training resource for modified Rankin Scale assessment in clinical trials. Stroke. 2007;38(8):2257–61.

152. Bruno A, Shah N, Lin C, Close B, Hess DC, Davis K, et al. Improving Modified Rankin Scale Assessment With a Simplified Questionnaire. Stroke. 2010;41:1048–50.

153. Dennis M, Mead G, Forbes J, Graham C, Hackett M, Hankey GJ, et al. Effects of fluoxetine on functional outcomes after acute stroke (FOCUS): a pragmatic, double-blind, randomised, controlled trial. Lancet. 2019;393(10168):265–74.

154. Kwon S, Hartzema AG, Duncan PW, Lai S. Disability Measures in Stroke:Relationship Among the Barthel Index, the Functional Independence Measure, and the Modified Rankin Scale. Stroke. 2004;35:918–23.

155. Schepers VPM, Ketelaar M, Dekker J, Lindeman E, Ketelaar M, Dekker J, et al. Responsiveness of functional health status measures frequently used in stroke research. Disabil Rehabil. 2006;28(17):1035–40.

156. Schepers VPM, Ketelaar M, Visser-Meily JMA, Dekker J, Lindeman E. Responsiveness of functional health status measures frequently used in stroke research. Disabil Rehabil. 2006 Sep;28(17):1035–40.

157. De Deyn PP, De Reuck J, Deberdt W, Vlietinck R, Orgogozo JM, Raoult B. Treatment of acute ischemic stroke with piracetam. Stroke. 1997;28(12):2347–52.

158. The National Institute of Neurological Disorders and Stroke rt-PA Stroke Study. Tissue plasminogen activator for acute ischemic stroke. N Engl J Med. 1995;333:1581–7.

159. Carod-Artal FJ, Egido JA. Quality of life after stroke: the importance of a good recovery. Cerebrovasc Dis. 2009;27 Suppl 1:204–14.

160. Price DD, McGrath PA, Rafii A, Buckingham B. The validation of visual analogue scales as ratio scale measures for chronic and experimental pain. Pain. 1983 Sep;17(1):45–56.

161. Price DD, Bush FM, Long S, Harkins SW. A comparison of pain measurement characteristics of mechanical visual analogue and simple numerical rating scales. Pain. 1994;56(2):217–26.

162. Wallenstein S, Heidricj G, Kaiko R, Houde R. Clinical evaluation of mild analgesics in post partum pain. Br J Clin Pharmacol. 1980;10(2 S):335S-337S.

163. Rhind VM, Bird HA, Wright V. A comparison of clinical assessments of disease activity in rheumatoid arthritis. Ann Rheum Dis. 1980;39(2):135–7.

164. Huskisson EC, Jones J, Scott PJ. Application of visual-analogue scales to the measurement of functional capacity. Rheumatol Rehabil. 1976 Aug;15(3):185–7.

165. Downie WW, Leatham PA, Rhind VM, Pickup ME, Wright V. The visual

analogue scale in the assessment of grip strength. Ann Rheum Dis. 1978;37(4):382–4.

166. Herr K a, Mobily PR. Comparison of Selected Pain Assessment Tools for Use With the Elderly. App Nurs Res. 1993;6(1):39–46.

167. Hilari K, Boreham LD. Visual analogue scales in stroke: What can they tell us about health-related quality of life? BMJ Open. 2013;3(9):1–5.

168. Price CIM, Curless RH, Rodgers H. Can stroke patients use visual analogue scales? Stroke. 1999;30(7):1357–61.

169. Pickard AS, Johnson JA, Feeny DH, Shuaib A, Carriere KC, Nasser AM. Agreement between Patient and Proxy Assessments of Health-Related Quality of Life after Stroke Using the EQ-5D and Health Utilities Index. Stroke. 2004;35(2):607–12.

170. Dorman P, Slattery J, Farrell B, Dennis M, Sandercock P. Qualitative comparison of the reliability of health status assessments with the EuroQol and SF-36 questionnaires after stroke. Stroke. 1998;29(1):63–8.

171. Segal ME, Schall RR. Relation to Disability in Stroke Survivors. Stroke. 1994;25:2391–7.

172. Mathias SD, Bates MM, Pasta DJ, Cisternas MG, Feeny D, Patrick DL. Use of the Health Utilities Index with stroke patients and their caregivers. Stroke. 1997 Oct;28(10):1888–94.

173. Sneeuw KC, Aaronson NK, de Haan RJ, Limburg M. Assessing quality of life after stroke. The value and limitations of proxy ratings. Stroke. 1997 Aug;28(8):1541–9.

174. Sprangers MAG, Schwartz CE. The challenge of response shift for quality-of-life-based clinical oncology research. Ann Oncol. 1999;10:747–9.

175. Kingsley C, Frca M, Patel S, Bmedsci M. Patient-reported outcome measures and patient- reported experience measures. BJA Educ. 2017;17(February):137–44.

176. Dorman P, Waddell F, Slattery J, Dennis M, Sandercock P. Is the EuroQol a Valid Measure of Health-Related Quality of Life After Stroke? Stroke. 1997;28:1876–82.

177. Shinar D, Gross CR, Bronstein KS, Licata-Gehr EE, Eden DT, Cabrera AR, et al. Reliability of the activities of daily living scale and its use in telephone interview. Arch Phys Med Rehabil. 1987 Oct;68(10):723–8.

178. Korner-Bitensky N, Wood-Dauphinee S. Barthel Index information elicited over the telephone. Is it reliable? Am J Phys Med Rehabil. 1995;74(1):9–18.

179. Adamson J, Beswick A. Is Stroke the Most Common Cause of Disability ? PhD ,* BSc ,†. 2004;13(4):171–7.

180. Report G, Stroke I, Party W. The National Sentinel Stroke Audit 2010 Round 7 National and Local Results for the Clinical Audit 2010 Generic Report Prepared on behalf of the Intercollegiate Stroke Working Party. 2011;(March).

181. Points M. Scottish Stroke Improvement Programme 2018 National Report. 2018;(July):2018–9.

182. Sandercock P, Wardlaw JM, Lindley RI, Dennis M, Cohen G, Murray G, et al. The benefits and harms of intravenous thrombolysis with recombinant tissue plasminogen activator within 6 h of acute ischaemic stroke (the third international stroke trial [IST-3]): A randomised controlled trial. Lancet. 2012;379(9834):2352–63.

183. Westendorp WF, Vermeij JD, Vermeij F, Den Hertog HM, Dippel DWJ, van de Beek D, et al. Antibiotic therapy for preventing infections in patients with acute stroke. Cochrane Database Syst Rev. 2012;(1).

184. Visvanathan A, Dennis M, Whiteley W, Visvanathan A, Dennis M, Whiteley W. Parenteral fluid regimens for improving functional outcome in people with acute stroke (Review) Parenteral fluid regimens for improving functional outcome in people with acute stroke. 2015;(9).

185. Power TE, Swartzman LC, Robinson JW. Patient Education and Counseling Cognitive-emotional decision making (CEDM): A framework of patient medical decision making. Patient Educ Couns [Internet]. 2011;83(2):163–9. Available from: http://dx.doi.org/10.1016/j.pec.2010.05.021

186. Frank C. A patient's experience in dementia care. 2017;63:22–6.

187. Finney LJ, Arora NK, Bakos AD, Aziz N, Rowland J. Information needs and sources of information among cancer patients : a systematic review of research (1980 – 2003). 2005;57:250–61.

188. Ménard C, Merckaert I, Razavi D, Libert Y. Decision-making in oncology: A selected literature review and some recommendations for the future. Curr Opin Oncol. 2012;24(4):381–90.

189. Killen A, Flynn D, De Brun A, O'Brien N, O'Brien J, Thomas AJ, et al. Support and information needs following a diagnosis of dementia with Lewy bodies. Int psychogeriatrics. 2016 Mar;28(3):495–501.

190. Forster A, Brown L, Smith J, House A, Knapp P, Wright JJ, et al. Information provision for stroke patients and their caregivers. Cochrane Database Syst Rev [Internet]. 2012;(11). Available from: http://doi.wiley.com/10.1002/14651858.CD001919.pub3

191. Holloway RG, Arnold RM. AHA/ASA Scientific Statement Palliative and End-of-Life Care in Stroke. :0–33.

192. Royal College of Physicians. National clinical guideline for stroke. 2016.

193. The Brain Injury Association. Coping with grief after brain injury [Internet]. Headway. 2017. Available from: https://www.headway.org.uk/news/national-news/coping-with-grief-after-brain-injury/

194. Fried TR, Byers AL, Gallo WT, Ness PH Van, Towle VR, Leary JRO, et al. Prospective Study of Health Status Preferences and Changes in Preferences Over Time in Older Adults. 2006;166.

195. Klein A, Kuehner C, Schwarz S. Attitudes in the general population towards hemi-craniectomy for middle cerebral artery (MCA) infarction. A population-based survey. Neurocrit Care. 2012 Jun;16(3):456–61.

196. Albrecht GL, Devlieger PJ. The disability paradox : high quality of life against all odds. 1999;48:977–88.

197. Lawton J. Lay experiences of health and illness : past research and future agendas. Sociol Health Illn. 2003;25:23–40.

198. Index B, Index A. Follow-up services for stroke survivors after hospital discharge – a randomized control study. 2002;593–603.

199. Bo K, Hoon S, Hoon K, Jeon K, Rae Y, Nam W, et al. Six-month functional recovery of stroke patients : a multi-time-point study. 2005;173–80.

200. Nowell LS, Norris JM, White DE, Moules NJ. Thematic Analysis : Striving to Meet the Trustworthiness Criteria. Int J Qual Methods. 2017;16:1–13.

201. McKevitt C, Redfern J, Mold F, Wolfe C. Qualitative studies of stroke: A systematic review. Stroke. 2004;35(6):1499–505.

202. Harrison M, Ryan T, Gardiner C, Jones A. Psychological and emotional needs, assessment, and support post-stroke: a multi-perspective qualitative study. Top Stroke Rehabil [Internet]. 2017 Feb

17;24(2):119–25. Available from: https://doi.org/10.1080/10749357.2016.1196908

203. Johnston B, Narayanasamy M. Exploring psychosocial interventions for people with dementia that enhance personhood and relate to legacy-an integrative review. BMC Geriatr [Internet]. 2016;1–25. Available from: http://dx.doi.org/10.1186/s12877-016-0250-1

204. Newell SA, Sanson-fisher RW, Savolainen NJ. Systematic Review of Psychological Therapies for Cancer Patients : Overview and Recommendations for Future. 2002;94(8).

205. Reid J, Ski CF, Thompson DR. Psychological Interventions for Patients with Coronary Heart Disease and Their Partners : A Systematic Review. 2013;8(9).

206. Sørensen L V, Waldorff FB, Waldemar G. Early counselling and support for patients with mild Alzheimer's disease and their caregivers: A qualitative study on outcome. Aging Ment Health [Internet]. 2008 Jul 1;12(4):444–50. Available from: https://doi.org/10.1080/13607860802224342

207. Weis J. Support groups for cancer patients. 2003;763–8.

208. Compare A, Germani E, Proietti R, Janeway D. Clinical Psychology and Cardiovascular Disease : An Up-to-Date Clinical Practice Review for Assessment and Treatment of Anxiety and Depression. 2011;148–56.

209. Mead N, Lester H, Chew-graham C, Gask L, Bower P. Effects of befriending on depressive symptoms and distress : systematic review and meta-analysis. 2010;96–101.

210. Improvement NHS. CANCER Psychological care after stroke cognitive and mood disorders.

211. Kneebone II, Kneebone II. Stepped psychological care after stroke Stepped psychological care after stroke. 2016;8288.

212. NHS Iothian. Edinburgh Community Stroke Service. 2017.

213. Mckinstry B. General practice. 2000;(October):867–71.

214. Ditto PH, Druley JA, Moore KA, Danks JH, Smucker WD. Fates worse than death: the role of valued life activities in health-state evaluations. Health Psychol. 1996 Sep;15(5):332–43.

215. Ditto PH, Smucker WD, Danks JH, Jacobson JA, Houts RM, Fagerlin A, et al. Stability of Older Adults' Preferences for Life-Sustaining Medical Treatment. Heal Psychol. 2003;22(6):605–15.

216. Fried TR, Tinetti ME, Iannone L. Primary Care Clinicians' Experiences With Treatment Decision Making for Older Persons With Multiple Conditions. 2011;171(1):75–80.

217. Reuben DB. NIH Public Access. 2010;302(24):2686–94.

218. Davis B. Mediators of the relationship between hope and well-being in older adults. Clin Nurs Res. 2005;14(3):253–72.

219. Wrobleski KK, Snyder CR. Hopeful thinking in older adults: back to the future. Exp Aging Res. 2005;31(2):217–33.

220. Campbell TC, Carey EC, Jackson VA, Saraiya B, Yang HB, Back AL, et al. Discussing Prognosis. Cancer J. 2010;16(5):461–6.

221. Mistry A, Wilson S, Priestman T, Damery S, Haque M. How do the information needs of cancer patients differ at different stages of the cancer journey? A cross-sectional survey. JRSM Short Rep [Internet]. 2010;1(4):30. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21103122%5Cnhttp://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=PMC2984359

222. Guba EG, Lincoln YS. Fourth Generation Evaluation. Newbury Park ; London ; New Delhi: Sage Publications; 1989.

223. Kon A, Davidson JE, Morrison W, Danis M, White DB. Shared Decision Making in Intensive Care Units: An American College of Critical Care Medicine and American Thoracic Society Policy. Crit Care Med. 2016;44(1):188–201.

224. Klein A, Kuehner C, Schwarz S. Attitudes in the general population towards hemi-craniectomy for Middle Cerebral Artery (MCA) Infarction. A population-based survey. Neurocrit Care. 2012;16(3):456–61.

225. Boer ME De, Depla M, Wojtkowiak J, Visser MC, Widdershoven GAM, Francke AL, et al. Life-and-death decision-making in the acute phase after a severe stroke : Interviews with relatives. Palliat Med. 2015;29(5):451–7.

226. Pham MT. Emotion and Rationality: A Critical Review and Interpretation of Empirical Evidence. Rev Gen Psychol. 2007;11(2):155–78.

227. Forster A, Brown L, Smith J, House A, Knapp P, Wright JJ, et al. Information provision for stroke patients and their caregivers. Cochrane Database Syst Rev. 2012;(11):CD001919–CD001919.

228. Stacey D, Legare F, Col NF, Bennett CL, Barry MJ, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2014;2014(1).

229. Klerings I, Weinhandl AS, Thaler KJ. Information overload in healthcare: too much of a good thing? Z Evid Fortbild Qual Gesundhwes. 2015;109(4–5):285–90.

230. Shared Decision Making Collaborative: A consensus statement. 2011.

231. Ramsay P, Huby G, Rattray J, Salisbury LG, Walsh TS, Kean S. A

longitudinal qualitative exploration of healthcare and informal support needs among survivors of critical illness: The RELINQUISH protocol. BMJ Open. 2012;2(4):1–7.

232. Addington-Hall J, Lay M, Altmann D, McCarthy M. Symptom Control, Communication With Health Professionals, and Hospital Care of Stroke Patients in the Last Year of Life as Reported by Surviving Family, Friends, and Officials. Stroke. 1995;26:2242–8.

233. Creutzfeldt CJ, Holloway RG, Curtis JR. Palliative Care: A Core Competency for Stroke Neurologists. Stroke. 2015;46(9):2714–9.

234. Brereton L, Nolan M. “You do know he’s had a stroke, don’t you?” Preparation for family care-giving - The neglected dimension. J Clin Nurs. 2000;9(4):498–506.

235. Brereton L, Nolan M. “Seeking”: A key activity for new family carers of stroke survivors. J Clin Nurs. 2002;11(1):22–31.

236. Kerr SM, Smith LN. Stroke: An exploration of the experience of informal caregiving. Clin Rehabil. 2001;15(4):428–36.

237. Pindus DM, Mullis R, Lim L, Wellwood I, Rundell AV, Aziz NAA, et al. Stroke survivors’ and informal caregivers’ experiences of primary care and community healthcare services – A systematic review and meta-ethnography. PLoS One. 2018;13(2):1–23.

238. Denman A. Determining the needs of spouses caring for aphasic partners. Disabil Rehabil. 1998 Nov;20(11):411–23.

239. Sennfält S, Ullberg T. Informal caregivers in stroke: Life impact, support, and psychological well-being—A Swedish Stroke Register (Riksstroke) study. Int J Stroke. 2019;0(0):1–9.

240. Chan D, Livingston G, Jones L, Sampson EL. Grief reactions in dementia carers: A systematic review. Int J Geriatr Psychiatry.

2013;28(1):1–17.

241. Pope C, Mays N. Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. BMJ. 1995;311(6996):42–5.

242. Corbin J, Strauss A. Grounded Theory Research: Procedures, Canona and Evaluative Criteria. Zeitschrift fur Sociol. 1990;19(6):418–27.

243. Boyd EA, Lo B, Evans LR, Malvar G, Luce JM, White DB. “It’s not just what the doctor tells me:” Factors that influence surrogate decision-makers’ perceptions of prognosis*. Crit Care Med. 2012;38(5):1270–5.

244. Hamilton IJ. Out of hours understanding grief and bereavement. Br J Gen Pract. 2016;66(651):523.

245. Charon R. Narrative medicine: A Model for Empathy, Reflection, Profession, and Trust Rita. JAMA. 2001;286:1897–902.

246. Armstrong MJ. Shared decision-making in stroke : an evolving approach to improved patient care. Stroke Vasc Neurol. 2017;2:e000081.

247. Baile WF, Buckman R, Lenzi R, Glober G, Beale E, Kudelka A. SPIKES — A Six-Step Protocol for Delivering Bad News : Application to the Patient with Cancer. Oncologist. 2000;5:302–11.

248. Hardavella G, Aamli-Gaagnat A, Frille A, Saad N, Niculescu A, Powell P. Top tips to deal with challenging situations: Doctor–patient interactions. Breathe. 2017;13(2):129–35.

249. Werner A, Steihaug S. Conveying hope in consultations with patients with life-threatening diseases : the balance between supporting and challenging the patient. Scand J Prim Health Care. 2017;35(2):143–52.

250. Clayton JM, Hancock K, Parker S, Butow PN, Walder S, Carrick S, et

al. Sustaining hope when communicating with terminally ill patients and their families: a systematic review. Psychooncology. 2008;17(7):641–59.

251. Salander PR, Bergenheim T, Henriksson R. The creation of protection and hope in patients with malignant brain tumours. Soc Sci Med. 1996;42(7):985–96.

252. Zier LS, Sottile P, Hong SY, Weissfield L, White DB. Surrogate Decision Makers' Interpretation of Prognostic Information: A Mixed-Methods Study. Ann Intern Med. 2012;156(5):360–6.

253. Anne-Mei, Hak T. Collusion in doctor-patient communication about imminent death : an ethnographic study. Br Med J. 2001;174:1376–81.

254. Ghandourh WA, Rt M. Palliative care in cancer : managing patients ' expectations. J Med Radiat Sci. 2016;63:242–57.

255. Back AL, Arnold RM, Quill TE. Hope for the Best, and Prepare for the Worst. Ann Intern Med [Internet]. 2003;138(5):439–43. Available from: https://doi.org/10.7326/0003-4819-138-5-200303040-00028

256. Quill TE, Arnold RM, Platt F. "I Wish Things Were Different": Expressing Wishes in Response to Loss, Futility, and Unrealistic Hopes. Ann Intern Med [Internet]. 2001;135(7):551–5. Available from: https://doi.org/10.7326/0003-4819-135-7-200110020-00022

257. Tilden VP, Tolle SW, Nelson CA, Fields J. Family decision-making to withdraw life-sustaining treatments from hospitalized patients. Nurs Res. 2001;50(2):105–15.

258. Braun UK, Beyth RJ, Ford ME, McCullough LB. Voices of African American, Caucasian, and Hispanic surrogates on the burdens of end-of-life decision making. J Gen Intern Med. 2008;23(3):267–74.

259. Hodges LJ, Humphris GM, Macfarlane G. A meta-analytic investigation

of the relationship between the psychological distress of cancer patients and their carers. Soc Sci Med. 2005;60(1):1–12.

260. Maly RC, Umezawa Y, Leake B, Silliman RA. Mental health outcomes in older women with breast cancer: impact of perceived family support and adjustment. Psychooncology. 2005 Jul;14(7):535–45.

261. Peris A, Bonizzoli M, Iozzelli D, Migliaccio ML, Zagli G, Bacchereti A, et al. Early intra-intensive care unit psychological intervention promotes recovery from post traumatic stress disorders, anxiety and depression symptoms in critically ill patients. Crit Care [Internet]. 2011;15(1):R41. Available from: http://ccforum.com/content/15/1/R41

262. Papathanassoglou ED. Psychological support and outcomes for ICU patients. Nurs Crit Care. 2010;15(3):118–28.

263. Wendler D, Rid A. Systematic review: the effect on surrogates of making treatment decisions for others. Ann Intern Med. 2011;154(5):336–46.

264. alzhiemers scotland. No Title [Internet]. Available from: www.alzscot.org/information_and_%0Aresources/information_sheet/1788_loss_and_bereavement_in_people_with_%0Adementia

265. The Brain Injury Association. No Title [Internet]. 2017. [cited 2019 Sep 4]. Available from: https://www.headway.org.uk/news-and-campaigns/news/coping-with-grief-after-brain-injury/

266. The Stroke Association. Bereavement and stroke. 2017.

267. Mcalister FA, Connor AMO, Wells G, Grover SA, Laupacis A. When should hypertension be treated? The different perspectives of Canadian family physicians and patients. Can Med J. 2000;163(4):403–8.

268. Steel N, Ness GJ, House A, Ness AR. Thresholds for taking

antihypertensive drugs in different professional and lay groups : questionnaire survey Aggression and violent behaviour in general practice : population based survey in the north of England. Br Med J. 2000;320:1446–7.

269. Slevin ML, Stubbs L, Plant HJ, Wilson P, Gregory WM, Armes PJ. Attitudes to chemotherapy : comparing views of patients with cancer with those of doctors , nurses , and general public. Br Med J. 1990;300:1458–60.

270. Weissman JS, Cooper Z, Hyder JA, Lipsitz S, Jiang W, Zinner MJ, et al. End-of-Life Care Intensity for Physicians, Lawyers, and the General PopulationEnd-of-Life Care Intensity for Physicians vs NonphysiciansLetters. JAMA [Internet]. 2016;315(3):303–5. Available from: https://doi.org/10.1001/jama.2015.17408

271. Murray E, Pollack L, White M, Lo B. Clinical decision-making : physicians ' preferences and experiences. BMC Fam Pract. 2007;8(10):1–10.

272. Mahmoodi M, Safari A, Vossoughi M et al. Stroke specific quality of life questionnaire : Test of reliability and validity of the Persian version. Iran J Neurol. 2015;14(2):94–100.

273. Elbers RG, Rietberg MB, Wegen EEH Van, Kwakkel G. Self-report fatigue questionnaires in multiple sclerosis , Parkinson ' s disease and stroke : a systematic review of measurement properties. Qual Life Res. 2012;21:925–44.

274. Department of Health. One Chance to Get it Right : One Year On Report. An overview of progress on commitments made: the system-wide response to the Independent Review of the Liverpool Care Pathway. 2015.

275. Baillie J, Anagnostou D, Sivell S, Godwin J Van, Byrne A, Nelson A.

Symptom management , nutrition and hydration at end-of-life : a qualitative exploration of patients ' , carers ' and health professionals ' experiences and further research questions. BMC Palliat Care. 2018;17(60):1–13.

276. Azoulay E, Pochard F, Chevret S, Jourdain M, Bornstain C, Wernet A. Impact of a Family Information Leaflet on Effectiveness of Information Provided to Family Members of Intensive Care Unit Patients: A Multicenter, Prospective, Randomized, Controlled Trial. Am J Respir Crit Care Med. 2002;165:438–42.

277. Lawton J, Waugh N, Noyes K, Barnard K, Harden J, Bath L, et al. Improving communication and recall of information in paediatric diabetes consultations : a qualitative study of parents ' experiences and views. BMC Pediatr [Internet]. 2015;1–9. Available from: http://dx.doi.org/10.1186/s12887-015-0388-6

278. Liddell C, Rae G, Brown TRM, Johnston D, Coates V, Mallett J. Giving patients an audiotape of their GP consultation : a randomised controlled trial. Br J Gen Pract. 2004;54:667–72.

279. Tsulukidze M, Durand M, Barr PJ, Mead T, Elwyn G. Patient Education and Counseling Providing recording of clinical consultation to patients – A highly valued but underutilized intervention : A scoping review. Patient Educ Couns [Internet]. 2014;95(3):297–304. Available from: http://dx.doi.org/10.1016/j.pec.2014.02.007

280. Tattersall MHN, Butow PN. Consultation audio tapes : an underused cancer patient information aid and clinical research tool. Lancet Oncol. 2002;3:431–7.

281. Eden OB, Black I, Emery AEH. The Use of Taped Parental Interviews to Improve Communication with Childhood Cancer Families. Pediatr Hematol Oncol. 1993;10(2):157–62.

282. Hee T, Guan H, Butow PN, Coory M, Budge D, Collie L, et al. Provision of taped conversations with neonatologists to mothers of babies in intensive care : randomised controlled trial. Br Med J. 2007;334.

283. Rylance G. Should audio recordings of outpatient consultations be presented to patients ? Arch Dis Child. 1992;67:622–4.

284. Mishra PK, Mathias H, Millar K, Nagrajan K, Murday A. A randomized controlled trial to assess the effect of audiotaped consultations on the quality of informed consent in cardiac surgery. Arch Surg. 2010;145(4):383–8.

285. Leahy M, Douglass J, Barley V, Jarman M CG. Audiotaping the heart surgery consultation: qualitative study of patients' experiences. Heart. 2005;91:1469–70.

286. Krackow KA, Buyea CM. Use of audiotapes for patient education, medical record documentation, and informed consent in lower extremity reconstruction. Orthopedics. 2001;24(7):683–5.

287. Selph RB, Shiang J, Engelberg R, Curtis JR, White DB. Empathy and life support decisions in intensive care units. J Gen Intern Med. 2008;23(9):1311–7.

288. Themessl-Huber M, Humphris G, Dowell J, Macgillivray S, Rushmer R, Williams B. Audio-visual recording of patient-GP consultations for research purposes: A literature review on recruiting rates and strategies. Patient Educ Couns. 2008;71(2):157–68.

289. Coleman T. Using video-recorded consultations for research in primary care: advantages and limitations. Fam Pract. 2000;17(5):422–7.

290. Forcino RC, Barr PJ, O'Malley AJ, Arend R, Castaldo MG, Ozanne EM, et al. Using CollaboRATE, a brief patient-reported measure of shared decision making: Results from three clinical settings in the United States. Heal Expect. 2018;21(1):82–9.

291. Elwyn G, Barr PJ, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: A fast and frugal patient-reported measure of shared decision making in clinical encounters. Patient Educ Couns [Internet]. 2013;93(1):102–7. Available from: http://dx.doi.org/10.1016/j.pec.2013.05.009

292. Banks JL, Marotta CA. Outcomes validity and reliability of the modified rankin scale: Implications for stroke clinical trials - A literature review and synthesis. Stroke. 2007;38(3):1091–6.

293. Flynn D, Nesbitt DJ, Ford GA, McMeekin P, Rodgers H, Price C, et al. Development of a computerised decision aid for thrombolysis in acute stroke care. BMC Med Inform Decis Mak [Internet]. 2015;15(1):6. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4326413&tool=pmcentrez&rendertype=abstract

294. Kaiser K, Cheng WY, Jensen S, Clayman ML, Schwiep F, Chawla A, et al. Development of a shared decision-making tool to assist patients and clinicians with decisions on oral anticoagulant treatment for atrial fibrillation Original article Development of a shared decision-making tool to assist patients and clinicians with deci. Curr Med Res Opin. 2015;31(12):2261–72.

295. Devereaux PJ, Anderson DR, Gardner MJ, Putnam W, Flowerdew GJ, Brownell BF, et al. Differences between perspectives of physicians and patients on anticoagulation in patients with atrial fibrillation: Observational study. Br Med J. 2001;323(7323):1218–21.

296. Eckman MH, Wise RE, Naylor, Katherine et al. Developing an Atrial Fibrillation Guideline Support Tool (AFGuST) for Shared Decision Making. Curr Med Res Opin. 2015;31(4):603–14.

297. Kunneman M, Branda ME, Noseworthy PA, Linzer M, Burnett B, Dick S, et al. Shared decision making for stroke prevention in atrial

fibrillation : study protocol for a randomized controlled trial. Trials. 2017;18(443):1–9.

298. Sandercock P, Wardlaw JM, Lindley RI, Dennis M, Cohen G, Murray G, et al. The benefits and harms of intravenous thrombolysis with recombinant tissue plasminogen activator within 6 h of acute ischaemic stroke (the third international stroke trial [IST-3]): A randomised controlled trial. Lancet. 2012;379:2352–63.

299. Moons KGM, Royston P, Vergouwe Y, Grobbee DE, Altman DG. Prognosis and prognostic research: what, why, and how? Br Med J [Internet]. 2009;338:b375. Available from: https://www.bmj.com/content/338/bmj.b375.long

300. Braitman LE, Davidoff F. Predicting Clinical States in Individual Patients. Ann Intern Med [Internet]. 1996;125(5):406–12. Available from: https://doi.org/10.7326/0003-4819-125-5-199609010-00008

301. Kwakkel G, Wagenaar RC, Kollen BJ, Lankhorst GJ. Predicting disability in stroke - A critical review of the literature. Age Ageing. 1996;25(6):479–89.

302. Laupacis A, Sekar N, Stiell IG. Clinical prediction rules. A review and suggested modifications of methodological standards. JAMA. 1997;277(6):488–94.

303. Steyerberg EW, Moons KGM, Windt DA Van Der, Hayden JA, Perel P, Schroter S, et al. Prognosis Research Strategy (PROGRESS) 3 : Prognostic Model Research. plos Med. 2013;10:e1001381.

304. Harrell FEJ, Lee KL, Mark DB. Multivariable prognostic models: issues in developing models, evaluating assumptions and adequacy, and measuring and reducing errors. Stat Med. 1996 Feb;15(4):361–87.

305. Concato J, Peduzzi P, Holford TR, Feinstein AR. Importance of events per independent variable in proportional hazards analysis I.

Background, goals, and general strategy. J Clin Epidemiol. 1995;48(12):1495–501.

306. Peduzzi P, Concato J, Feinstein AR, Holford TR. Importance of events per independent variable in proportional hazards regression analysis II. J Clin Epidemiol. 1995;48(12):1503–10.

307. Vittinghoff E, McCulloch CE. Relaxing the rule of ten events per variable in logistic and cox regression. Am J Epidemiol. 2007;165(6):710–8.

308. Hemingway H, Croft P, Hayden JA, Abrams K, Timmis A, Briggs A, et al. Prognosis research strategy (PROGRESS) 1 : A. Br Med J. 2013;346(e5595):1–11.

309. Ranganathan P, Pramesh C, Aggarwal R. Common pitfalls in statistical analysis: Logistic regression. Perspect Clin Res. 2017;8(3):148–51.

310. Weir N, Dennis MS. Towards a national system for monitoring the quality of hospital-based stroke services. Stroke. 2001;32(6):1415–21.

311. Turner M, Barber M, Dodds H, Dennis M, Langhorne P, Macleod MJ. The impact of stroke unit care on outcome in a Scottish stroke population, taking into account case mix and selection bias. J Neurol Neurosurg Psychiatry. 2015;86(3):314–8.

312. Ayis SA, Coker B, Rudd AG, Dennis MS, Wolfe CDA. Predicting independent survival after stroke: a European study for the development and validation of standardised stroke scales and prediction models of outcome. J Neurol Neurosurg Psychiatry [Internet]. 2013;84(3):288–96. Available from: http://jnnp.bmj.com/cgi/doi/10.1136/jnnp-2012-303657

313. Weimar C, König IR, Kraywinkel K, Ziegler A, Diener HC. Age and National Institutes of Health Stroke Scale Score Within 6 Hours after Onset Are Accurate Predictors of Outcome after Cerebral Ischemia:

Development and External Validation of Prognostic Models. Stroke. 2004;35:158–62.

314. Austin PC, Steyerberg EW. Interpreting the concordance statistic of a logistic regression model : relation to the variance and odds ratio of a continuous explanatory variable. BMC Med Res Methodol. 2012;12:1–8.

315. Dennis M, Cranswick G, Deary A, Fraser A, Graham C, Grant S, et al. Effectiveness of thigh-length graduated compression stockings to reduce the risk of deep vein thrombosis after stroke (CLOTS trial 1): A multicentre, randomised controlled trial. Lancet. 2009;373:1958–65.

316. Chun HYY, Whiteley WN, Dennis MS, Mead GE, Carson AJ. Anxiety after stroke the importance of subtyping. Stroke. 2018;49:556–64.

317. Menlove L, Crayton E, Kneebone I, Allen-Crooks R, Otto E, Harder H. Predictors of anxiety after stroke: A systematic review of observational studies. J Stroke Cerebrovasc Dis. 2015;24:1107–17.

318. Lincoln NB, Brinkmann N, Cunningham S, Dejaeger E, De Weerdt W, Jenni W, et al. Anxiety and depression after stroke: A 5 year follow-up. Disabil Rehabil. 2013;35:140–5.

319. Morrison V, Pollard B, Johnston M, MacWalter R. Anxiety and depression 3 years following stroke: Demographic, clinical, and psychological predictors. J Psychosom Res. 2005;59:209–13.

320. Ayerbe L, Ayis S, Rudd AG, Heuschmann PU, Wolfe CDA. Natural history, predictors, and associations of depression 5 years after stroke: The South London stroke register. Stroke. 2011;42:1907–11.

321. Kouwenhoven SE, Kirkevold M, Engedal K, Kim HS. Depression in acute stroke: Prevalence, dominant symptoms and associated factors. A systematic literature review. Disabil Rehabil. 2011;33:539–56.

322. Norrving B. Long-term prognosis after lacunar infarction. Lancet Neurol [Internet]. 2003 Apr 1;2(4):238–45. Available from: https://doi.org/10.1016/S1474-4422(03)00352-1

323. Myint PK, Bachmann MO, Loke YK, Musgrave SD, Price GM, Hale R, et al. Important factors in predicting mortality outcome from stroke: Findings from the Anglia Stroke clinical network evaluation study. Age Ageing. 2017;46(1):83–90.

324. Cumming a. D. Good medical practice. 2010;1–16.

325. Thomas R, Wilson DM, Justice C, Birch S, Sheps S. A literature review of preferences for end-of-life care in developed countries by individuals with different cultural affiliations and ethnicity. J Hosp Palliat Nurs [Internet]. 2008;10(3):142–63. Available from: http://search.ebscohost.com/login.aspx?direct=true&db=cin20&AN=2009938945&lang=ja&site=ehost-live

326. Mead GE, O'Keeffe ST, Jack CI, Maèstri-Banks AM, Playfer JR, Lye M. What factors influence patient preferences regarding cardiopulmonary resuscitation? J R Coll Physicians Lond [Internet]. 1995;29(4):295—298. Available from: http://europepmc.org/abstract/MED/7473323

327. Hagerty RG, Butow PN, Ellis PA, Lobb EA, Pendlebury S, Leighl N, et al. Cancer patient preferences for communication of prognosis in the metastatic setting. J Clin Oncol Off J Am Soc Clin Oncol. 2004 May;22(9):1721–30.

328. Innes S, Payne S. Advanced cancer patients' prognostic information preferences: a review. Palliat Med [Internet]. 2008 Nov 14;23(1):29–39. Available from: https://doi.org/10.1177/0269216308098799

329. Nipp RD, Greer JA, El-Jawahri A, Moran SM, Traeger L, Jacobs JM, et al. Coping and prognostic awareness in patients with advanced cancer. J Clin Oncol. 2017;35(22):2551–7.

330. Visvanathan A, Dennis M, Mead G, Whiteley WN, Lawton J, Doubal FN. Shared decision making after severe stroke—How can we improve patient and family involvement in treatment decisions? Int J Stroke. 2017;12(9):920–2.

331. Creutzfeldt CJ, Longstreth WT, Holloway RG. Predicting decline and survival in severe acute brain injury: The fourth trajectory. BMJ. 2015;351(August):6–8.

332. NA C. Death Foretold: Prophecy and Prognosis in Medical Care. University of Chicago Press; 1999.

333. Hagerty RG, Butow PN, Ellis PM, Lobb EA, Pendlebury SC, Leighl N, et al. Communicating With Realism and Hope: Incurable Cancer Patients' Views on the Disclosure of Prognosis. J Clin Oncol [Internet]. 2005 Feb 20;23(6):1278–88. Available from: https://doi.org/10.1200/JCO.2005.11.138

334. Kutner JS, Steiner JF, Corbett KK, Jahnigen DW, Barton PL. Information needs in terminal illness. Soc Sci Med [Internet]. 1999;48(10):1341–52. Available from: http://www.sciencedirect.com/science/article/pii/S0277953698004535

335. Parker SM, Clayton JM, Hancock K, Walder S, Butow PN, Carrick S, et al. A Systematic Review of Prognostic/End-of-Life Communication with Adults in the Advanced Stages of a Life-Limiting Illness: Patient/Caregiver Preferences for the Content, Style, and Timing of Information. J Pain Symptom Manage. 2007;34(1):81–93.

336. Northouse PG, Northouse LL. Communication and Cancer. J Psychosoc Oncol [Internet]. 1988 Apr 5;5(3):17–46. Available from: https://doi.org/10.1300/J077v05n03_02

337. van Vliet L, Francke A, Tomson S, Plum N, van der Wall E, Bensing J. When cure is no option: How explicit and hopeful can information be

given? A qualitative study in breast cancer. Patient Educ Couns [Internet]. 2013;90(3):315–22. Available from: http://www.sciencedirect.com/science/article/pii/S073839911100187X

338. Wee B. End of life care: How do we move forward? J R Coll Physicians Edinb. 2017;47(4):369–73.

339. Krawczyk M, Gallagher R. Communicating prognostic uncertainty in potential end-of-life contexts: Experiences of family members. BMC Palliat Care [Internet]. 2016;15(1):1–8. Available from: http://dx.doi.org/10.1186/s12904-016-0133-4

340. Wray F, Clarke D. Longer-term needs of stroke survivors with communication difficulties living in the community: A systematic review and thematic synthesis of qualitative studies. BMJ Open. 2017;7(10):1–18.

341. Baker C, Worrall L, Rose M, Hudson K, Ryan B, O'Byrne L. A systematic review of rehabilitation interventions to prevent and treat depression in post-stroke aphasia. Disabil Rehabil. 2018 Aug;40(16):1870–92.

342. Walsh ME, Galvin R, Loughnane C, Macey C, Horgan NF. Factors associated with community reintegration in the first year after stroke: a qualitative meta-synthesis. Disabil Rehabil. 2015;37(18):1599–608.

343. Stroebe M, Schut H. The dual process model of coping with bereavement: Rationale and description. Death Stud. 1999;23(3):197–224.

344. Forte DN, Kawai F, Cohen C. A bioethical framework to guide the decision-making process in the care of seriously ill patients. BMC Med Ethics. 2018;19(1):1–8.

345. NHS Scotland. Effective Communication for Healthcare [Internet]. 2017. Available from: http://www.ec4h.org.uk/wp-

content/uploads/2017/06/Dying-conversation-guide-220917.pdf

346. Bernacki R, Hutchings M, Vick J, Smith G, Paladino J, Lipsitz S, et al. Development of the Serious Illness Care Program: A randomised controlled trial of a palliative care communication intervention. BMJ Open. 2015;5(10).

347. Guo KL. DECIDE: A decision-making model for more effective decision making by health care managers. Health Care Manag (Frederick). 2008;27(2):118–27.

348. Murtagh FEM, Preston M, Higginson I. Patterns of dying: Palliative care for non-malignant disease. Clin Med (Northfield Il). 2004;4(1):39–44.

349. Lunney JR, Lynn J, Foley DJ, Lipson S, Guralnik JM. Patterns of functional decline at the end of life. JAMA. 2003 May;289(18):2387–92.

350. Lehman R. How long can I go on like this? Dying from cardiorespiratory disease. Br J Gen Pract. 2004;54(509):892.

351. Evans LR, Boyd EA, Malvar G, Apatira L, Luce JM, Lo B, et al. Surrogate decision-makers' perspectives on discussing prognosis in the face of uncertainty. Am J Respir Crit Care Med. 2009;179(1):48–53.

352. Society NZIC. Recommended language for communicating end-of-life concepts Recommended language for communicating end-of-life concepts. 2014. p. 0–1.

353. Selman LE, Brighton LJ, Hawkins A, McDonald C, O'Brien S, Robinson V, et al. The Effect of Communication Skills Training for Generalist Palliative Care Providers on Patient-Reported Outcomes and Clinician Behaviors: A Systematic Review and Meta-analysis. J Pain Symptom Manage [Internet]. 2017;54(3):404-416.e5. Available from: http://dx.doi.org/10.1016/j.jpainsymman.2017.04.007

354. Tait AR, Voepel Lewis T, Zikmund-Fisher BJ FA. The Effect of Format on Patients' Understanding of the Risks and Benefits of Clinical Research: A comparison between Text, Tables and Graphics. J Heal Commun [Internet]. 2010;15(5):487–501. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3624763/pdf/nihms412728.pdf

355. Akl EA, Oxman AD, Herrin J, Vist GE, Terrenato I, Sperati F, Costiniuk C, Blank D SH. Using alternative statistical formats for presenting risk and risk reductions. Cochrane Database Syst Rev. 2011;(3).

356. Chief Scientist office. Realistic conversations for shared decision-making in practice [Internet]. NHS Education for Scotland. 2019 [cited 2020 Jun 4]. Available from: https://learn.nes.nhs.scot/24729/realistic-medicine/realistic-conversations-shared-decision-making-in-practice

357. Manning M, Hickey A, MacFarlane A, Franklin S. Perspectives of people with aphasia post-stroke towards recovery & living successfully. A systematic review and qualitative evidence synthesis. Int J Integr Care. 2017;17(5):586.

358. Stroke Association. Communication aids and computer-based therapy after stroke. 2013;1–12.

Appendix A: Publications

Leading Opinion (invited)

International Journal of Stroke
2017, Vol. 12(9) 920–922

DOI: 10.1177/1747493017730766
journals.sagepub.com/home/wso
SAGE

Shared decision making after severe stroke—How can we improve patient and family involvement in treatment decisions?

Akila Visvanathan[1], Martin Dennis[1], Gillian Mead[1], William N Whiteley[1], Julia Lawton[2] and Fergus Neil Doubal[1]

Abstract

People who are well may regard survival with disability as being worse than death. However, this is often not the case when those surviving with disability (e.g. stroke survivors) are asked the same question. Many routine treatments provided after an acute stroke (e.g. feeding via a tube) increase survival, but with disability. Therefore, clinicians need to support patients and families in making informed decisions about the use of these treatments, in a process termed shared decision making. This is challenging after acute stroke: there is prognostic uncertainty, patients are often too unwell to participate in decision making, and proxies may not know the patients' expressed wishes (i.e. values). Patients' values also change over time and in different situations. There is limited evidence on successful methods to facilitate this process. Changes targeted at components of shared decision making (e.g. decision aids to provide information and discussing patient values) increase patient satisfaction. How this influences decision making is unclear. Presumably, a "shared decision-making tool" that introduces effective changes at various stages in this process might be helpful after acute stroke. For example, by complementing professional judgement with predictions from prognostic models, clinicians could provide information that is more accurate. Decision aids that are personalized may be helpful. Further qualitative research can provide clinicians with a better understanding of patient values and factors influencing this at different time points after a stroke. The evaluation of this tool in its success to achieve outcomes consistent with patients' values may require more than one clinical trial.

Keywords

Acute stroke therapy, treatment, stroke outcomes, shared decision making, patient preferences, communication

Received: 2 June 2017; accepted: 9 August 2017

Involving patients and their families in making decisions about the treatments they receive after a severe stroke can help them achieve outcomes that are most acceptable to them. In this article, we offer ideas for improving decision making after stroke, drawing on current evidence in various patient groups and highlighting where further research is needed. Many people who are well regard survival with severe disability to be worse than death.[1] However, when people with severe disability (e.g. stroke survivors) are asked whether death is better than severe disability, they usually answer: "no."[2] Decision making in the setting of acute stroke is particularly challenging because a severely affected patient may not be able to answer as their previously well self or their disabled future self.

Shared decision making is a dynamic process in which patients and clinicians share information, express treatment preferences, and agree decisions. This is a gold standard in clinical care. Yet, there is limited evidence on successful methods to facilitate this process.[3] To date, there are no trials evaluating shared decision making on treatments after stroke. However, the effect of decision aids on information provision, a step

[1]Centre for Clinical Brain Sciences, University of Edinburgh, Edinburgh, UK
[2]Usher Institute for Population Sciences, Edinburgh, UK

Corresponding author:
Akila Visvanathan, Centre for Clinical Brain Sciences, University of Edinburgh, The Chancellors Building, Edinburgh, EH16 4SB, UK.
Email: avisvana@exseed.ed.ac.uk

towards shared decision making, increases patient knowledge and satisfaction in various patient groups including stroke.[4]

Sensible decisions are made with knowledge about likely outcomes with different treatment strategies and knowledge about a patient's wishes for the future (i.e. patient values).[5] We know this from studies on patients with multiple sclerosis[6] and in geriatrics.[7]

How information provision and eliciting patient values impacts on decision making remains unclear.

Ideally, we want to develop a tool that targets several components of the shared decision making process that is successful in helping patients achieve outcomes in keeping with their values. To do this, we need to understand the challenges to adopting this process after stroke.

Firstly, there is considerable statistical and clinical uncertainty about prognosis after stroke.[8] Providing information that is uncertain may hinder patients and families when making decisions about the appropriateness of treatments.

Secondly, individuals place different values on different outcomes after stroke. This is because different outcomes (e.g. ability to talk, walk) may impact differently on different individuals' quality of life. Many factors can affect this including culture and religion.[9]

Thirdly, it may be difficult to elicit patient values after a stroke and be certain of the accuracy of previously expressed wishes. This is because, those severely affected from their stroke may have dysphasia or cognitive impairments, preventing them from communicating their values. In these circumstances, clinicians often rely on proxies who may not know the patient's values well. Even where a patient has expressed a previous wish, this may change over time[2] or when faced with the reality. For example, healthy people versus those who survived but were disabled after hemicraniectomy had differing views on survival with disability.[1,2]

There are a number of key decisions about treatments after stroke. Some reduce both mortality and long-term disability such as thrombectomy.[10] However, routine treatments like tube feeding[11] increase the chance of survival with disability. Given that different individuals place different values on different outcomes, it is crucial that patients and families are intimately involved in making decisions about the use of these treatments.

To do this, more guidance is required. Firstly, clinicians need to be able to provide accurate information on prognosis. This may require clinicians to complement their professional judgement with predictions from prognostic models. Existing models that predict outcome after stroke have high specificity for survival or very poor outcome only.[8] Models that predict recovery of functions (e.g. mobility, speech) updated with data on early patient progress (e.g. early infection, continence) could improve accuracy of predictions.[12]

Secondly, decision aids that are personalized could help information provision. In the development of a decision aid for thrombolysis after acute stroke, patients and relatives emphasized that information should be framed positively (e.g. independence rather than dependence).[13] Presenting information in different formats adapted to specific impairments (e.g. aphasia) using visually attractive methods (e.g. coloured charts) also aided clarity and relevance.[13]

Thirdly, clinicians need to gain a better understanding of individual patient's values for possible outcomes after stroke and factors influencing this. By encouraging patients and families to bring agendas to clinical meetings, clinicians have an opportunity to gain insight into factors affecting decision making. Further qualitative research (e.g. by interviewing stroke survivors and their families over time) can provide an awareness into patient values pre- and post-stroke, changes over time, and factors affecting decisions. Although the generalizability of such information is potentially challenging, the information gained would be invaluable to clinicians discussing appropriateness of treatments after severe stroke.

To summarize, practicing shared decision making on treatments after severe stroke can be challenging. We recommend the development of a tool that incorporates changes at various stages in this process. Evaluation of this may require more than one clinical trial.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Akila Visvanathan is funded by the Chief Scientist Office. Fergus Doubal is funded by the Stroke Association/ Garfield Weston Foundation, NRS fellowship scheme. No other author declared any funding.

References

1. Klein A, Kuehner C and Schwarz S. Attitudes in the general population towards hemi-craniectomy for Middle Cerebral Artery (MCA) Infarction. A population-based survey. *Neurocrit Care* 2012; 16: 456–461.
2. Vahedi K, Benoist L, Kurtz A, et al. Quality of life after decompressive craniectomy for malignant middle cerebral artery infarction. *J Neurol Neurosurg Psychiatry* 2005; 76: 1181–1182.
3. Dwamena F, Holmes-Rovner M, Gaulden CM, et al. Intervention for providers to promote a patient-centered approach in clinical consultations. *Cochrane Database Syst Rev* 2012; 12: CD003267.

4. Forster A, Brown L, Smith J, et al. Information provision for stroke patients and their caregivers. *Cochrane Database Syst Rev* 2012; 2: CD001919–CD001919.
5. Creutzfeldt CJ and Holloway RG. Treatment decisions after severe stroke: uncertainty and biases. *Stroke* 2012; 43: 3405–3408.
6. Wilson L, Loucks A, Bui C, et al. Patient centered decision making: use of conjoint analysis to determine risk-benefit trade-offs for preference sensitive treatment choices. *J Neurol Sci* 2014; 344: 80–87.
7. Mead GE, O'Keeffe ST, Jack CL, Maestri-Banks AM, Playfer JR and Lye M. What factors influence patient preferences regarding cardiopulmonary resuscitation? *J R Coll Physicians Lond* 1995; 29: 295–298.
8. Thompson DD, Murray GD, Sudlow CLM, Dennis M and Whiteley WN. Comparison of statistical and clinical predictions of functional outcome after ischemic stroke. *PLoS One* 2014; 9: e110189.
9. Thomas R, Wilson DM, Justice C, Birch S and Sheps S. A literature review of preferences for end-of-life care in developed countries by individuals with different cultural affiliations and ethnicity. *J Hosp Palliat Nurs* 2008; 10: 142–163.
10. Meurer WJ, Barth BE, Gaddis G, Vilke GM and Lam SHF. Rapid systematic review: intra-arterial thrombectomy ("Clot Retrieval") for selected patients with acute ischemic stroke. *J Emerg Med* 2016; 52: 255–261.
11. Dennis M, Lewis S, Cranswick G and Forbes J. FOOD: a multicentre randomized trial evaluating feeding policies in patients admitted to hospital with a recent stroke. *Health Technol Assess (Rockv)* 2006; 10: 1–91.
12. Lingsma HF, Roozenbeek B, Steyerberg EW, Murray GD and Maas AIR. Early prognosis in traumatic brain injury: from prophecies to predictions. *Lancet Neurol* 2010; 9: 543–554.
13. Flynn D, Nesbitt DJ, Ford GA, et al. Development of a computerised decision aid for thrombolysis in acute stroke care. *BMC Med Inform Decis Mak* 2015; 15: 6.

PLOS ONE

RESEARCH ARTICLE

Maintaining hope after a disabling stroke: A longitudinal qualitative study of patients' experiences, views, information needs and approaches towards making treatment decisions

Akila Visvanathan[1]*, Gillian Mead[1], Martin Dennis[1], William Whiteley[1], Fergus Doubal[1], Julia Lawton[2]

1 Centre for Clinical Brain Sciences, The University of Edinburgh, Edinburgh, United Kingdom, **2** Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, Edinburgh, United Kingdom

* avisvana@exseed.ed.ac.uk

OPEN ACCESS

Citation: Visvanathan A, Mead G, Dennis M, Whiteley W, Doubal F, Lawton J (2019) Maintaining hope after a disabling stroke: A longitudinal qualitative study of patients' experiences, views, information needs and approaches towards making treatment decisions. PLoS ONE 14(9): e0222500. https://doi.org/10.1371/journal.pone.0222500

Editor: Alexandra Sawyer, University of Brighton, UNITED KINGDOM

Received: January 24, 2019

Accepted: September 1, 2019

Published: September 13, 2019

Data Availability Statement: All relevant data are within the paper. However, access to full datasets is available upon request due to ethical restrictions involving potentially identifiable information. To access the data, interested researchers may contact: SCOTLAND A REC, ETHICS DEPARTMENT, 2ND FLOOR WAVERLEY GATE, 2-4 WATERLOO PLACE, EH1 3EG.

Abstract

Background

Some treatments after a disabling stroke increase the likelihood patients will survive longer but with significant disability. Patients and doctors should make collaborative decisions regarding these treatments. However, this can be challenging. To better understand treatment decision-making in acute disabling stroke, we explored the experiences, views and needs of stroke survivors in hospital and six months later.

Methods

Fifteen patients who had a disabling stroke were interviewed within a week of their diagnosis; eleven were re-interviewed six months later. Data were analysed thematically and longitudinally.

Results

Patients' functional abilities prior to their stroke and need for hope of functional recovery appeared to impact on their involvement in decision-making. In the early period post stroke, patients who were functionally independent pre- stroke described being emotionally devastated and ill-prepared for the consequences of stroke. They appeared unaware that treatments offered might extend their life but with significant disability and took all treatments in the hope of functional recovery. Those who were dependent pre-stroke appeared to be more stoic, had considered treatment implications and decided against such treatments. At follow-up, all patients had varying unmet psychological needs which appeared to contribute to poor quality of life. In the early period post stroke, patients looked for various ways to cultivate and maintain hope of functional recovery. While patients continued to look for hope at

Funding: This study was supported by Chief Scientist Office CAF/16/01 (https://www.cso.scot.nhs.uk/outputs/cso-funded-research/caf/) to AV. The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: The authors have declared that no competing interests exist.

six months, they also reported wishing they had been given realistic information in the early period after stroke in order to prepare for the consequences.

Conclusion

Stroke survivors may benefit from psychological support. A collaborative approach towards treatment decision-making may not be realistic in all patients especially when they may be emotionally distressed and looking to maintain a positive outlook. Communication strategies to balance maintaining hope without providing false hope may be appropriate. Patients' information needs may need reassessed at different time points.

Introduction

Each year approximately 150,000 people have a stroke in the UK. [1] In the UK, stroke is the leading cause of reported severe disability. [2] Almost two-thirds of stroke survivors leave hospital with a disability. [3] More than half are left dependent on others for everyday activities and may require long-term, institutional care (e.g., in hospital or a care home). [3,4] Therefore, suffering a stroke can be life-changing and stroke patients need to access appropriate treatment during the acute phase as well as follow-on rehabilitation.

In the UK, acute treatment of stroke and follow-on rehabilitation has improved in recent years. [5,6] Relative to 20 years ago, patients generally have better access to treatment and care. [7] Yet there remain significant challenges with respect to stroke care. Notably, there are different options for treatments during the acute phase, which are each associated with different outcomes. Some treatments (e.g. thrombolysis [8] and mechanical thrombectomy[9]) improve functional outcomes for patients who survive the stroke (i.e. it is less likely for patients to be left with significant physical disability as a result of these treatments). However, other treatments (e.g., intermittent pneumatic compression for prevention of deep venous thrombosis, [10] antibiotics for treating infections, [11] parenteral fluids [12] and enteral feeding [feeding through a tube placed into the stomach through the nose or surgically into the abdomen] [13]) increase the likelihood that patients who have suffered a severe stroke and been left with significant disability will survive longer. Therefore, the net effect is that more patients will survive with significant disability as a result of these latter treatments.

Therefore, a key decision that patients, along with their doctors need to make is: should the patient receive treatment that increases the likelihood that s/he will survive the stroke but with a significant disability *or* forego such treatments and, in turn, accept the increased risk that s/he will die. This is a difficult question and there are no easy answers. Making decisions regarding stroke treatments typically warrants careful discussion between the patient, their family, their doctor and the multidisciplinary team–a "shared decision-making" process. [14] Yet, in practice, (particularly, in the early period after an acute disabling stroke) implementing effective shared decision-making can be challenging. [15] This issue has been under-studied with respect to acute stroke. Exploring these challenges goes to the heart of the issues considered in this paper.

Firstly, acutely unwell patients may be in shock as result of having been given a life-changing diagnosis. Literature from critically unwell patients [16] including in coronary care [17] have highlighted how a sudden deterioration in health may leave patients fearful and distressed; [18] especially when they have not considered a situation where they may be left disabled. Critically ill patients, such as those who have suffered a severe stroke, may lack capacity

(that is, lack the ability to understand, process and weigh up information to make a decision) [17] and their inability to engage with health professionals may make them ineffective partners in a shared decision-making process. [18] However, much of the research around this issue has focused on the experiences of patients with chronic, progressive conditions such as dementia [19] (rather than stroke) and how these patients engage with health professionals to make treatment decisions. The experiences and reactions to diagnosis of those who have suffered an acute disabling stroke are under-reported–we go on to explore this key area in this paper.

Secondly, an important step in shared decision-making is for health professionals to provide necessary information to patients. This is intended to enable patients to arrive at an appropriate treatment decision having properly weighed the outcome-related risks, such as those outlined above. In conditions such as cancer and dementia, providing information to patients has been shown to help them understand their diagnosis and make decisions regarding treatments. [20–22]Decision aids (such as leaflets and educational programmes) in stroke have been reported to help patients understand their diagnosis. However, most of these aids have been tested just before patients are discharged from hospital or in the outpatient setting. Moreover, those severely affected by the stroke had been excluded from these studies. [23] Hence, the transferability of these interventions to an acute setting and to patients severely disabled as a result of their stroke is uncertain. While guidelines published by professional bodies such as the General Medical council,[24] American Heart Association [25] and Royal College of Physicians [26] iterate the need for early, timely and tailored information delivery to patients, we need to consider how this recommendation may affect those who have had a severe stroke who, like many critically unwell patients, may not be able to fully process this information. [17] Overall, the information needs of acute disabling stroke patients to make decisions about their treatments have not been fully considered. This is therefore a key focus of study in this paper.

Thirdly, literature in stroke, [27] brain injury [28] and older patients [29] has reported how patients, who have survived these illnesses and been left with a significant disability, when asked several months later, appear to have learnt to adapt to their situation (a process termed 'response shift') and therefore, report higher quality of life than anticipated. [30,31] In contrast when individuals who are well are asked about their preference for treatment which could leave them significantly disabled, they often report that they do not wish to receive such treatment: that is, they do not want to survive if they will be left significantly disabled. [32] Therefore, patients' treatment preferences appear to be inconsistent. This so-called 'disability paradox' adds to the challenges associated with decision-making in acute stroke. [33] For doctors to be able to support patients in making treatment decisions, they need in-depth insight into each individual's values, preferences and goals and how, and why these may change over time.

In this longitudinal qualitative study, we aimed to address several gaps in research involving acute stroke patients. Specifically, we explored how decisions were made regarding treatments in the context of an acute severe disabling stroke. To better understand this, we explored the early experiences of patients with a disabling stroke in hospital, their needs *[for information]* in the early period after a life-changing diagnosis and their views about surviving, potentially with significant disability. To gain deeper insight into their ongoing wishes and needs, at six months post-diagnosis, we explored their feelings about their situation *[being significantly disabled]* and views regarding information that would have been useful to them in the early period in hospital after their stroke.

While shared decision-making in acute stroke is a team approach, where various members of the multidisciplinary team (e.g. doctors, nurses, physiotherapists and dieticians) have input into patient management, the focus of our study is on decision-making regarding treatments

that extended survival of the significantly disabled patient. These discussions are primarily conducted between the patient and their hospital doctor. Therefore, our recommendations are intended specifically for doctors taking care of acute severe stroke patients in hospital.

Materials and methods

Research design and methods

This study was informed by an epistemological position which recognises that illness experiences and, relatedly, treatment decision-making are socially and contextually informed. [34] This position informed our approach to both data collection and analysis. For instance, we developed topic guides (Table 1) which allowed us to explore what patients' lives were like before suffering a stroke. We also explored their experiences soon after their admission in order to set the context for understanding the treatment decisions which were subsequently made.

Initial interviews took place within a week of a patient's admission to the stroke unit. This time point was chosen to capture their early experiences after a disabling stroke. Also, we recognised that most treatment decisions that we were interested in exploring (such as initiation of enteral feeding) should have been taken within a week of admission.

Where possible, we undertook follow-up interviews at six months following first admission to the stroke unit. We chose this time frame because we recognised that, by six months, most patients would have plateaued with respect to their functional recovery.[35–37] Had we interviewed them at an earlier point in time (for example, at three months following first admission to the stroke unit), their recovery might have still been ongoing. By contrast, had we interviewed at a later point in time (for example, at one or two years following first admission to the stroke unit), this might have meant that other factors (for example, increasing age and frailty, recurrent stroke, declining cognition or death) might have adversely affected patients' ability to be interviewed.

Table 1. Guide to the topics covered in patient interviews.

Baseline	
Background	• The pre-stroke functional status of the patient: how they were managing at home before the stroke, any formal or informal care required, and their interactions with their family. • Reported preferences on surviving with significant disability: if they had made any advanced statements or had any thoughts of what they may want in terms of treatments if they had an illness that may result in them surviving with potentially significant disability.
Experiences	• Patients' feelings about their situation post stroke: how they felt about their diagnosis and how they felt they were coping with the situation • Patients' experiences in hospital in the early phase after the stroke: their interactions with staff
Needs	• Patients' perception of information in general: whether this may help them understand their diagnosis, potential prognosis and help them make treatment decisions. • Their understanding about the goals of treatments that were being offered after acute stroke and what they would need to make decisions about these treatments
Six month follow up	
Experiences	• Patients' thoughts and feelings having survived a physically disabling stroke, how they were managing on a day to day basis, their thoughts on their recovery process since hospital discharge
Needs	• back to their time in hospital, their thoughts on what (for example, information or support) could have been given to them in hospital which may have been useful to them.

https://doi.org/10.1371/journal.pone.0222500.t001

Recruitment and data collection

We recruited adult patients who had been admitted to a stroke unit in a large teaching hospital in the United Kingdom. Our aim was to explore decision-making regarding stroke treatments that increased the likelihood that the patient who has been left with significant disability as a result of stroke will survive longer; to be eligible to participate, the stroke needed to have caused significant physical disability and the patient needed to have had decisions made regarding treatments (such as enteral feeding, parenteral fluids, antibiotics or intermittent pneumatic compression). Therefore, we recruited patients whose extent of disability was at least a modified Rankin scale score of four as a result of the stroke (i.e. they were unable to walk or attend to their own bodily needs without assistance).

The medical team (consultants, registrars and other trainee doctors who looked after the patients on a daily basis) identified eligible individuals who had the capacity to consent to participating in the study (i.e. the patient was able to understand and retain information and communicate decisions). If the patient's speech or swallow was affected, the medical team assessed them to ensure this did not affect their decision-making capacity and that they were able to fully participate in an interview. In each case, before approaching the patient regarding in this study, the medical team also considered whether participating might cause distress.

Once the medical team determined that the patient was suitable to participate, they asked the patient for permission for the researcher (AV) to approach them and provide further information about the study. AV was a clinical doctor specialising in geriatric medicine who had previously worked in the stroke unit. However, patients were not informed about AV's clinical background and they were advised that she would not be able to provide any treatment advice or medical information specific to their care.

AV then provided information about the study and obtained the patient's formal written consent to participate. We made every effort to recruit patients of different ages, genders and ethnic backgrounds. However, we recognised that patients with an acute disabling stroke are a group who are hard to recruit: many patients are medically unwell and the impact of the diagnosis was noticeably distressing to some of them. Therefore, we made a pragmatic decision to interview all eligible individuals who had agreed to take part. As the clinical team did not keep a log, it is not possible to report the total numbers approached and, of those, how many declined to participate.

We endeavoured to recruit sufficient participants to address our study aims while not creating a dataset which would be too large and unwieldly to analyse in-depth. In practice, this meant that we stopped recruitment after on-going analysis of the interviews indicated that sufficient data had been obtained to address the study aims and that a point had been reached where patients were volunteering similar views. Hence we recognised that recruiting additional patients would not enhance the quality or diversity of the data collected.

Prior to the start of each interview, AV reassessed patients' capacity to participate. This was done because we recognised that patients' capacity might have changed from when they had initially been assessed as suitable to take part. Initial interviews were conducted in a private room in the stroke unit at a time convenient to the patient. Table 1 summarises the main areas explored. Where possible, we conducted six month follow-up interviews in the patient's place of residence (i.e., either own home or care home). Telephone interviews were considered where the multidisciplinary team felt that it would not be safe for AV to visit the patient. Before contacting the patient to arrange the interviews, AV phoned their general practitioner to check the patient still had capacity to participate. This was part of the consent process at recruitment. Prior to follow-up interviews, AV reassessed the patient's capacity. We summarize the main areas explored in these interviews in Table 1.

AV kept a reflexive diary. This detailed her interactions with the participants, including a record of why, based on what patients said in interviews, she had decided it would be insensitive or inappropriate to pursue certain lines of questioning. For instance, when AV explored patients' feelings about potentially living with disability, only physical aspects of disability were discussed (for example, immobility and inability to perform activities of daily living). This was because recruited patients were assessed to have physical disability only, and exploring irrelevant disabilities (such as cognitive or intellectual) may cause the patient unnecessary worry. Also, as we will go onto describe, it became apparent to AV that, in the early stages post stroke, some patients did not appear to understand that the goals of some stroke treatments were to extend their life but they will be significantly disabled and that decisions needed to be taken regarding these treatments. Making this known to them either acutely or six months later could have caused undue distress.

Initial interviews took place between September 2017 and January 2018 and lasted 25 to 66 minutes. Six month interviews took place between April 2018 and July 2018 and lasted 32 to 56 minutes. All interviews were digitally recorded and transcribed in full with the patient's consent.

Data analysis

AV (who has received training in qualitative methods, including qualitative data analysis) and JL (a very experienced, non-clinical qualitative researcher) undertook data analysis. All data were analysed thematically using the method of cross-comparison.[38] This approach entailed repeated read through of all interviews to allow familiarization with the data (immersion). Interviews were then cross-compared to identify key findings which cut across different accounts (themes). Both inductive and deductive approaches were used; this allowed unanticipated themes to emerge from data as well as identification of material needed to address the study aims. Data were also analysed longitudinally to establish whether, and why, peoples' needs and views changed over time. AV and JL analysed the data separately and wrote separate reports. They then met to discuss their interpretations, resolve any areas of disagreement (which were found to be minimal), and reach agreement on the main findings and themes. A coding frame was then developed which captured these findings and themes. Coded datasets were subjected to further analysis to allow development of more nuanced interpretations of the data and identification of illustrative quotations. Nvivo 11, a qualitative software package produced by QSR International, was used to facilitate data coding and retrieval.

Ethical approval

This study was approved by Scotland A Research Ethics Committee (Ref: 17/SS/0029).

To safeguard participants' confidentiality, pseudonyms are used.

Results

Fifteen patients were interviewed within a week of their stroke. None were able to mobilise independently or wash and dress themselves without help after the stroke. Five also had speech impairment. The medical team assessed and confirmed that this did not affect their capacity to participate in interviews. Although we tried to include patients of varying backgrounds, most were of similar ages (70s) and ethnicities (White British).

At six months, thirteen patients had survived. Eleven had capacity to take part in an interview. All surviving patients had varying degrees of physical disability. Of these, two had ongoing speech problems but this did not affect their ability to participate in an interview. Eight of the eleven patients with capacity were living at home, two in care homes and one in hospital.

Ten interviews took place in person. One interview took place over the phone due to safety concerns raised by the multidisciplinary team in hospital and the patient's general practitioner.

Table 2 summarises the characteristics of our sample.

We found that patients' pre-stroke functional status; specifically, whether they were largely independent or dependent on others for their activities of daily living (for example, showering

Table 2. Characteristics of study participants.

Patient characteristics	Number of participants (n = 15)
Mean age in years (range)	79 (53–93)
Female/Male	9/ 6
Independent prior to stroke	11
Formal care package prior to stroke	4
Do not Attempt Resuscitation order (in the first week)	3 in hospital, 2 from the community, 10 none
First stroke	15
Comorbidities (Charlson index: 0, 1–2, 3–4, > = 5) Max score = 33	Score 0(no comorbidities) = 6
	Score 1-2(mild comorbidities) = 5
	Score 3–4 (moderate comorbidities) = 3
	Score 5 and above (severe comorbidities) = 1
Type of stroke [39]	Total anterior circulation: 7
	Lacunar: 5
	Partial anterior circulation: 2
	Posterior: 1
Post stroke	
Modified Rankin score (mRs) (Scores 0–6) [40]	mRs 4[a] = 4
	mRs 5[b] = 11
Speech problem not affecting capacity or participation in interview	5
Fed enterally (Nasogastric or gastrostomy)	5
At six months	
Survived	13; 11 with capacity
Modified Rankin score (mRs) Scores 0–6 [40]	mRS 1 [c] = 1
	mRs 3[d] = 7
	mRs 4 = 2
	mRs 5 = 3
	mRs 6 [e] = 2
Place of residence	At home = 8
	Nursing home = 4 (2 did not have capacity to be interviewed)
	Hospital = 1
Speech problem not affecting capacity or participation in interview	2
Fed enterally (nasogastric or gastrostomy)	0

[a] Moderately severe disability; unable to walk or attend to own bodily needs without assistance

[b] Severe disability; bedridden, incontinent and requiring constant nursing care and attention

[c] No significant disability despite symptoms; able to carry out all usual activities

[d] Moderate disability; requiring some help but able to walk without assistance

[e] Dead

https://doi.org/10.1371/journal.pone.0222500.t002

and dressing), appeared to influence their experiences, views and involvement in making treatment decisions. Therefore, where appropriate, we have separated our reporting according to these two groups.

We begin by describing patients' backgrounds and pre-stroke functional status. We then explore patients' experiences and reactions to their diagnosis in hospital in the early period after a disabling stroke. We describe how patients' need for hope appeared to influence their needs *[for information and support]* and views *[regarding treatments]* in the early period after a disabling stroke.

We then go onto consider how patients' pre-stroke background and functional status appeared to affect their feelings about their situation six months later and how, and why, on reflection of their time in hospital, their needs *[for information]* may have changed based on the situation they now found themselves in.

Pre-stroke background and early reactions to diagnosis of stroke

Patients who were independent pre-stroke. The majority of patients reported either living alone or with their family and described how they were constantly doing things for others. While this kept them busy, these patients also described how being part of a close network of family and friends gave them a sense of purpose. For instance, Dorothy, who was in her late 70s, described her role as a helper to her disabled friend: *'I'm always helping other people. I've got. . .my friend. . .I usually drive her about because she's in a wheelchair. '(Dorothy).*

Likewise, Edith, who was in her early 80s, described how she loved cooking and being involved in the lives of her grandchildren: *"I go away shopping an awful lot. And I make, like, pots of soup and I give it to my grandchildren."*

These patients described how they had never considered a situation where they might be left disabled and how the stroke had come as a surprise to them: '*And life so far, never had any problem. It's just come as such a surprise, 'cause I'm not a person to give in to anything.' (Dorothy)*

The sudden loss of independence resulting from the stroke was described as devastating and as having given rise to a sense of loss, uselessness and profound apprehension relating to what other people would think about them in their disabled state. This included Colin, a man in his 70s who had lived alone and previously worked in healthcare. He described his feelings of anguish as he reported how he felt he had lost his dignity:

> '*Not walking, talking. I feel embarrassed when I meet people. They'll say to me, look at the state of him. Well, there was today a girl came and washed me and it was the first time. It's just that I'm not used to it. I feel absolutely terrible. I told her though, I'm so sorry . . .to see me in such a state, you know, all your private parts just hanging out and she's washing it all. . ..I was just lying there and I was shutting my eyes hoping that she wouldn't be long. . . .' (Colin)*

However, many described how they had quickly transitioned from shock and distress to focusing on regaining their pre-stroke functional abilities. This included Edith who reported wanting to be able to do her own shopping again, '*I don't want to get restricted from anything*' and Larry, a man in his 50s, who reminisced about his independent past where he cared for his wife and children, and described wanting '*the use of my arm and leg again*'.

While continuing to focus on regaining their independence, these patients also reported that, should the circumstances arise where they were unable to independently care for themselves at home, they would accept formal or informal care. These patients suggested that they had family and friends to live for and, therefore, for them, survival, even with disability,

seemed acceptable. For instance, Larry expressed his wish to '*be part of the family again so [my] wife don't have to do everything*'. Similarly, Edith, who often helped her family by caring for her grandchildren, described how she felt she had so much left to live for, and also how she had people in her life who would care for her if necessary:

'I like to be amongst my family all the time. I can revolve round it (referring to disability). Obviously if I find out I need a lot of help, I can get one of my granddaughters to stay with me and that, you know.' (Edith)

Patients who were dependent pre-stroke. These patients described prior restrictions to their mobility and ability to care for themselves, which had meant that they already had a formal care package which allowed them to live at home. In contrast to the group above, these patients described a general deterioration in their quality of life over the preceding years and also lacking a strong family network. In addition to a formal care package, some of these patients required help from friends and family with shopping and housework. This included Harriet, a woman in her late 80s, who was largely housebound. Harriet described how her nephew (her next of kin) visited her once a year and dealt with her finances and how she was reliant on the kindness of her neighbour who came in and helped her on a regular basis: '*Oh he [nephew] visits, yeh, he does the 'big stuff' you know, like me house, money and that but [name of neighbour deleted] she's brilliant, she is. Does my shopping and all that, keeps an eye on me*".

These patients reported how their pre-stroke illnesses had led to them leading very restricted lives. They also described how, while they had not been content with this situation, they had adapted to it. For example, Nigel, a man in his 70s, described what it was like to have a neurological condition which had meant that his life had been dictated by his illness:

'I don't go out nearly as much. I don't have as many circle of friends. I used to go out every six weeks to a lunch at [Place name removed]. I've had to curtail that, because my carers clash with the times.' (Nigel)

Due to their generally poor (and deteriorating) health, these patients reported multiple previous hospital admissions, where, on discharge, they had not returned to their previous level of functioning. Therefore, they described being mentally prepared for, and unsurprised by, a further deterioration in their abilities because of the stroke. Consequently, these patients, in contrast to those who were independent prior to the stroke, reported having thought about a situation where they might be left significantly disabled. In the event of this happening, Nigel, like others, described how he would not like his life to be prolonged:

'I don't relish that idea to get spoon-fed. . .. . .on a permanent basis. I hate the idea of being shut up in my own house. No, I would hate to be a vegetable.' (Nigel)

Trying to cope with the diagnosis: Generating and sustaining hope

Regardless of their pre-stroke functional status, all patients described looking for hope of functional recovery. This included Nigel who described how: '*I am, I can and I bloody well will: where there's breath, there's hope*' and Graham, a man in his 60s who, prior to the stroke, owned his own business, and enjoyed outdoor activities, who described how:

(*Re: recovery*) *'I'll say [I am at] about 20% now. I can see the future higher up the ladder is there for me to climb up to it.' (Graham)*

In-keeping with their wish to maintain a positive outlook, patients reported using different coping mechanisms to generate hope. Some reported comparing their functional state to that of other patients in hospital, and described how they thought that others were less fortunate than themselves as they had impairments that they felt were more severe. Such patients reported how this fuelled their hope that they may return to their pre-stroke state:

'When I was sitting in bed and watching the others, I kept thinking I'm lucky I've not got it as bad as they have, you know. I can swallow but I've just got to watch not to take a big mouthful.' (Dorothy, a woman in her 70s, who was unable to mobilise or independently self-care post stroke)

Others described how they valued speaking to stroke survivors they knew who had made full functional recovery and been discharged home. Indeed, such patients described seeking out stroke survivors, often with help from their family and friends, and welcoming hearing encouraging stories about their recovery:

'That was what she [friend] went through. I mean, I know that she's okay. She's a hundred per cent recovered but she was in a bad way. So that was good to understand that, just that there is light at the end of the tunnel, if you like. So that's a positive experience, positive discussion I've had with someone who I know and I know she's not lying to me. She's looking good. She talks good. She's not got any signs of a stroke.' (Graham)

Most patients also described how they needed information that was framed positively in order to help them maintain an optimistic outlook. In keeping with their need for hope, patients also described not wanting to engage with information that was 'negative'; that is, which alluded to a lack of recovery or the possibility of living with significant disability. Many, like Graham, described even being prepared to accept information that was not necessarily correct, as long as it gave them hope:

'I want to know I'm going to get back to a hundred per cent; that's what I believe inside that I'll get back to. I think it's vital to move forward, even if it's. . .I was going to say even if it's not completely true, but you've got to have a positive outlook. But if you come along and say, well you've got no chance, you're going to be, you know, wrapped up in a wheelchair for the rest of your life, that's not going to help me.'(Graham)

Indeed, some described how they might lose trust in health professionals if given discouraging information. For example, Olivia, a woman in her early 80s recalled a situation where potentially dispiriting information would have been unhelpful:

'Well if somebody had said to my friend who died of the stroke, oh this is a very serious condition you've got yourself into, I don't know if we'll be able to get you out of this, well it wouldn't have done him any good at all would it? I mean, where's the trust that staff are helping?'(Olivia)

Treatment decision-making following diagnosis

It was against the above backdrop, that decisions about treatments such as intermittent pneumatic compression, enteral feeding, parenteral fluids and antibiotics were made.

Patients who were independent pre-stroke. Patients in this group generally reported taking all treatments that were on offer and, in their interviews, appeared to be unaware of the

purposes of these treatments or even that treatment decisions had needed to be made. In keeping with their need for hope, many described assuming that treatments they were given were to help them make a full functional recovery. For example, Edith who was bed-bound after the stroke and needed a hoist to transfer from bed to chair described how she had been happy to take antibiotics for a urine infection because she assumed that these would help improve her mobility:

'*Oh, I'll take anything like that. Well, to get me on my feet.' (Edith)*

Given their understanding of these treatments, some patients, including Graham, expressed their surprise that others might refuse them:

'*I overheard someone very recently saying that if they're not getting better they'd not want to be treated you know, they want to die, not me; I'm a fighter to the end, you know'.(Graham)*

Patients who were dependent pre-stroke. In contrast, these patients described having recalled the conversations with their doctors where treatment plans relevant to their situation had been discussed. They reported how they had informed their doctor that they would not want to have treatments that might leave them significantly disabled and therefore, when offered, they had declined these treatments.

This included Harriet, who declined enteral feeding as she felt that this might impact negatively on her already deteriorating health and quality of life:

'*Oh gosh, no. That would be the last straw. I'd ask the Lord to take me away if that [referring to accepting enteral feeding] happened'. (Harriet)*

Similarly, Nigel, described how he had decided he did not want any treatments (referring to enteral feeding and intermittent pneumatic compression) that would increase the possibility of him being more dependent than he already was:

'*I hate the idea of being shut up in my own house, no. I hate not knowing what is happening around me' (Nigel)*

Six month follow-up

Reactions to living with disability. At six months, none of the surviving patients had returned to their pre-stroke functional state and, since hospital discharge, many had experienced a further deterioration in their health and functional abilities.

Patients who were independent pre-stroke. Nearly three quarters of patients who were independent prior to the stroke required a formal care package to be able to manage at home at six months. This was a cause for despair for many such patients who described how, when they had left hospital, they had remained hopeful that they were going to be independent again. This included Brenda, a woman in her 80s, who shared her upset and grief at now needing carers to help her with daily care:

'*Everyone kept saying, well, it'll improve, but you don't really realise how bad you're going to be. I didn't realise how much of a setback it was going to be. When people said they had a stroke, I didn't realise what they were going through, whereas I certainly do now.' (Brenda)*

Brenda, like many others who had been independent pre-stroke, reported a mixture of disbelief and frustration and described feeling unprepared for the reality of the situation she was now in:

'*Very frustrating, because I can't do what I normally do, like I went onto the computer yesterday to put in [husband's name] prescription as I normally do, and I couldn't press the bracket key, you know, the upper case.' (Brenda)*

Indeed, it was evident from these patients' accounts that their inability to do things they had previously taken for granted was a source of considerable grief. This included Irene, a woman in her 80s, who was previously independent and had regularly cared for her grandchildren. She now shared the anguish, embarrassment and distress she felt because of being unable to look after herself:

'I'm always embarrassed about asking somebody to help me do things that I feel I could be able to do myself, you know. For instance my left leg just now is sore because the way I've been lying I was . . .it's over and I've got to get somebody to straighten it out for me. I can't do that myself which I get quite annoyed about.' (Irene)

Some described how they were struggling to cope on a day-to-day basis and expressed their grief with their current situation:

'*My walking and my balance is terrible. Well sometimes . . .I've fell a couple of times and my leg . . .got bruises on my other . . .while I was trying to collect things.*

I'm just . . .how can I say . . .depressed. My words don't come out right. My sentences don't come out right.' (Colin)

Some patients also described having felt abandoned by staff once they were discharged from hospital. They noted how all therapy (specifically physiotherapy) had stopped following hospital discharge and suggested that if this therapy had been continued, they would not have been in the situation (disability requiring help from others) they were now in. This included Edith who described feeling alone and hopeless as a consequence:

'*Oh, they're finished with you once you're out of the hospital. They don't entertain you at all after that. To me they should carry it [referring to physiotherapy] on.'(Edith)*

This feeling of abandonment caused patients considerable upset. Edith, for instance, who had previously found meaning and purpose in her life by caring for her grandchildren now needed a hoist to transfer in the care home. Like others, she shared her feelings of despair and of not having anything left to look forward to in her life:

'*I can go out when my sons come up if they've got. . .they take me outside in a wheelchair Some days they're getting me in the car and I lower myself into it but I don't ever get out of the car, nothing like that. They'll open the windows and take me to the seaside and open the windows and let me look out and things like that but I feel it's like a wasted life. You're here for a wee while, the next place you go to that's your dying off place that's that. That's what I feel.' (Edith)*

Despite reporting feeling helpless and upset, some patients also described clinging onto hope of some functional recovery. This included Irene who recounted how she wished for an improvement in her balance:

'The physiotherapists were trying to get my balance sorted but it was hopeless. I kept falling back or to the side. So, unless I get that done there's no way I can stand even, you know. I would like to improve on that, you know. Even just to stand up and get out of bed, just to move from here to the chair without having to use the stand aid, you know.'(Irene)

A similar account was provided by Edith who described how she battled to cling onto hope and the possibility of some improvement:

"Well, I can't imagine myself being like this to the end. It's not me. Oh, yes, definitely. They said apparently you can't get any better but I did. I can get better. My brain's fine and if I got help, through time I'd get this leg moving more because I'd like to be a wee bit more independent when it comes to the toilet and that if I can use. . .get on to one of these things that you push anyway. To be able to walk, maybe with a Zimmer. (Edith)

Patients who were dependent pre-stroke. These patients, like those who were independent pre-stroke, described needing more help than before to be able to carry on with basic daily activities (such as showering, dressing and mobilising to the toilet) However, in contrast to those who were independent pre-stroke, it was evident from their accounts that this group of patients had given up battling for hope of further functional recovery. This included Nigel, who, six months previously, had already described a situation where he was largely housebound but had been able to mobilise independently (though slowly) indoors, was able to prepare a simple lunch and had got out (albeit only occasionally) to see his friends. Now, he described being fully housebound and needing help from his carers to get to the toilet and perform simple kitchen tasks. Despite this deterioration, he described, in a very 'matter-of-fact' manner how he:

'Would like just to have a more active life, If it (his mobility) comes, it comes, and if it doesn't come, well that's fair enough.' (Nigel)

Likewise, Harriet, described how, against a background of deteriorating health, she had previously been able to shower herself and entertain friends for afternoon tea but was now needing help to shower and was no longer able to invite her friends over. She reported that, while she wished to improve, she had accepted her situation:

'I have a minder who comes in; my only visitor really . . . She comes and gives me a shower in the morning. I'd like to do that you know. . .but I'm coping with all that. I've got a special seat in my bathroom, where I sit for the shower'. (Harriet, a woman in her late 80s)

Retrospective views regarding information in the early period after the stroke

When patients were asked to consider what would have been useful for to them to have known before they were discharged from hospital, all patients, regardless of their pre-stroke functional status, reported their wish to have been given information which would have helped them better understand and prepare for the situation they were now in. For instance, Irene, in her current state, was in a care home and required hoist for transfers and a catheter to manage urinary incontinence. She reported:

"Well, I think we wanted more information, you know. Excuse me. Just to understand why we're like this, you know." (Irene)

Likewise, Brenda who was now needing carers to help her mobilise to the toilet and to shower, described how she wished she had been given information on what her future may have looked like:

'An idea. You can't precisely say when it's going to happen, an idea of what image of what's ahead.' (Brenda)

However, while these patients described their wish to have had information in hospital, they were not specific about the type and timing of this information.

Interpretation

In this study involving patients who had an acute disabling stroke, we have highlighted how the functional status of patients prior to their stroke and their need for hope of functional recovery appeared to impact on their experiences, views and involvement in decision-making. First, patients who were functionally independent prior to their stroke were emotionally devastated in the early period post stroke and described feeling abandoned and struggling to find a sense of purpose six months later. They also appeared to be unaware that treatments in the early period post stroke might extend their life, but that they might be significantly disabled. These patients did not engage in treatment decision-making and took all treatments in the hope of functional recovery. In contrast, those who were dependent prior to the stroke were more stoic, had considered treatment implications and were more involved in treatment decision-making. They often chose not to have treatments that might prolong their already deteriorating health and poor quality of life. While they reported adapting to and accepting their increased need for care six months later, they were also saddened by their increased disability and social isolation.

Second, in the early stages post stroke, stroke survivors looked for various ways to cultivate and maintain hope that they would recover to their pre-stroke functional state. This included seeking positive information from doctors and other sources. At six months, many of the same patients (especially those who had been independent prior to the stroke) continued to be hopeful of improvement in their functional abilities. However, they also reported wishing they had been given realistic information in the early period after their stroke in order to prepare for the situation they were now faced with. Therefore, there appeared to be a mismatch between patients' need to maintain hope of functional recovery and their retrospective wish to have had realistic information in the early period after their stroke. We refer to this as the "hope-information paradox".

Reactions to diagnosis- and the need for psychological support

Our study provides empirical support for recommendations provided by the Stroke Association [3] and Harrison et al [41], that stroke survivors may benefit from psychological support on discharge from hospital. Psychological support has been shown to be beneficial in patients with dementia [42], cancer [43] and myocardial infarction [44] because it reduces rates of depression, improves patients' ability to cope with their situation, better optimises patients' remaining abilities and improves their quality of life. This would be an important consideration for stroke patients, who, as we observed, had unmet psychological needs which seemed to contribute to a poor or suboptimal quality of life. In addition, our findings suggest that the type and amount of support required by patients who had suffered a disabling stroke may depend upon their functional status prior to the stroke and may also change over time. Therefore, different forms of psychological support (e.g. counselling[45], support groups [46],

clinical psychology [47] and be-friending services[48]) may be appropriate for different patients at different time points. For example, those who had been functionally independent prior to the stroke may initially benefit from attending clinical psychology services and emotional support groups in order to come to terms with their diagnosis and loss of independence. Such patients would also benefit from be-friending services and peer support in the longer term to address social isolation as would patients who were functionally dependent prior to the stroke. A stepped care approach to psychological care after a stroke (that is, where patients are identified and treated and 'stepped up' to more intensive treatments based on their clinical need) was proposed by the National Institute of Health and Excellence in 2011 [49,50]., Although there are pathways into psychological services for stroke patients in the U.K, [41,51], patients in our study did not seem to have benefited from this. We recommend that the multidisciplinary team in hospital, in collaboration with specialist neuropsychology services if appropriate, assess the type and amount of psychological support each patient needs prior to hospital discharge and collaborate with community services to assess ongoing patient needs.

Involving patients in making treatment decisions

Similar to acutely unwell patients in the intensive care unit [18], we also found that it was not possible to involve some patients in treatment decision-making in the early period after their stroke. This was especially the case for those who had been functionally independent prior to their stroke. As we have shown, such patients may not appreciate that, in the early stages post stroke, some treatments might extend their life, but with significant disability. They may also struggle to engage with health professionals in order to make treatment decisions in the early stages post-stroke. We have also highlighted how the emotional impact of a life-changing diagnosis and patients' need for hope may not be conducive to them receiving and understanding realistic information, rationally weighing up the pros and cons of treatment and/or expressing their preferences for these treatments [16,18]–these all being key to effective shared decision-making as described early on in this paper. Trying to involve these patients in making collaborative decisions may cause unnecessary psychological distress. [52] By contrast, patients who were already significantly disabled before the stroke, like frail older patients with chronic progressive conditions, may be mentally prepared for further deteriorations in their health, have considered consequences of different treatment options and have often decided not to have treatments that may prolong an already unsatisfactory quality of life. [53–56] Hence these patients may be in a better position to be more engaged in the treatment decision-making process. We recommend that health professionals explore patients' pre-stroke functional status and consider if and whether the emotional impact of diagnosis may prove it challenging to involve them in making treatment decisions.

The hope- information paradox

The need for hope which we have reported in this paper is not exclusive to stroke patients: for cancer patients and older patients too, communication of hope by health professionals is said to help such patients adjust to their diagnosis and improve their welfare and quality of life. [21,57,58] Striking a balance between providing a patient hope that s/he will functionally recover while not providing false hope is challenging. [59] We report two further dilemmas for health professionals. First, shortly after their stroke, some patients volunteered that if their doctor were to provide them unfavourable information regarding the likelihood of their recovery at that point, they would lose confidence in their doctor, thereby detrimentally affecting the doctor-patient relationship. Second, when asked at six months to look back to the period shortly after their stroke, patients described wishing that their doctors had given them realistic

information that could have prepared them better for their current (unfavourable) functional status.

While there are no easy answers with respect to resolving the "hope-information paradox", one potential solution is to consider using existing cancer communication strategies in the stroke context. Potentially relevant cancer communication approaches include 'Ask-Tell-Ask' and 'Hope for the Best, Plan for the Worst' approaches. For example, under the 'Ask-Tell-Ask' approach, a doctor would communicate poor cancer prognosis, then respond to the patient's emotions and finally transition to talking about next steps. Under 'Hope For The Best, Plan For The Worst' approach, a doctor would join with the patient in embracing their hopes while simultaneously asking them to explore a back-up plan based on their prognosis. This could help cultivate the patient's hope by seeking to understand their diagnosis and prognosis and thereafter re-orient the patient's care based on the patient's goals and objectives. [59] Yet there are some challenges to directly adapting cancer communication strategies for using in the stroke context: the illness trajectories for cancer and stroke are different. [59] Specifically, relative to cancer, stroke is an acute medical condition, many treatment decisions need to be taken early, and the trajectory of the patient's condition is difficult to predict.[60] By appreciating that stroke patients too, like other patients, may require different types of information at different points in their illness trajectory,[20,61] health professionals may consider reassessing stroke patients' need for information at different points during their hospital admission.

While it is difficult to make concrete conclusions from our small study, we recommend doctors consider the following:

1. Exploring the social context and early experiences of patients to gain an understanding of their views and needs.
2. Being aware that patients may need psychological support, and that this best assessed prior to hospital discharge.
3. Being aware that, while guidelines exist, they may not apply to acute stroke patients: a shared decision-making approach may not always be appropriate.
4. Adapting strategies used in cancer when communicating hope but maintaining realism for patients who have had an acute disabling stroke.
5. Assessing the information needs of acute disabling stroke patients at various points during their hospital admission.

Strengths and limitations

We were successful in engaging and interviewing a group of patients at a time when they are often 'hard to reach' and therefore excluded from research. Following up these patients at six months has given us important insight into their ongoing (and changing) needs for information and support. However, due to the impact of a disabling stroke on patients' physical and psychological states, it sometimes proved challenging to probe and explore some of their experiences and views in-depth. Our sample size was relatively small and all participants were recruited from one tertiary teaching hospital. This reduced the diversity of our sample and hence, potentially, the transferability of the findings to other populations. [62] Patients in this study had capacity: our findings are therefore not applicable to those without mental capacity.

Recommendations for further research

Future researchers could consider investigating the views and needs of stroke patients from different socio-economic and ethnic minority backgrounds who may have different

information and support needs. Interviewing doctors who look after severe stroke patients could give us important insight into how, and why, doctors may have made decisions on behalf of the patient or what other factors they may have considered in the context of treatment decision-making.

Conclusions

Survivors of an acute disabling stroke have unmet psychological needs which may contribute to a poor quality of life post stroke. These needs must be identified and addressed to help patients cope with their situation. A shared approach with respect to treatment decision-making may not always be possible or appropriate for patients who have had an acute disabling stroke, especially when they may be emotionally distressed and wishing to maintain a hopeful outlook. Health professionals should therefore exercise professional judgement when trying to involve patients in decision-making in the early period after a disabling stroke. The mismatch between patients' ongoing need to maintain hope of functional recovery at six months, but retrospectively wishing they had been given realistic information in the early period after their stroke further adds to challenges of shared decision-making. In order to achieve a balance between maintaining hope while not providing false hope, communication strategies used in cancer may be adapted to the acute stroke setting. We also recommend reassessing the information needs of patients at different time points in hospital.

Acknowledgments

We would like to thank all the participants in this study for their invaluable time.

Author Contributions

Conceptualization: Akila Visvanathan, Julia Lawton.

Data curation: Akila Visvanathan.

Formal analysis: Akila Visvanathan, Julia Lawton.

Funding acquisition: Akila Visvanathan.

Investigation: Akila Visvanathan, Julia Lawton.

Methodology: Akila Visvanathan, Julia Lawton.

Project administration: Akila Visvanathan.

Resources: Akila Visvanathan.

Software: Akila Visvanathan.

Supervision: Gillian Mead, Martin Dennis, William Whiteley, Fergus Doubal, Julia Lawton.

Validation: Akila Visvanathan.

Visualization: Akila Visvanathan.

Writing – original draft: Akila Visvanathan.

Writing – review & editing: Akila Visvanathan, Gillian Mead, Martin Dennis, William Whiteley, Julia Lawton.

References

1. Townsend N. W., K.; Bhatnagar P.; Smolina K.; Nichols M.; Leal J.; Luengo-Fernandez R.; Rayner M. No Title. In: Coronary heart disease Statistics 2012 edition: British Heart Foundation, London. 2012. p. 107.
2. Adamson J, Beswick A. Is Stroke the Most Common Cause of Disability? PhD, * BSc, †. 2004; 13 (4):171–7.
3. Association Stroke. State of the Nation Stroke Statistics. 2018;(February). Available from: https://www.stroke.org.uk/system/files/sotn_2018.pdf
4. Report G, Stroke I, Party W. The National Sentinel Stroke Audit 2010 Round 7 National and Local Results for the Clinical Audit 2010 Generic Report Prepared on behalf of the Intercollegiate Stroke Working Party. 2011;(March).
5. Chang P, Prabhakaran S. Recent advances in the management of acute ischemic stroke [version 1; referees: 2 approved] Referee Status: 2018; 6(0):2–9.
6. Points M. Scottish Stroke Improvement Programme 2018 National Report. 2018;(July):2018–9.
7. Report AP. Sentinel Stroke National Audit Programme (SSNAP) Clinical audit. 2019;(March 2018).
8. Sandercock P, Wardlaw JM, Lindley RI, Dennis M, Cohen G, Murray G, et al. The benefits and harms of intravenous thrombolysis with recombinant tissue plasminogen activator within 6 h of acute ischaemic stroke (the third international stroke trial [IST-3]): A randomised controlled trial. Lancet [Internet]. 2012; 379(9834):2352–63. Available from: https://doi.org/10.1016/S0140-6736(12)60768-5 PMID: 22632908
9. Goyal M, Menon BK, van Zwam WH, Dippel DWJ, Mitchell PJ, Demchuk AM, et al. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. Lancet (London, England). 2016 Apr; 387(10029):1723–31.
10. Dennis M, Sandercock P, Reid J, Graham C, Forbes J, Murray G. Effectiveness of intermittent pneumatic compression in reduction of risk of deep vein thrombosis in patients who have had a stroke (CLOTS 3): a multicentre randomised controlled trial. Lancet [Internet]. 2013; 382(9891):516–24. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23727163 https://doi.org/10.1016/S0140-6736(13)61050-8 PMID: 23727163
11. Westendorp WF, Vermeij JD, Vermeij F, Den Hertog HM, Dippel DWJ, van de Beek D, et al. Antibiotic therapy for preventing infections in patients with acute stroke. Cochrane Database Syst Rev. 2012;(1).
12. Visvanathan A, Dennis M, Whiteley W, Visvanathan A, Dennis M, Whiteley W. Parenteral fluid regimens for improving functional outcome in people with acute stroke (Review) Parenteral fluid regimens for improving functional outcome in people with acute stroke. 2015;(9).
13. Dennis M, Lewis S, Cranswick G, Forbes J. FOOD: A multicentre randomized trial evaluating feeding policies in patients admitted to hospital with a recent stroke. Health Technol Assess (Rockv). 2006; 10 (2):1–91.
14. Officer CM, Report A. REALISTIC. 2014;
15. Visvanathan A, Dennis M, Mead G, Whiteley WN, Lawton J, Doubal FN. Shared decision making after severe stroke—How can we improve patient and family involvement in treatment decisions? Int J Stroke. 2017; 12(9).
16. Power TE, Swartzman LC, Robinson JW. Patient Education and Counseling Cognitive-emotional decision making (CEDM): A framework of patient medical decision making. Patient Educ Couns [Internet]. 2011; 83(2):163–9. Available from: https://doi.org/10.1016/j.pec.2010.05.021 PMID: 20573468
17. Wilson T, Miller J, Teare S, Penman C, Pearson W, Marlett NJ, et al. Patient perspectives on engagement in decision-making in early management of non-ST elevation acute coronary syndrome: A qualitative study. BMC Med Inform Decis Mak. 2017; 17(1):1–7. https://doi.org/10.1186/s12911-016-0389-x
18. Zussman R. Sociological Perspectives on Medical Ethics and Decision-Making. Annu Rev Sociol [Internet]. 1997 Aug 1; 23(1):171–90. Available from: https://doi.org/10.1146/annurev.soc.23.1.171
19. Frank C. A patient's experience in dementia care. 2017; 63:22–6.
20. Finney LJ, Arora NK, Bakos AD, Aziz N, Rowland J. Information needs and sources of information among cancer patients: a systematic review of research (1980–2003). 2005; 57:250–61.
21. Ménard C, Merckaert I, Razavi D, Libert Y. Decision-making in oncology: A selected literature review and some recommendations for the future. Curr Opin Oncol. 2012; 24(4):381–90. https://doi.org/10.1097/CCO.0b013e328354b2f6 PMID: 22572724
22. Killen A, Flynn D, De Brun A, O'Brien N, O'Brien J, Thomas AJ, et al. Support and information needs following a diagnosis of dementia with Lewy bodies. Int psychogeriatrics. 2016 Mar; 28(3):495–501.
23. Forster A, Brown L, Smith J, House A, Knapp P, Wright JJ, et al. Information provision for stroke patients and their caregivers. Cochrane Database Syst Rev [Internet]. 2012;(11). Available from: http://doi.wiley.com/10.1002/14651858.CD001919.pub3

24. General Medical Council. Treatment and care towards the end of life: good practice in decision making. Gen Med Counc [Internet]. 2010;1–85. Available from: https://www.gmc-uk.org/-/media/documents/treatment-and-care-towards-the-end-of-life—english-1015_pdf-48902105.pdf%0Ahttps://www.gmc-uk.org/Treatment_and_care_towards_the_end_of_life___English_1015.pdf_48902105.pdf%0Ahttp://www.gmc-uk.org/static/document
25. Holloway RG, Arnold RM. AHA/ASA Scientific Statement Palliative and End-of-Life Care in Stroke.:0–33.
26. Party SW. National clinical guideline for stroke. 2016;
27. Sarnowski B Von, Guerra WK, Kohlmann T, Moock J, Khaw A V, Kessler C, et al. Long-term health-related quality of life after decompressive hemicraniectomy in stroke patients with life-threatening space-occupying brain edema. Clin Neurol Neurosurg [Internet]. 2012; 114(6):627–33. Available from: https://doi.org/10.1016/j.clineuro.2011.12.026 PMID: 22236827
28. No Title [Internet]. 2017. Available from: https://www.headway.org.uk/news/national-news/coping-with-grief-after-brain-injury/
29. Fried TR, Byers AL, Gallo WT, Ness PH Van, Towle VR, Leary JRO, et al. Prospective Study of Health Status Preferences and Changes in Preferences Over Time in Older Adults. 2006;166.
30. Sprangers MAG, Schwartz CE. Integrating Response Shift Into Health Related Quality of Life Research a Theorical Model.Pdf. 1999; 48:1507–15.
31. Editorial The challenge of response shift for quality-of-life-based clinical oncology research. 1999;747–9.
32. Klein A, Kuehner C, Schwarz S. Attitudes in the general population towards hemi-craniectomy for middle cerebral artery (MCA) infarction. A population-based survey. Neurocrit Care. 2012 Jun; 16(3):456–61. https://doi.org/10.1007/s12028-012-9677-1 PMID: 22311231
33. Albrecht GL, Devlieger PJ. The disability paradox: high quality of life against all odds. 1999; 48:977–88.
34. Lay experiences of health and illness: past research and future agendas. 2003; 25:23–40.
35. Index B, Index A. Follow-up services for stroke survivors after hospital discharge–a randomized control study. 2002;593–603.
36. Dennis M, Sandercock P, Graham C, Forbes J. The Clots in Legs or sTockings after Stroke (CLOTS) 3 trial: A randomised controlled trial to determine whether or not intermittent pneumatic compression reduces the risk of post-stroke deep vein thrombosis and to estimate its cost-effectiveness. Health Technol Assess (Rockv). 2015; 19(76).
37. Bo K, Hoon S, Hoon K, Jeon K, Rae Y, Nam W, et al. Six-month functional recovery of stroke patients: a multi-time-point study. 2005;173–80.
38. Corbin J, Strauss A. Grounded Theory Research: Procedures, Canona and Evaluative Criteria. Zeitschrift fur Sociol. 1990; 19(6):418–27.
39. Bamford J, Sandercock P, Dennis M, Burn J, Warlow C. Classification and natural history of clinically identifiable subtypes of cerebral infarction. Lancet (London, England). 1991 Jun; 337(8756):1521–6.
40. Quinn TJ, Dawson J, Walters MR, Lees KR. Reliability of the modified rankin scale: A systematic review. Stroke. 2009; 40(10):3393–5. https://doi.org/10.1161/STROKEAHA.109.557256 PMID: 19679846
41. Harrison M, Ryan T, Gardiner C, Jones A. Psychological and emotional needs, assessment, and support post-stroke: a multi-perspective qualitative study. Top Stroke Rehabil [Internet]. 2017 Feb 17; 24(2):119–25. Available from: https://doi.org/10.1080/10749357.2016.1196908 PMID: 27309492
42. Johnston B, Narayanasamy M. Exploring psychosocial interventions for people with dementia that enhance personhood and relate to legacy- an integrative review. BMC Geriatr [Internet]. 2016;1–25. Available from: https://doi.org/10.1186/s12877-015-0167-0
43. Newell SA, Sanson-fisher RW, Savolainen NJ. Systematic Review of Psychological Therapies for Cancer Patients: Overview and Recommendations for Future. 2002; 94(8).
44. Reid J, Ski CF, Thompson DR. Psychological Interventions for Patients with Coronary Heart Disease and Their Partners: A Systematic Review. 2013; 8(9).
45. Sørensen L V, Waldorff FB, Waldemar G. Early counselling and support for patients with mild Alzheimer's disease and their caregivers: A qualitative study on outcome. Aging Ment Health [Internet]. 2008 Jul 1; 12(4):444–50. Available from: https://doi.org/10.1080/13607860802224342 PMID: 18791891
46. Weis J. Support groups for cancer patients. 2003;763–8.
47. Compare A, Germani E, Proietti R, Janeway D. Clinical Psychology and Cardiovascular Disease: An Up-to-Date Clinical Practice Review for Assessment and Treatment of Anxiety and Depression. 2011;148–56.

24. General Medical Council. Treatment and care towards the end of life: good practice in decision making. Gen Med Counc [Internet]. 2010;1–85. Available from: https://www.gmc-uk.org/-/media/documents/treatment-and-care-towards-the-end-of-life—english-1015_pdf-48902105.pdf%0Ahttps://www.gmc-uk.org/Treatment_and_care_towards_the_end_of_life___English_1015.pdf_48902105.pdf%0Ahttp://www.gmc-uk.org/static/document
25. Holloway RG, Arnold RM. AHA/ASA Scientific Statement Palliative and End-of-Life Care in Stroke.:0–33.
26. Party SW. National clinical guideline for stroke. 2016;
27. Sarnowski B Von, Guerra WK, Kohlmann T, Moock J, Khaw A V, Kessler C, et al. Long-term health-related quality of life after decompressive hemicraniectomy in stroke patients with life-threatening space-occupying brain edema. Clin Neurol Neurosurg [Internet]. 2012; 114(6):627–33. Available from: https://doi.org/10.1016/j.clineuro.2011.12.026 PMID: 22236827
28. No Title [Internet]. 2017. Available from: https://www.headway.org.uk/news/national-news/coping-with-grief-after-brain-injury/
29. Fried TR, Byers AL, Gallo WT, Ness PH Van, Towle VR, Leary JRO, et al. Prospective Study of Health Status Preferences and Changes in Preferences Over Time in Older Adults. 2006;166.
30. Sprangers MAG, Schwartz CE. Integrating Response Shift Into Health Related Quality of Life Research a Theorical Model.Pdf. 1999; 48:1507–15.
31. Editorial The challenge of response shift for quality-of-life-based clinical oncology research. 1999;747–9.
32. Klein A, Kuehner C, Schwarz S. Attitudes in the general population towards hemi-craniectomy for middle cerebral artery (MCA) infarction. A population-based survey. Neurocrit Care. 2012 Jun; 16(3):456–61. https://doi.org/10.1007/s12028-012-9677-1 PMID: 22311231
33. Albrecht GL, Devlieger PJ. The disability paradox: high quality of life against all odds. 1999; 48:977–88.
34. Lay experiences of health and illness: past research and future agendas. 2003; 25:23–40.
35. Index B, Index A. Follow-up services for stroke survivors after hospital discharge–a randomized control study. 2002;593–603.
36. Dennis M, Sandercock P, Graham C, Forbes J. The Clots in Legs or sTockings after Stroke (CLOTS) 3 trial: A randomised controlled trial to determine whether or not intermittent pneumatic compression reduces the risk of post-stroke deep vein thrombosis and to estimate its cost-effectiveness. Health Technol Assess (Rockv). 2015; 19(76).
37. Bo K, Hoon S, Hoon K, Jeon K, Rae Y, Nam W, et al. Six-month functional recovery of stroke patients: a multi-time-point study. 2005;173–80.
38. Corbin J, Strauss A. Grounded Theory Research: Procedures, Canona and Evaluative Criteria. Zeitschrift fur Sociol. 1990; 19(6):418–27.
39. Bamford J, Sandercock P, Dennis M, Burn J, Warlow C. Classification and natural history of clinically identifiable subtypes of cerebral infarction. Lancet (London, England). 1991 Jun; 337(8756):1521–6.
40. Quinn TJ, Dawson J, Walters MR, Lees KR. Reliability of the modified rankin scale: A systematic review. Stroke. 2009; 40(10):3393–5. https://doi.org/10.1161/STROKEAHA.109.557256 PMID: 19679846
41. Harrison M, Ryan T, Gardiner C, Jones A. Psychological and emotional needs, assessment, and support post-stroke: a multi-perspective qualitative study. Top Stroke Rehabil [Internet]. 2017 Feb 17; 24(2):119–25. Available from: https://doi.org/10.1080/10749357.2016.1196908 PMID: 27309492
42. Johnston B, Narayanasamy M. Exploring psychosocial interventions for people with dementia that enhance personhood and relate to legacy- an integrative review. BMC Geriatr [Internet]. 2016;1–25. Available from: https://doi.org/10.1186/s12877-015-0167-0
43. Newell SA, Sanson-fisher RW, Savolainen NJ. Systematic Review of Psychological Therapies for Cancer Patients: Overview and Recommendations for Future. 2002; 94(8).
44. Reid J, Ski CF, Thompson DR. Psychological Interventions for Patients with Coronary Heart Disease and Their Partners: A Systematic Review. 2013; 8(9).
45. Sørensen L V, Waldorff FB, Waldemar G. Early counselling and support for patients with mild Alzheimer's disease and their caregivers: A qualitative study on outcome. Aging Ment Health [Internet]. 2008 Jul 1; 12(4):444–50. Available from: https://doi.org/10.1080/13607860802224342 PMID: 18791891
46. Weis J. Support groups for cancer patients. 2003;763–8.
47. Compare A, Germani E, Proietti R, Janeway D. Clinical Psychology and Cardiovascular Disease: An Up-to-Date Clinical Practice Review for Assessment and Treatment of Anxiety and Depression. 2011;148–56.

Reporting "specific abilities" after major stroke to better describe prognosis

Akila Visvanathan, MbChB,† William Whiteley, PhD,† Gillian Mead, PhD,† Julia Lawton, PhD,‡,[2] Fergus N Doubal, PhD,† and Martin Dennis, MD†,[1]

Introduction: If health professionals are to involve major stroke patients and their families in making decisions about treatments, they need to describe prognosis in terms that are easily understood. We suggest that referring to "specific abilities", such as ability to be independent, walk, talk, eat normally, be continent, live without severe pain, live without major anxiety or depression and to live at home may be more easily understood than terms such as disabled based on the modified Rankin scale (mRs). *Objective:* We aimed to describe the "specific abilities" and quality of life of patients in each mRs level at six months after major stroke. *Patients and methods:* A longitudinal cohort study of patients admitted to hospital with major stroke with follow up at six months. *Results:* We recruited 403 patients, mean age 77.5yrs. The number (%) in each mRs level at six months was 0 (no problems): 8 (2%), 1: 45(11.2%), 2: 7(1.7%), 3: 149(37.1%), 4: 46(11.4%), 5: 36(9.0%) and 6(dead) 111(27.6%). Patients within each mRs level varied with respect to their "specific abilities" and quality of life. For example, of the 36(9%) patients with mRs 5, 30 (83%) could talk, 14(39%) were continent, 33(92%) were not in severe pain, 22(61%) did not have major anxiety/depression and 5(14%) could live at home. Their median utility (derived from HRQoL) was -0.08 (range -0.35 to 0.43). *Discussion and Conclusions:* Describing prognosis with the mRs does not convey the variation in specific abilities and HRQoL amongst patients with major stroke. Therefore, describing prognosis in terms of "specific abilities" may be more appropriate.

Key Words: Major strok—Specific abilities—Prognosis—Communication

Introduction

Health professionals are encouraged to involve patients and families in making treatment decisions.[1] This is particularly relevant in the context of a major stroke where an early treatment decision to accept or decline treatments may influence outcomes.[2] For example, accepting treatments such as intermittent pneumatic compression[3] and early tube feeding[4] increase the likelihood that the patient will survive, but be left with significant disability whereas declining these treatments may result in earlier death. However, terms such as 'disability' may have varied meanings to different people. Similarly, where health related quality of life (HRQoL) is reported, this is expressed as utilities (i.e. the desirability of a health outcome between -1 (worse health state) to 1 (excellent health state)) derived from the EQ5D or similar scales.[5] However, this may not be easily communicated. Furthermore, different individuals would have different perceptions of their HRQoL.

Although the deficits and needs of stroke survivors with respect to their mobility, communication and psychological well-being has been reported,[6] treatment

From the †Centre for Clinical Brain Sciences, The University of Edinburgh, Chancellor's Building, 49 Little France Crescent, Edinburgh EH16 4SB, United Kingdom.; and ‡The Usher Institute, The University of Edinburgh, 8 Teviot Place, Edinburgh EH8 9AG, United Kingdom.

Received March 19, 2020; revision received May 21, 2020; accepted May 22, 2020.

Funding: Chief Scientist Office, Scottish Government. (Ref: CAF/16/01)

Corresponding author. E-mail: avisvana@exseed.ed.ac.uk.

[1]Departmental tel: 01314659614

[2]Tel: 0131 6506197

1052-3057/$ - see front matter

https://doi.org/10.1016/j.jstrokecerebrovasdis.2020.104993

decisions early on after a major stroke are often made based on predictions of death or severe disability.[7] This is because disability scales such as the modified Rankin scale (mRs) which has seven levels ranging from 0 (No problems) to 6 (Dead)[8] and the Barthel Index (BI), a functional scale describing the ability of patients to perform several different activities of daily living are familiar to health professionals.[9] Furthermore, there are statistical models which have been validated for use in research to predict death and disability.[10] In contrast, there is considerable uncertainty with respect to the recovery of patients' specific abilities (e.g. mobility, speech) and a lack of adequately validated statistical models to predict these abilities.[11]

An important step in involving patients and families in decision-making is for health professionals to be able to effectively communicate information on patient prognosis in terms that are easily understood and on which they might base their decisions.

We hypothesised that patients and their families might find it more helpful if we described patients' prognosis in terms of "specific abilities";[2] i.e. ability to be independent, to walk, to talk, to eat normally, to be continent, to live without severe pain, to live without major anxiety or depression and to live at home. Patients admitted with major stroke described seeking hope, so expressing outcomes in positive terms (abilities), rather than negative ones (disabilities) may be more appropriate.[12] A first step towards communicating prognosis effectively was to describe the "specific abilities" and HRQoL of patients six months after major stroke and to relate these to their mRs.

Materials and Methods

We adhered to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for cohort studies.[13]

We prospectively recruited a longitudinal cohort of adults (>18 years) within 10 days of a major stroke in a UK teaching hospital and followed them up at about six months. Eligible patients had mRs 3-5 (described as a 'poor' outcome in clinical trials)[14] or mRs 0-2 (a 'good' outcome) but a deficiency due to the stroke with respect to at least two specific abilities. Patients or proxies (where the patient lacked capacity) provided written informed consent.

At baseline and at six months, we determined patients' mRs using the simplified modified Rankin scale questionnaire (smRsq),[15] their BI (scored 0-100)[8] and HRQoL with the EQ5D-5L.[5] We derived utilities using the published crosswalk calculator.[16] Proxies completed assessments where patients were unable to do so. We derived "specific abilities" based on single items from these commonly used and validated scales or for abilities which were not addressed by these scales i.e. eating, talking and living at home, by asking a specific question. For example, we derived 'able to be continent' from answers provided to urine and bowel continence items on BI and 'able to eat normally' by asking patients/ families the patients' ability to eat food at six months (i.e. normal diet, oral modified diet, nasogastric feed, feed through percutaneous endoscopic gastrostomy or radiologically inserted gastrostomy). We dichotomised each "specific ability" into 'able' or 'unable' based on judgements of stroke professionals at the recruiting hospital. (Table 1).

The Scotland A Research Ethics Committee (Ref: 17/SS/0029) approved our protocol. We used Stata 15 (Timberlake, 2017) for analyses.

Table 1. *Definitions of "specific abilities" after stroke based on dichotomies on single items from smRsq, BI, EQ5D-5L, or specific questions.*

Specific abilities at six months	Measure	Able	Unable
To be independent	smRsq	0-2	3-5
To walk	smRsq	Able	Unable
To talk*	Specific question**	No dysphasia, Mild or Moderate dysphasia	Severe dysphasia, Mute
To eat normally	Specific question**	Normal or Oral modified	Nasogastric tube, Percutaneous gastrostomy or Radiologically inserted gastrostomy
To be continent	BI	Continent or occasional accidents	Incontinent/catheterised
To live without severe pain	EQ5D 5L	No pain, mild or moderate pain or discomfort	Severe or extreme pain or discomfort
To live without major anxiety or depression	EQ5D 5L	Not anxious/ depressed, slightly or moderately anxious/ depressed	Severely or extremely anxious/ depressed
To live at home	Specific question**	Own home or families home	Residential home, Care home or Hospital

*language assessment only.
**options given and dichotomised.

Results

We recruited 403 patients between 10th May 2017 and 25th May 2018. Their mean age was 77.5 (SD 11.7) and 209/403 (52%) had a baseline mRs of five. (Table 2)

At six months the number and percentage of patients in each mRs level was 0 (no problems): 8(2%), 1: 45(11.2%), 2: 7 (1.7%), 3: 149(37.1%), 4: 46(11.4%), 5: 36(9.0%) and 6 (dead) 111(27.6%). Few (60/402, 15%) had a 'good' outcome, i.e. mRs 0-2. One patient was uncontactable. (Table 3)

Patients within each mRs level, especially mRs 3, 4 and 5, varied with respect to their "specific abilities" and HRQoL (Table 3). For example, of the 36 (9%) patients with mRs 5, 30(83%) could talk, 14(39%) were continent, 33 (92%) were not in severe pain, 22(61%) did not have major anxiety/depression and 5(14%) could live at home. Their median utility was -0.08 but ranged from -0.35 to 0.43. Of the 45 (11.2%) patients with mRs 1, all were able to talk, eat normally, be continent, not have major anxiety/depression and live at home, but two patients (4%) were in severe pain. Their median utility was 0.84 but ranged from 0.32 to 1.

Table 2. *Baseline characteristics of cohort*

Variable	Categories	Total n=403	%
Age (years) mean (Standard Deviation (SD))		77.5 (11.7)	
Gender	Male	179	44.4
	Female	224	55.6
Independent before stroke*		308	76.4
Living alone before stroke*		158	39.2
Pre-existing dementia		49	12.2
Atrial fibrillation	Current	47	11.7
	Past	89	22.1
Previous stroke or transient ischaemic attack		123	30.5
Stroke Subtype	Haemorrhagic	63	15.6
	Ischaemic	340	84.4
Able to lift arms after stroke*		152	37.8
Able to walk after stroke*		28	6.9
Able to talk*		248	61.5
Baseline mRs	0	0	0
	1	2	0.5
	2	4	1
	3	17	4.2
	4	171	42.4
	5	209	51.9
Baseline Barthel Index (BI) Mean (SD)		31.5 (25.6)	
Baseline Utility Mean (SD)		0.23 (0.36)	

*Six Simple variable.

Discussion/Conclusion

In this cohort of patients with major stroke, few had a 'good' outcome based on their mRs (mRs 0-2) at six months. There was considerable variation in "specific abilities" and HRQoL within each mRs level, especially amongst those with mRs 3-5 at six months after major stroke. Therefore, by describing patients' "specific abilities," health professionals may be able to give patients and their families a fuller picture of what the patients' future life might look like. This may allow better discussion of patient preferences and involvement in making treatment decisions.

Several previous attempts have been made to relate physical disability to HRQoL by assigning utility scores to mRs levels.[17,18] Our findings broadly agree with their findings; i.e. patients with higher mRs tended to have lower utilities. However, we have also shown that utilities varied, with a wide range within each mRs level.

Studies have reported that patients and their caregivers (often family members) require psychological support after major stroke[6,19] and have also described how the psychological support needs of caregivers of patients who are physically dependent after stroke may differ.[20] Our findings add to this; for instance, the knowledge that a proportion of physically disabled patients may also suffer from major anxiety and depression may allow health professionals to assess these patients and deliver early tailored information to them and their family members. This may include information on relevant support services for both patients and their families e.g. counselling and neuropsychology.[21]

Strengths and limitations

We have successfully recruited and followed up patients with major stroke who are often excluded from research studies. Our cohort was of modest size (n=403), were recruited prospectively and with minimal loss to follow up.

However, based on our inclusion criteria of major stroke patients, some mRs levels at six months included only small numbers of patients. Therefore, estimates based on these groups may be imprecise. We also recruited patients from a single centre only which may reduce the generalisability of our results. HRQoL assessments were completed by proxies where the patient was unable to do so. Therefore, for some "specific abilities" which were derived from EQ5D-5L (e.g. to live without severe pain and to live without major anxiety/depression), it is impossible to know if the answers provided by proxies were the same as the patients would have provided.[22–24] Utilities are also derived from assessments completed by healthy (non-disabled) individuals rather than those who are disabled. However, in the absence of alternative methods to obtain patients' assessments of their HRQoL (where patients lacked capacity) and deriving utilities, it is difficult to know how these could be improved.

Table 3. *Specific abilities and utilities in each mRs level at six months, n=402*

	mRs at about six months after stroke							
	0	1	2	3	4	5	6	All
Number (%)	8(2.0)	45(11.2)	7(1.7)	149(37.1)	46(11.4)	36(9.0)	111(27.6)	402(100)
Mean utility (Standard Deviation)	0.90(0.09)	0.82(0.14)	0.78(0.12)	0.37(0.37)	0.20(0.19)	-0.08(0.15)	0	0.50 (0.36)
Median Utility (total range)	0.88 (0.74 to 1)	0.84 (0.32 to 1)	0.84 (0.61 to 0.91)	0.32 (-0.01 to 1)	0.21 (-0.26 to 0.72)	-0.08 (-0.35 to 0.43)	0	0.62 (-0.35 to 1)
Specific abilities: n (% in mRs category)								
Live independently (smRsq)	8(100)	45(100)	7(100)	0	0	0	0	60(15)
Walk (smRsq)	8(100)	45(100)	7(100)	149(100)	0	0	0	209(52)
Talk	8(100)	45(100)	7(100)	137(92)	43(93)	30(83)	0	270(67)
Eat normally	8(100)	45(100)	7(100)	149(100)	45(98)	33(92)	0	287(71)
Be continent (BI)	8(100)	45(100)	7(100)	147(99)	38(83)	14(39)	0	259(64)
Live without major anxiety or depression (EQ5D-5L)	8(100)	45(100)	6(86)	132(89)	37(80)	22(61)	0	250(62)
Live without severe pain (EQ5D-5L)	8 (100)	43 (96)	7(100)	143 (96)	41 (89)	33 (92)	0	275(68)
Live at home	8(100)	45(100)	7(100)	137(92)	17(37)	5(14)	0	219 (54)

We collected data on "specific abilities" judged to be useful to patients and their family members by stroke doctors in the hospital where recruitment took place. We acknowledge that different individuals may have different opinions on "specific abilities" that may be useful and how these should be defined.

Some specific abilities could have been derived from several measures in our cohort. For instance, 'to walk' could have been derived from three measures: a) smRsq specific question: 'Can you walk from one room to another without the aid from another person?' b) Single item from BI: Mobility on a level surface or c) Dimension from EQ5D-5L: Mobility. We used the smRsq as our primary measure to define 'to walk' as we felt that there was less ambiguity in defining 'able' and 'unable' based on 'yes' or 'no' to the specific question. This is in contrast to BI and EQ5D which have several levels or dimensions respectively and we would need to decide a cut-off to define 'able' and 'unable'. As shown in Supplementary tables 1 and 2, each measure would categorise different numbers of patients as being 'able' or 'unable' to walk. Varying our cut-offs for 'able' and 'unable' would also change our results.

A useful next step would be to obtain feedback from patients and families on how they wish prognosis to be communicated to them in the context of a major stroke. Beyond that, we could develop statistical models to predict patients' "specific abilities". These might allow clinicians to provide more formal predictions of patients having a "specific ability" in the future and guide shared decision-making regarding treatments after major stroke.

Conclusions

We have shown that describing prognosis based on mRs does not convey the variation in "specific abilities" and HRQoL amongst patients with major stroke. Therefore, describing patients' "specific abilities" may be more appropriate. This may help patients and families prepare for the potential impact of major stroke and also to be involved in making treatment decisions.

Acknowledgement

None

Statement of Ethics

The Scotland A Research Ethics Committee (Ref: 17/SS/0029) approved our protocol

All participants provided informed written consent

Disclosure Statement

This research was funded by the Chief Scientist Office (CAF/16/01). Grant holder: Akila Visvanathan. Dr William Whiteley is also funded by the Chief Scientist Office and Dr Fergus Doubal is funded by the Stroke Association. The funders have no incentive in this work and the funding has no relevance to this paper.

Funding Sources

This research was funded by the Chief Scientist Office (CAF/16/01). Grant holder: Akila Visvanathan. The funder had no involvement in the preparation of data or manuscript.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.jstrokecerebrovasdis.2020.104993.

References

1. Chief Medical Officer. Realistic medicine: Scottish government [internet]. 2014. Available from: https://www.gov.scot/publications/chief-medical-officers-annual-report-2014-15/
2. Visvanathan A, Dennis M, Mead G, Whiteley WN, Lawton J, Doubal FN. Shared decision making after severe stroke—How can we improve patient and family involvement in treatment decisions? Int J Stroke 2017;12(9):920-922.
3. Dennis M, Sandercock P, Reid J, Graham C, Forbes J, Murray G. Effectiveness of intermittent pneumatic compression in reduction of risk of deep vein thrombosis in patients who have had a stroke (CLOTS 3): a multicentre randomised controlled trial. Lancet (London, England) 2013;382(9891):516-524.
4. Dennis M, Lewis S, Cranswick G, Forbes J. FOOD: A multicentre randomized trial evaluating feeding policies in patients admitted to hospital with a recent stroke. Health Technol Assess (Rockv) 2006;10:1-91.
5. Golicki D, Niewada M, Buczek J, Karlin A, Kobayashi A, Janssen MF, et al. Validity of EQ-5D-5L in stroke. Qual Life Res 2015;24:845-850.
6. McKevitt C, Redfern J, Mold F, Wolfe C. Qualitative studies of stroke: A systematic review. Stroke 2004;35(6):1499-1505.
7. Creutzfeldt CJ, Holloway RG. Treatment decisions after severe stroke: Uncertainty and Biases. Stroke 2012;43(12):3405-3408.
8. Sulter G, Steen C, De Keyser J. Use of the Barthel index and modified Rankin scale in acute stroke trials. Stroke 1999;30(8):1538-1541.
9. Quinn T.J.Ã., Dawson J., Walters M.R., Lees K.R.Topical review Functional outcome measures in contemporary stroke trials. 2009;4:200–5.
10. Teale EA, Forster A, Munyombwe T, Young JB. A systematic review of case-mix adjustment models for stroke. Clin Rehabil 2012;26:771-786.
11. Kwah LK, Herbert RD. Prediction of walking and arm recovery after stroke: A critical review. Brain Sci 2016;6(4).
12. Visvanathan A, Mead G, Dennis M, Whiteley W, Doubal F, Lawton J. Maintaining hope after a disabling stroke: A longitudinal qualitative study of patients' experiences, views, information needs and approaches towards making treatment decisions. PLoS One 2019;14:e0222500.
13. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: Guidelines for reporting observational studies. Int J Surg 2014;12(12):1495-1499.

14. Sulter G, Steen C, De Keyser J. Acute stroke trials. Trials 1999:1538-1541.
15. Bruno A, Akinwuntan AE, Lin C, Close B, Davis K, Baute V, et al. Simplified modified rankin scale questionnaire: Reproducibility over the telephone and validation with quality of life. Stroke 2011;42:2276-2279.
16. Euroqol. EuroQOL Crosswalk calculator [Internet]. 2019 [cited 2018 Aug 3]. Available from: https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/valuation-standard-value-sets/crosswalk-index-value-calculator/
17. Broderick JP, Adeoye O, Elm J. Evolution of the modified rankin scale and its use in future stroke trials. Stroke 2017;48:2007-2012.
18. Rivero-Arias O, Ouellet M, Gray A, Wolstenholme J, Rothwell PM, Luengo-Fernandez R. Mapping the modified rankin scale (mRS) measurement into the generic EuroQol (EQ-5D) health outcome. Med Decis Mak 2010;30(3):341-354.
19. Kendall M, Cowey E, Mead G, Barber M, McAlpine C, Stott DJ, et al. Outcomes, experiences and palliative care in major stroke: A multicentre, mixed-method, longitudinal study. Cmaj 2018;190(9):E238-E246.
20. Sennfält S, Ullberg T. Informal caregivers in stroke: Life impact, support, and psychological well-being—A Swedish stroke register (Riksstroke) study. Int J Stroke 2019;0(0):1-9.
21. Kneebone I.I., Kneebone I.I.Stepped psychological care after stroke Stepped psychological care after stroke. 2016;8288.
22. Pickard AS, Johnson JA, Feeny DH, Shuaib A, Carriere KC, Nasser AM. Agreement between patient and proxy assessments of health-related quality of life after stroke using the EQ-5D and health utilities index. Stroke 2004;35(2):607-612.
23. Dorman P, Slattery J, Farrell B, Dennis M, Sandercock P. Qualitative comparison of the reliability of health status assessments with the EuroQol and SF-36 questionnaires after stroke. Stroke 1998;29(1):63-68.
24. Segal ME, Schall RR. Relation to disability in stroke survivors. Stroke 1994;25:2391-2397.

Visvanathan et al. BMC Medical Informatics and Decision Making (2020) 20:98
https://doi.org/10.1186/s12911-020-01137-7

BMC Medical Informatics and Decision Making

RESEARCH ARTICLE Open Access

The considerations, experiences and support needs of family members making treatment decisions for patients admitted with major stroke: a qualitative study

A. Visvanathan[1*], G. E. Mead[1], M. Dennis[1], W. N. Whiteley[1], F. N. Doubal[1] and J. Lawton[2]

Abstract

Background: Treatment decision-making by family members on behalf of patients with major stroke can be challenging because of the shock of the diagnosis and lack of knowledge of the patient's treatment preferences. We aimed to understand how, and why, family members made certain treatment decisions, and explored their information and support needs.

Method: Semi-structured interviews with family members ($n = 24$) of patients with major stroke, within 2 weeks of hospital admission. Data were analysed thematically.

Results: Families' approach to treatment decision-making lay on a spectrum according to the patient's state of health pre-stroke (i.e. patient's prior experience of illness and functional status) and any views expressed about treatment preferences in the event of life-threatening illness. Support and information needs varied according to where they were on this spectrum. At one extreme, family members described deciding not to initiate life-extending treatments from the outset because of the patients' deteriorating health and preferences expressed pre-stroke. Information from doctors about poor prognosis was merely used to confirm this decision. In the middle of the spectrum were family members of patients who had been moderately independent pre-stroke. They described the initial shock of the diagnosis and how they had initially wanted all treatments to continue. However, once they overcame their shock, and had gathered relevant information, including information about poor prognosis from doctors, they decided that life-extending treatments were no longer appropriate. Many reported this process to be upsetting and expressed a need for psychological support. At the other end of the spectrum were family members of previously independent patients whose preferences pre-stroke had not been known. Family members described feeling extremely distressed at such an unexpected situation and wanting all treatments to continue. They described needing psychological support and hope that the patient would survive.

(Continued on next page)

* Correspondence: avisvana@exseed.ed.ac.uk
[1]Clinical Academic Fellow (Chief Scientist Office), Centre for Clinical Brain Sciences, The University of Edinburgh, 49 Chancellor's Building, Edinburgh EH16 4SB, UK
Full list of author information is available at the end of the article

(Continued from previous page)
Conclusion: The knowledge that family members' treatment decision-making approaches lay on a spectrum depending on the patient's state of health and stated preferences pre-stroke may allow doctors to better prepare for discussions regarding the patient's prognosis. This may enable doctors to provide information and support that is tailored towards family members' needs.

Keywords: Major stroke, Decision-making, Family members, Experiences, Needs

Background

Some treatment decisions need to be made early after a major stroke. Treatments such as hemicraniectomy [1] enteral tube feeding [2] and intermittent pneumatic compression [3] increase the likelihood the patient will survive but with significant disability. However, declining these treatments may increase the likelihood of death. Treatment decision-making following major stroke is particularly challenging because most patients do not have the mental capacity and/or are too medically unwell to understand the consequences of treatments. To ascertain patient preferences in these situations, professional organisations such as the General Medical Council and The American College of Critical Care Medicine encourage doctors to involve proxies (often family members) in decision-making [4, 5]. This recommendation is supported by literature which suggests that families know patients' preferences the best, [6–10] and seeking patients' preferences from others is a way of extending patients' autonomy [11, 12]. Furthermore, patients generally want their family members to be involved in decision-making [13] and most families want to be involved [14–16]..

However, making decisions concerning life and death is not easy for families for several reasons.

Firstly, family members may not know the patient's preferences and hence they may make decisions based on their own values rather than those of the patient [17, 18]. They may also find it difficult to make decisions that are potentially not life-extending, even if these are consistent with what patients may have previously expressed [19]. Patients may also change their views regarding the acceptability of treatments and potential outcomes once they are faced with a situation of critical illness or significant disability [20–22]. Therefore, family members are faced with two challenges; first, to make decisions based on the current situation; and, second, to predict how the patient may react if left significantly disabled.

Secondly, families may be in shock and making treatment decisions under these circumstances may be overwhelming. This challenge has been reported in various contexts, including in intensive care and severe stroke settings [5, 23, 24].

Thirdly, an important step in facilitating decision-making is for doctors to provide necessary information to families [4, 25, 26]. In the early period after a major stroke, families may be distressed. Hence, too much information may be overwhelming [27] and, families may want information that is specific to their situation along with support from doctors to make treatment decisions [28–30]. Recognising the information and support needs of families in the context of a major stroke is crucial to doctors who may need to tailor their communication to help families make decisions [31–34]..

A mixed methods study has acknowledged the need for effective communication of prognosis and psychological support for family members in the context of dealing with consequences of severe stroke [35]. Literature in stroke have also indicated that family members who make decisions on behalf of the patient wish for information on prognosis [36, 37]. However, to our knowledge, there is a lack of research exploring how and why family members make certain treatment decisions in the early period after a major stroke.

Thus, in this qualitative study, we aimed to address gaps in research on treatment decision-making by family members of patients admitted with major strokes. Specifically, we explored how family members made decisions regarding treatments given in the early period after a stroke that may increase the likelihood of the patient surviving longer, but with significant disability. We explored the factors considered by family members when deliberating about treatments, their early experiences in hospital when these decisions were made and their information and support needs. Based on our results, we provide recommendations for doctors communicating with family members of patients with major stroke in hospital.

Methods

Study design

We used semi-structured interviews informed by a topic guide to allow flexibility for participants to discuss issues and experiences which were important to them, including those unforeseen at the study outset and ensure the discussion remained relevant to addressing the study aims [38]. Based on reviews of the literature and discussion with clinical colleagues, we developed a topic guide (Table 1) which allowed us to explore, with families, what the patients' lives were like before the stroke and

Table 1 Topic guide

Interview time	Topics explored
Initial	• How family members saw the patients' life before the stroke; how patients were coping and if they required any help for their day to day activities. The patients' previous medical illnesses and experience with health care. • Whether patients had made any pre-stated wishes about treatments in the event of a critical illness and if so, the context in which these wishes were stated. • The emotional reactions of family members to stroke diagnosis and their initial experiences in hospital; if and how they reacted to, and came to terms with, the diagnosis and potential poor prognosis • The factors considered by family members when decisions needed to be made on treatments that were life-extending, but may leave the patient with potentially significant disability; how they arrived at a decision, and why • Based on family members' experiences in hospital, their early needs; how and why information or support may be useful to them, whether these changed over the first 2 weeks in hospital and if so, how and why.

how this may have influenced their views and approaches. We also explored their experiences soon after the patient's admission to hospital in order to set the context for understanding the treatment decisions which were made. Data collection and analysis took place concurrently, enabling issues identified in early interviews to inform areas explored in later ones [39]..

Interviews took place within the first 2 weeks of the patient's admission to hospital with a major stroke. This time point was chosen as we wished to capture the early experiences of family members when making treatment decisions. Furthermore, we recognised that most treatments we were interested in exploring (i.e. hemicraniectomy, enteral tube feeding, intermittent pneumatic compression, antibiotics and parenteral fluids) should have been discussed, and decisions made, during this time.

Recruitment and sampling

We recruited adult family members of patients admitted with major stroke to a large teaching hospital in the United Kingdom. This hospital recruits an average of 500 people a year who are physically disabled as a result of stroke. Around 200 of these patients would be significantly disabled and over 80% of these patients would not have mental capacity. Over 95% of patients are ethnically white, and over a third above the age of 75. To be eligible for our study, the patient needed to be significantly disabled as a result of the stroke and not have mental capacity to participate in decision-making. We defined these patients as having had a major stroke. Treatments (such as hemicraniectomy, enteral tube feeding, parenteral fluids, antibiotics or intermittent pneumatic compression) also needed to have been discussed and decisions made between the doctor and family member.

The medical team identified eligible patients. They considered whether the family member would be appropriate to approach regarding the study (i.e. participation would not be too distressing for them) and, if considered suitable, they asked them if they would be interested in taking part. Where family members were agreeable to being approached, the researcher (AV) then provided them with further information and if family members agreed to take part, AV then obtained informed written consent. AV is a clinical doctor with a Bachelor of Medicine degree (MbChB) specialising in geriatric medicine. Based on her clinical background, she has an interest in improving the involvement of family members in decision-making. She has previously worked in the stroke unit but not during the study duration or the year preceding commencement of this study. Participants were not informed about AV's clinical background or personal goals.

Recruitment continued till data saturation was achieved; that is when no new findings were identified in new data collected. Interviews were conducted in a private room in the ward where the patient was admitted at a time convenient to the family member. These interviews took place between May 2017 and November 2017 and lasted 20 to 55 min. All interviews were digitally audio recorded and transcribed in full. Table 1 summarizes the main areas explored in these interviews.

Data analysis

AV (who received formal training in qualitative methods including analysis) and JL (a very experienced non clinical qualitative researcher) analysed the interviews thematically using the method of constant comparison [39]. Both inductive and deductive approaches were used, which allowed unanticipated themes to emerge from data as well as identification of material needed to address the study aims. JL and AV read the interviews repeatedly and cross compared them to identify issues and themes that cut across different individuals' accounts. Upon discussion and agreement, a coding frame was developed that captured key themes.

We further analysed coded datasets to develop more nuanced interpretations of the data and identify illustrative quotations. We used a qualitative analysis software package (Nvivo version 11, QSR International Pty Ltd.) to facilitate data coding and retrieval.

Ethics approval

The study was approved by Scotland A Research Ethics Committee (Ref: 17/SS/0029).

To maintain anonymity, participant numbers are used below. For example, FM01 is used to indicate family member 1 and P01 is used to indicate patient 1.

Results

We interviewed 24 family members. Demographic information and relevant patient data is presented in Table 2.

Family members' decision-making regarding treatments on behalf of the patient admitted with major stroke lay on a spectrum. At one extreme, family members (the majority) described deciding not to initiate treatments from the outset. In the middle of the treatment decision-making spectrum, were family members who initially asked for all treatments to continue but later decided that life-extending treatments were no longer appropriate. At the other end of the spectrum were family members who wanted all treatments to continue at all costs.

Below, we will consider the factors determining these different decision-making approaches. We will then explore how the different approaches adopted by family members seemed to influence their early experiences in hospital, and their accompanying information and support needs. Where possible, we will report our findings based on where family members were on the treatment decision-making spectrum we have identified.

Table 2 characteristics of family members (participants) and the patients

Characteristics of family members (participants) ***n*** = 24	
Mean age in years (range)	62 (32–75)
Gender	8 male, 16 female
Relationship to the patient	3 partners, 19 children, 2 others (cousin, sister)
Ethnicity	All British white
Occupation	13 retired from work, 11 still working
Characteristics of patients (*n* = 24)	
Mean age in years (range)	85 (55–101)
Gender	7 male, 17 female
Occupation	22 retired, 2 working
Functional status prior to the stroke	11 independent, 13 required care (either a package of care at home or in a care home)
First stroke	23
Had community do not resuscitate order (DNAR)	7
Had pre-existing major comorbidities including dementia, heart failure and renal failure	11

Reflecting on patients' health pre-stroke, and preferences for life-extending treatments

Family members who had decided not to initiate life-extending treatments

Family members at one end of the treatment decision-making spectrum described how the patient who had been admitted to hospital, many of whom in their 80s' or 90s', already had chronic progressive conditions (e.g., dementia and arthritis) prior to their stroke. They described how, over the years, these conditions had resulted in gradual decline in their health and quality of life. Hence, family members noted how these patients had not been fully independent prior to stroke and how some had either lived in a care home or had been reliant on others for aspects of their care, such as washing and dressing. Family members further noted how this dependence on others had been a source of frustration and distress to the patient.

For example, FM01, the family member of P01 noted how P01 had various chronic medical conditions including arthritis and heart disease, and although had lived at home, had needed carers to come in four times a day. FM01 also described how P01's dependency on others had led to P01 being unhappy with life and extremely low in mood:

> *'P01's depressed … every time I go up P01'll say to me I don't want to be here, [name removed]. I seem to get it every week In fact..... P01 had said to me I love you but I want you to put the pillow over my head…' (FM01).*

According to these family members, which included FM01 and FM02 (who is quoted below), patients' increasing frailty and dependence on others had meant that, in many cases, they had indicated their preference, either to their family or their doctor, for not wanting their already poor quality of life to be extended:

> *'Well, P02 has been very unwell for the last nine months now. P02 had caecal carcinoma, so we have been involved with the hospital for a long time. So, we have had all the discussion about, what interventions P02 would want, so...I was in no doubt about what P02 wanted, which is not much.' (FM02).*

Many of these family members also reported how the patient had thought ahead to a circumstance where a decision might need to be taken regarding resuscitation:

> *'P03 already has a DNR in place. PO3's a very strong [gender removed].. P03 knew...well told us this is what...if it comes to a point where all the numbers stack up against P03, and finds requiring a DNR,*

which P03 wants, that would be the line to take. Do not resuscitate'. (FM03).

Family members who had decided to withdraw life-extending treatments over time

Family members who were in the middle of the treatment decision-making spectrum described how, although the patient had generally been quite old (late 70s' or early 80s'), they had been determined and able to maintain moderately independent lives. This included FM04 who described how P04, in [gender removed] 80s', had continued to lead a busy and active life right up to P04's stroke:

'When we got to 80, and [name removed] retired; well, P04 continued to work whenever P04 got the chance – P04 couldn't retire – and what P04's done since P04 was 80 is chopped wood and split logs … and even on Sunday, the day before this, P04 was working splitting logs. So P04 was very, very active and very strong'. (FM04).

FM05, likewise, described how P05 had been very determined and, despite having had multiple health problems and hospital admissions, had only needed minimal help to live independently:

'Well, P05's physically very strong, mentally very strong and P05's had things before which P05's come back from, in the hospital, heart attacks and quadruple bypass surgery and so on and P05's quite tenacious about life in general. We just do some shopping and cleaning for P05.' (FM05).

In keeping with their relative independence, family members noted how they felt that the patient had not generally thought about a circumstance where they may be left significantly disabled in any meaningful way. Hence, as FM06, the family member of P06 in [gender removed] 80s' noted, any comments the patient had previously made which had alluded to treatment preferences could not necessarily be interpreted as their true preferences, because they felt that these individuals had not properly considered a future situation of critical illness and/or significant disability:

'P06's friend had a stroke and went into a home … and that allowed me to introduce the subject of what would you like to do in the long term if you weren't able to live in your own home? And P06's response was, oh, I've never really thought about it. But well, if I couldn't stay in my own home I'd probably want to come and live with you. But I said that won't be possible as I work full time, and P06 says 'oh well, I'd go to a home then.'(FM06).

Family members who had asked for all treatments to continue at all costs

The minority of family members at the other end of the treatment decision-making spectrum reported how the patient had been relatively young and independent prior to their admission. Hence, family members reported that they did not feel that these individuals had considered a situation of critical illness and, therefore, they were not aware of them having articulated their own wishes for treatments in a situation where they might be left significantly disabled. This included FM07 the family member of P07 in [gender removed] 50s:

'Not really something that P07 would speak about; like, we like to get away every now and again, sort of, just we go camping and stuff like this; we'll walk at weekends. It's not really something that … I don't think P07's thought about the, sort of, long term'. (FM07).

Early hospital experiences and accompanying needs

Family members who had decided not to initiate life-extending treatments

Family members of patients who had already been physically dependent before the stroke, described how these patients had had multiple previous hospital admissions and therefore, how these previous experiences had made it easier for them to understand and accept that the patients' prognosis might be very poor. For instance, FM08, the family member of P08 in [gender removed] 90s' who had had a previous stroke, described how FM08 was familiar with being in hospital and was accepting of the fact that P08 was very unwell and might not survive:

'I mean, we kind of predicted that this was maybe the way it was going to go with this second stroke P08's had, the second time P08's been here; so there's a bit of history, so it's easier for all of us to understand the predicament we're in'. (FM08).

Given these experiences, and their confidence in knowing what the patient would have wanted with respect to life-extending treatments, these family members reported how they had determined that initiating such treatments would not be in the patient's best interests. This included FM09 who described how he had considered P09's preferences and had concluded that the situation P09 was now in (significantly disabled and requiring 24 h care) would not be the kind of life P09 would want to endure:

'P09 said P09 did not want people looking after [gender removed] and I think the point with P09's situation is that massive stroke – it's unlikely P09 will recover from it. If P09 does recover … P09's going to need full-time care, so that's … for P09 that's not an option; P09 wouldn't want that.' (FM09).

These family members thus described how they had already decided not to initiate life-extending treatments even before the doctor had provided their opinion on the patient's prognosis. Hence, as FM10, the family member of P10 in [gender removed] 90s', described, a discussion with the doctor was often used to justify a decision that had already been made, rather than to arrive at a decision:

'So, we've (referring to FM10, P10 and family) been very open about it and feel very strongly that no prolonging of life, given the quality of life that P10 has. So, that was the conversation I had with the consultant and it was rather nice and refreshing that the consultant was very open to listening and in total agreement with that, and also being quite honest as to the implications of the stroke, in terms of swallowing and the options, and things like that'. (FM10).

Family members who had decided to withdraw life-extending treatments over time

Family members of patients who had been moderately independent and had not formally expressed their preferences for life-extending treatments, described having been shocked and distressed by the diagnosis of a major stroke with poor prognosis. This included FM11 who shared [gender removed] astonishment at how, on the same day as the stroke, P11 had been leading a group tour of a historical site:

'Especially since P11 was, you know, completely fit and healthy one day, and, well, the same day, just suddenly, wallop. It was completely … changed P11, you know. So, yeah, it was a bit of a shock to the system'. (FM11).

These family members discussed how, because of their shock and distress, and not really knowing what the patient's preferences were, they had initially felt that they could not withhold any treatments that might have given them a chance of survival:

'So after two days of deterioration, so Doctor [name removed] said, what is your position on treatment and antibiotics; and I didn't really have … I didn't feel that I was in a … couldn't not doing treatment. So I was trying to think about what would P12 say. P12's really committed to life; so I said, well, I think if you felt it was okay I think P12 would want, wants to get better, P12's not ready to die'. (FM12).

Having initially asked for all treatments to be given, these family members reported how, over the days which followed this decision and as they got over their initial shock, they had reassessed the situation the patient was in and gathered evidence to make further decisions about (withdrawing) treatments. This included having discussions with family and friends about what the patient might have wanted with respect to treatments and future quality of life:

'And … initially my view was that because I didn't have enough medical knowledge, I thought that feeding P11 and giving the antibiotics and the other medication, we would start to see an improvement. And, you know, I had a hope … whether it was a forlorn hope or not that the treatment would have an effect. But P11's condition got worse- I'd spoken to various relatives and various friends of P11 and explained the situation and all of them said, oh P11 wouldn't want to carry on living like that.' (FM11).

They also described how such discussions had jogged their memory about situations where the patient had previously made informal comments about life-extending treatments or surviving with disability. They then reported how these remarks had led them to conclude that the patient would not have wanted to have been kept alive by tube feeding or if they needed full-time care. For example, FM13 described how P13 had been the main carer for [gender of partner removed] who had had a stroke, and had asked that no life-extending treatments be given to [name and gender of partner removed]:

'I don't think P13 would be very happy to be constantly fed and kept alive with tubes. My parent [gender removed] died with a stroke and P13 said the same thing, [gender of partner removed] wouldn't want this, wouldn't want that, wouldn't be happy if couldn't do XY and Z. So P13 was probably the most calm out of the whole family when [partner of P13] died.' (FM13).

Many also described how, when they were visiting the patient in hospital, they had observed them making gestures, such as removing oxygen masks and feeding tubes, which they interpreted as them wanting to reject these treatments:

'I think a lot of it was informed by the fact that P11 kept taking the feeding tubes out … And … just other signs. I mean, as P11's family member [gender removed], I know P11's facial expressions. And I just got the impression looking at P11 that P11 really wasn't happy in the situation that P11 was in. P11'd had enough and wanted it come to an end. P11 wouldn't want to be in a care home lying there, you know, effectively unable to do anything. And I think P11 was telling us that by removing the feeding tube and … telling us again by removing the oxygen'. (FM11).

While reflecting on the situation, and realising that the patient might not survive the stroke, many of these family members described how they had moved away from their initial hope that the patient would recover to a more pragmatic approach of looking for potentially realistic information from the doctor on the patient's likely (poor) prognosis. They then described how they used this information to decide on the appropriateness of (withdrawing) various life-extending treatments:

'Well each time a decision came along, I sat down with either Dr [name removed] or Dr [name removed] in the main and the main decision was on feeding and whether they should persist with it. So … yeah, I was given information. I asked them questions. We came to a judgment...' (FM11).

Although these family members described how, having reflected on the situation, they had decided that withdrawing treatments had been appropriate, they also noted how this process of decision-making (and treatment withdrawal) had been very upsetting for them. Some expressed how formal psychological support from hospital staff might have been helpful to them during this distressing time:

'You know, this is hard, very tough … some, kind of, counselling service available, preferably with people with some medical knowledge'. (FM11).

Family members who had asked for all treatments to continue at all costs

The minority of family members, where patients had been young and independent before the stroke, described how they had felt shocked, overwhelmed and emotionally unprepared for the situation they now found themselves in. For example, FM14, the family member of a previously independent [patient gender removed] in [patient gender removed] 60s', described how FM14 and [FM14's parent- gender removed] had felt helpless and extremely distressed seeing P14 in hospital in a physically dependent and agitated state:

'I saw P14, my [parent- gender removed] was in shock basically. It was quite upsetting to see P14 being sick and looked like P14 was not comfortable. It just felt yesterday nobody was helping P14 to try and get this bleed under control and trying to get P14 back. So it's, kind of, upsetting [sounding upset].' (FM14).

These family members expressed how, while feeling extremely distressed, they had looked for ways to maintain hope that the patient would survive. For example, FM14 described how FM14 thought back to instances in the past where P14, based on P14's determination to improve, had recovered well from minor illnesses. FM14 expressed how FM14 felt that, based on these previous situations, the current situation P14 was in would be one from which P14 would be able to pull through:

'I think P14 would cope with a lot. P14 can cope with a lot. P14 did have an operation on P14's arm and had to get a plate put in and they did say to P14 that P14 would only get … likely 45/50 per cent usage. But P14 pushed on and pushed on and got 90 per cent usage in P14's arm. They say P14 would only manage to get arm to here [lifting arm up from the table]. P14 can actually get arm to there [extending arm to 60 degrees]. And, you know, P14's a determined [patient gender removed].'(FM14).

In a related example, FM15 described how FM15 had looked for information from the doctor that gave FM15 hope that P15 would survive:

'To have heard from the doctor when [doctor gender removed] had said to us, you know, some people will survive, kind of, gave us a bit of hope; like, well, there is hope.' (FM15).

In their situation of extreme anguish, they expressed how they thought that all treatments should be given to the patient to promote the possibility (however small) of them surviving the major stroke:

'When it's a family member like you don't want them to withdraw treatment, you want them to give a 100 per cent and keep going no matter what. If a patient needs to be fed through a tube then they need to be fed through a tube and I don't think that's a decision that should be given to the family. It should just be...it should just happen'. (FM15).

These family members also expressed how they felt isolated at this difficult time and reported that emotional support would have been helpful:

> *'[FM14's parent- gender removed]'s not coping, we were just left, left like that. There's no one … Some sort of support would have been helpful, you know … but there was nothing..' (FM14).*

Discussion

Summary of key results

To our knowledge, this is the first qualitative study exploring early treatment decision-making by family members on behalf of patients with major stroke. Family members' approaches towards treatment decision-making lay on a spectrum, based on the patient's pre-stroke functional status and prior experiences of illnesses, and any views they had expressed about treatment preferences in the event of a critical illness which might result in significant disability or death.

At one extreme of the treatment decision-making spectrum, there were family members who had decided not to initiate life-extending treatments at stroke onset due to the patients' deteriorating health pre-stroke and stated treatment preferences pre-stroke. These family members looked for information from doctors to justify, rather than arrive at, their treatment decision. In the middle of this spectrum were family members of patients who were relatively independent, who decided to withdraw treatments over time once they got over the initial shock of the diagnosis and had time to gather relevant information from family, friends and doctors. At the other end of the spectrum were family members of previously independent patients whose treatment preferences were unknown. These family members asked for all treatments to continue at all costs and reported the need for hope of patient survival from doctors and psychological support.

Below, we place these findings into context of existing literature, and make recommendations for clinical practice.

The need to explore the patient's state of health before stroke

Our results agree with sociological literature reporting that the experiences of health and illness of individuals and relatedly, treatment decision-making, are socially and contextually informed [40]. Our results also corroborate results from studies involving family members of patients admitted to intensive care which have reported that, in addition to information regarding prognosis from doctors, the majority of family members estimated the patient's prognosis depending on their perceptions of the patient's strength of character, unique story of illness and survival and previous experiences and choices of treatments [41, 42].

Family members who decided not to initiate life-extending treatments appeared to have already experienced some anticipatory grief [43] and seemed to be prepared for the possibility that the patient might not survive. During the decision-making process, they had drawn on their previous experiences with those of the patient (for example, of the patient's multiple hospital admissions, and declining health and quality of life), and knowledge of the patient's treatment preferences. In contrast, where family members were unaware of the patient's preferences, they were generally in shock and unprepared for a situation of critical illness [19] and therefore, found treatment decisions more difficult to make [41]. Our study therefore further reiterates the need for doctors to explore the patient's preferences by gathering information from family members, perhaps through a narrative approach, i.e. by developing the patient's story [44].

Providing tailored information

As we have reported, the type of information that a family member might need varied depending on the patient's health state and stated preferences pre-stroke. Our findings therefore provide insight to doctors to help them better prepare for discussions about prognosis with family members. For example, before meeting with families of older and dependent patients, doctors can prepare themselves by ensuring that they can provide realistic information about the patient's (likely poor) prognosis and perhaps discuss treatments to optimise comfort. A practical four step approach may be appropriate, where the doctor initiates the discussion, clarifies understanding of prognosis with family members, identifies end-of-life goals and collaboratively develops an appropriate treatment plan focusing on comfort and symptom control [45]. For families of (relatively) independent patients, several meetings may be needed to share sufficient and relevant information, discuss preferences, weigh up pros and cons of available treatments and then arrive at decisions [31, 46, 47]..

In contrast, before meeting with families of young, previously fit and independent patients, doctors can prepare in advance on how best to deliver information, and address the likely emotional response (e.g. profound shock) as a result of the diagnosis. For example, doctors may consider using the 'SPIKES' protocol used in oncology which provides a six step strategy for breaking bad news and dealing with emotional responses [48]. Specifically, approaches such as active listening, observation of non-verbal communication, choosing words that may not be perceived negatively, breaking down information

into small pieces and offering another meeting at an agreed time may help families understand the situation of major stroke with poor prognosis better and help them cope with their emotions [48, 49]. Doctors should also consider how to balance the communication of hope with that of realism [50]. This can be complex [51]. Some family members may maintain a strong sense of hope that the patient may survive and recover despite accepting poor prognosis [52, 53]. Others may find hope by being overly optimistic about the patient's prognosis [29, 52, 54] and may not wish to obtain realistic information [55]. In contrast, some individuals may find hope when doctors discuss preparations for possible death and optimising comfort at end-of-life [56]. This further highlights the need for tailored communication, and doctors may consider adapting some communication strategies used in intensive care to the major stroke setting. For example, the use of the phrase 'hope for the best and prepare for the worst' can help manage expectations [57]. Using 'I wish' statements (e.g. 'I wish things were different') may also acknowledge the limits of available options while expressing empathy in a situation which may be futile, or where individuals may have unrealistic hopes [57, 58].

Exploring the need for psychological support

Our results indicate that the shock of stroke diagnosis and being involved in decisions not to continue life-extending treatments can be upsetting for family members [59–61]. There is evidence that the distress individuals may feel can linger for months or even years [62]. Therefore, when meeting with family members, doctors may consider exploring if they had support from friends and other family [63] and if they may wish counselling and emotional support from clinically trained staff (e.g. psychologists) to help reduce their distress [64, 65].

Recommendations for clinical practice

Based on our findings, we recommend doctors communicating with family members of patients with major stroke to consider the following:

1. To gather evidence regarding the patient's story using a narrative approach; specifically, on the patient's functional status pre-stroke and any previously stated preferences for life-extending treatments.
2. To tailor their communication of information depending on the individual's needs: i.e. information to confirm poor prognosis, that to facilitate shared decision-making or information to maintain hope (while being realistic and not offering false hope)
3. To be aware that family members may have unmet psychological and emotional needs which would need identified. Some may require more specialist input, e.g. clinical psychology.

Strengths and limitations

We engaged with a group of family members at a time which can be emotionally distressing for them and therefore, we were able to gain novel and important insight into their experiences, needs and approaches towards treatment decision-making. However, our sample size was relatively small and homogenous; all participants were of similar ethnicities and were recruited from one tertiary teaching hospital. Furthermore, since this study relied on participants 'opting-in', it is possible that individuals who participated were those who were more able to voice their experiences. Therefore, our sample of family members may not be representative of all family members of patients admitted with major stroke which may reduce the transferability and generalisability of our findings to other populations [66]..

Recommendations for further research

Future research could consider investigating the experiences, views and needs of families from different socio-economic and ethnic backgrounds, who may have different experiences and approaches towards treatment decisions. Staff training on communication strategies (e.g. using the 'SPIKES' protocol, 'Hope for the best, prepare for the worst') in major stroke would be helpful, and future research could consider further adapting and evaluating these strategies in the context of major stroke.

Conclusions

We identified a spectrum of treatment decision-making approaches by family members of patients with major stroke, defined by the patient's state of health and stated preferences pre-stroke, which influenced information and support needs of family members. The knowledge that such a spectrum exists may allow doctors to better prepare for discussions with family members regarding the patient's prognosis. Therefore, they may be able to provide information and support that is tailored towards family members' needs.

Abbreviations

FM: family member; P: Patient

Acknowledgements

We would like to thank all the participants for their invaluable time.

Authors' contributions

Conceptualization; A. V, G.M, M. D, W.W, F. D, J.L. Methodology; A. V, J.L. Software; A. V, J.L. Validation; A. V, M.D., W. W, G.M, F. D, J.L. Formal analysis; A. V, J.L. Investigation; A.V. Writing-original; A.V. Writing; Review and editing; M. D, W.W, G. M, J.L. Visualisation; A. V, J.L. Supervision; M. D, W.W, G. M, F.D, J.L. Project administration; A.V. Funding acquisition; A.V. The authors read and approved the final manuscript.

Funding
This study was funded by the Chief Scientist Office. The funder did not have any role in the design of the study, analysis, interpretation of data or writing of the manuscript.

Availability of data and materials
All data generated or analysed during this study are included in this published article and are not publicly available. This is to safeguard participant confidentiality. Transcripts are anonymised. Original recordings have been destroyed.

Ethics approval and consent to participate
The study was approved by Scotland A Research Ethics Committee (Ref: 17/SS/0029). All participants provided informed written consent to participate in the study and for information to be used for publication. Data have been anonymised.

Consent for publication
Not applicable.

Competing interests
FD is funded by the Stroke Association. WW is funded by the Chief Scientist Office. However, neither of these two co-authors was involved in data analysis, and their funding does not influence the presentation of data or interpretation of data in this manuscript. Other authors declare no competing interests.

Author details
[1]Clinical Academic Fellow (Chief Scientist Office), Centre for Clinical Brain Sciences, The University of Edinburgh, 49 Chancellor's Building, Edinburgh EH16 4SB, UK. [2]Usher Institute, The University of Edinburgh, Teviot Place, Edinburgh EH8 9AG, UK.

Received: 20 February 2020 Accepted: 26 May 2020
Published online: 01 June 2020

References

1. Goyal M, Menon BK, van Zwam WH, Dippel DWJ, Mitchell PJ, Demchuk AM, et al. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. Lancet (London, Engl). 2016;387(10029):1723–31.
2. Dennis M, Lewis S, Cranswick G, Forbes J. FOOD: A multicentre randomized trial evaluating feeding policies in patients admitted to hospital with a recent stroke. Health Technol Assess (Rockv). 2006;10:1–91.
3. Dennis M, Sandercock P, Graham C, Forbes J. The Clots in Legs or sTockings after Stroke (CLOTS) 3 trial: A randomised controlled trial to determine whether or not intermittent pneumatic compression reduces the risk of post-stroke deep vein thrombosis and to estimate its cost-effectiveness. Health Technol Assess (Rockv). 2015;19.
4. General Medical Council. Treatment and care towards the end of life: good practice in decision making. Gen Med Counc. 2010;1–85. Available from: https://www.gmc-uk.org/-/media/documents/treatment-and-care-towards-the-end-of-life---english-1015_pdf-48902105.pdf%0Ahttps://www.gmc-uk.org/Treatment_and_care_towards_the_end_of_life___English_1015.pdf_48902105.pdf%0Ahttp://www.gmc-uk.org/static/document.
5. Kon A, Davidson JE, Morrison W, Danis M, White DB. Shared decision making in intensive care units: an American College of Critical Care Medicine and American Thoracic Society Policy. Crit Care Med. 2016;44(1):188–201.
6. Shalowitz DI, Garrett-Mayer E, Wendler D. The accuracy of surrogate decision makers: a systematic review. Arch Intern Med. 2006;166(5):493–7.
7. Sachs GA, Stocking CB, Stern R, Cox DM, Hougham G, Sachs RS. Ethical aspects of dementia research: informed consent and proxy consent. Clin Res. 1994;42(3):403–12.
8. Hare J, Pratt C, Nelson C. Agreement between patients and their self-selected surrogates on difficult medical decisions. Arch Intern Med. 1992;152(5):1049–54.
9. Uhlmann RF, Pearlman RA, Cain KC. Physicians' and spouses' predictions of elderly patients' resuscitation preferences. J Gerontol. 1988;43(5):M115–21.
10. Bryant J, Skolarus LE, Smith B, Adelman EE, Meurer WJ. The accuracy of surrogate decision makers: Informed consent in hypothetical acute stroke scenarios. BMC Emerg Med. 2013;13(1).
11. Brudney D. Choosing for another: beyond autonomy and best interests. 2009.
12. Tonelli MR. Substituted judgment in medical practice: evidentiary standards on a sliding scale. J Law Med Ethics. 1997;25(1):2,22–9.
13. Sehgal A, Galbraith A, Chesney M, Schoenfeld P, Charles G, Lo B. How strictly do dialysis patients want their advance directives followed? JAMA. 1992;267(1):59–63.
14. Anderson WG, Arnold RM, Angus DC, Bryce CL. Passive decision-making preference is associated with anxiety and depression in relatives of patients in the intensive care unit. J Crit Care 2009;24(2):249–254. Available from: http://dx.doi.org/10.1016/j.jcrc.2007.12.010.
15. Heyland DK, Cook DJ, Rocker GM, Dodek PM, Kutsogiannis DJ, Peters S, et al. Decision-making in the ICU : perspectives of the substitute decision-maker. Intensive Care Med. 2003;29:75–82.
16. Johnson SK, Bautista CA, Hong SY, Weissfeld L, White DB. An Empirical Study of Surrogates ' Preferred Level of Control over Value-laden Life Support Decisions in Intensive Care Units. Am J Respir Crit Care Med. 20011;183:915–20.
17. Fagerlin A, Ditto PH, Danks JH, Houts RM, Smucker WD. Projection in surrogate decisions about life-sustaining medical treatments. Health Psychol. 2001;20(3):166–75.
18. Torke AM, Alexander GC, Lantos J. Substituted judgment: the limitations of autonomy in surrogate decision making. J Gen Intern Med. 2008;23(9):1514–7.
19. Majesko A, Hong SY, Weissfeld L, White DB. Identifying family members who may struggle in the role of surrogate decision maker. Crit Care Med. 2012;40(8):2281–6.
20. Klein A, Kuehner C, Schwarz S. Attitudes in the general population towards hemi-craniectomy for middle cerebral artery (MCA) infarction. A population-based survey. Neurocrit Care. 2012;16(3):456–61.
21. Von SB, Guerra WK, Kohlmann T, Moock J, Khaw AV, Kessler C, et al. Long-term health-related quality of life after decompressive hemicraniectomy in stroke patients with life-threatening space-occupying brain edema. Clin Neurol Neurosurg. 2012;114(6):627–33.
22. Sprangers MAG, Schwartz CE. Integrating response shift into health related quality of life research a Theorical model. Soc Sci Med. 1999;48:1507–15.
23. De Boer ME, Depla M, Wojtkowiak J, Visser MC, Widdershoven GAM, Francke AL, et al. Life-and-death decision-making in the acute phase after a severe stroke : interviews with relatives. Palliat Med. 2015;29(5):451–7.
24. Pham MT. Emotion and rationality: a critical review and interpretation of empirical evidence. Rev Gen Psychol. 2007;11(2):155–78.
25. Forster A, Brown L, Smith J, House A, Knapp P, Wright JJ, et al. Information provision for stroke patients and their caregivers. Cochrane Database Syst Rev. 2012;11:CD001919.
26. Stacey D, Legare F, Col NF, Bennett CL, Barry MJ, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2014;2014(1).
27. Klerings I, Weinhandl AS, Thaler KJ. Information overload in healthcare: too much of a good thing? Z Evid Fortbild Qual Gesundhwes. 2015;109(4–5):285–90.
28. Meeker MA. Family surrogate decision making at the end of life: seeing them through with care and respect. Qual Health Res. 2004;14(2):204–25.
29. Coulter MA. The needs of family members of patients in intensive care units. Intensive Care Nurs. 1989;5(1):4–10.
30. Wilkinson P. A qualitative study to establish the self-perceived needs of family members of patients in a general intensive care unit. Intensive Crit Care Nurs. 1995;11(2):77–86.
31. Shared Decision Making Collaborative: A consensus statement. 2011.
32. Visvanathan A, Dennis M, Mead G, Whiteley WN, Lawton J, Doubal FN. Shared decision making after severe stroke—how can we improve patient and family involvement in treatment decisions? Int J Stroke. 2017;12(9):920–2.
33. McKevitt C, Redfern J, Mold F, Wolfe C. Qualitative studies of stroke: a systematic review. Stroke. 2004;35(6):1499–505.
34. Ramsay P, Huby G, Rattray J, Salisbury LG, Walsh TS, Kean S. A longitudinal qualitative exploration of healthcare and informal support needs among survivors of critical illness: the RELINQUISH protocol. BMJ Open. 2012;2(4):1–7.
35. Kendall M, Cowey E, Mead G, Barber M, McAlpine C, Stott DJ, et al. Outcomes, experiences and palliative care in major stroke: a multicentre, mixed-method, longitudinal study. CMAJ. 2018;190(9):E238–46.

36. Addington-Hall J, Lay M, Altmann D, McCarthy M. Symptom control, communication with health professionals, and Hospital Care of Stroke Patients in the last year of life as reported by surviving family, friends, and officials. Stroke. 1995;26:2242–8.
37. Creutzfeldt CJ, Holloway RG, Curtis JR. Palliative care: a Core competency for stroke neurologists. Stroke. 2015;46(9):2714–9.
38. Pope C, Mays N. Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. BMJ. 1995;311(6996):42–5.
39. Corbin J, Strauss A. Grounded theory research: procedures, Canona and evaluative criteria. Zeitschrift fur Sociol. 1990;19(6):418–27.
40. Lawton J. Lay experiences of health and illness : past research and future agendas. Sociol Health Illn. 2003;25:23–40.
41. Boyd EA, Lo B, Evans LR, Malvar G, Luce JM, White DB. "It's not just what the doctor tells me:" factors that influence surrogate decision-makers' perceptions of prognosis*. Crit Care Med. 2012;38(5):1270–5.
42. Arnold RM, Kellum J. Moral justifications for surrogate decision making in the intensive care unit: implications and limitations. Crit Care Med. 2003;31: S347–53.
43. Hamilton IJ. Out of hours understanding grief and bereavement. Br J Gen Pract. 2016;66(651):523.
44. Charon R. Narrative medicine: a model for empathy, reflection, profession, and trust Rita. JAMA. 2001;286:1897–902.
45. Balaban R. A physician' s guide to talking about end-of-life care. J Gen Intern Med. 2000;15:195–200.
46. Frosch DL, Kaplan RM. Shared decision making in clinical medicine: past research and future directions. Am J Prev Med. 1999;17(4):285–94.
47. Armstrong MJ. Shared decision-making in stroke : an evolving approach to improved patient care. Stroke Vasc Neurol. 2017;2:e000081.
48. Baile WF, Buckman R, Lenzi R, Glober G, Beale E, Kudelka A. SPIKES — a six-step protocol for delivering bad news : application to the patient with Cancer. Oncologist. 2000;5:302–11.
49. Hardavella G, Aamli-Gaagnat A, Frille A, Saad N, Niculescu A, Powell P. Top tips to deal with challenging situations: doctor–patient interactions. Breathe. 2017;13(2):129–35.
50. Doubal F, Cowey E, Bailey F, Murray SA, Borthwick S, Somerville M, et al. The key challenges of discussing end-of-life stroke care with patients and families: a mixed-methods electronic survey of hospital and community healthcare professionals. J R Coll Physicians Edinb. 2018;48(3):217–24.
51. Werner A, Steihaug S. Conveying hope in consultations with patients with life-threatening diseases : the balance between supporting and challenging the patient. Scand J Prim Health Care. 2017;35(2):143–52.
52. Clayton JM, Hancock K, Parker S, Butow PN, Walder S, Carrick S, et al. Sustaining hope when communicating with terminally ill patients and their families: a systematic review. Psychooncology. 2008;17(7):641–59.
53. Salander PR, Bergenheim T, Henriksson R. The creation of protection and hope in patients with malignant brain tumours. Soc Sci Med. 1996;42(7): 985–96.
54. Zier LS, Sottile P, Hong SY, Weissfield L, White DB. Surrogate decision makers' interpretation of prognostic information: a mixed-methods study. Ann Intern Med. 2012;156(5):360–6.
55. Anne-Mei, Hak T. Collusion in doctor-patient communication about imminent death : an ethnographic study. Br Med J. 2001;174:1376–81.
56. Ghandourh WA, Rt M. Palliative care in cancer : managing patients expectations. J Med Radiat Sci. 2016;63:242–57.
57. Back AL, Arnold RM, Quill TE. Hope for the best, and prepare for the worst. Ann Intern Med. 2003;138(5):439–443. Available from: https://doi.org/10.7326/0003-4819-138-5-200303040-00028.
58. Quill TE, Arnold RM, Platt F. "I wish things were different": expressing wishes in response to loss, futility, and unrealistic hopes. Ann Intern Med. 2001; 135(7):551–555. Available from: https://doi.org/10.7326/0003-4819-135-7-200110020-00022.
59. Tilden VP, Tolle SW, Nelson CA, Fields J. Family decision-making to withdraw life-sustaining treatments from hospitalized patients. Nurs Res. 2001;50(2):105–15.
60. Braun UK, Beyth RJ, Ford ME, McCullough LB. Voices of African American, Caucasian, and Hispanic surrogates on the burdens of end-of-life decision making. J Gen Intern Med. 2008;23(3):267–74.
61. Hodges LJ, Humphris GM, Macfarlane G. A meta-analytic investigation of the relationship between the psychological distress of cancer patients and their carers. Soc Sci Med. 2005;60(1):1–12.
62. Wendler D, Rid A. Systematic review: the effect on surrogates of making treatment decisions for others. Ann Intern Med. 2011;154(5):336–46.
63. Maly RC, Umezawa Y, Leake B, Silliman RA. Mental health outcomes in older women with breast cancer: impact of perceived family support and adjustment. Psychooncology. 2005 Jul;14(7):535–45.
64. Peris A, Bonizzoli M, Iozzelli D, Migliaccio ML, Zagli G, Bacchereti A, et al. Early intra-intensive care unit psychological intervention promotes recovery from post traumatic stress disorders, anxiety and depression symptoms in critically ill patients. Crit Care. 2011;15(1):R41. Available from: http://ccforum.com/content/15/1/R41.
65. Papathanassoglou ED. Psychological support and outcomes for ICU patients. Nurs Crit Care. 2010;15(3):118–28.
66. Guba EG, Lincoln YS. Fourth Generation Evaluation. Newbury Park ; London ; New Delhi: Sage Publications; 1989.

Publisher's Note