Outcomes and Needs of Stroke Survivors after Acute Stroke and Early Supported Discharge (ESD) in an Irish Population, and at 3 and 6-months: A prospective cohort study.

Introduction

Stroke is the second leading cause of death in Western Europe, and the leading cause of severe long-term adult disability(1, 2). The burden of Stroke is increasing across the globe (3), with the economic burden of stroke across Europe now estimated at 60 billion (4).

The process of stroke survivors transitioning from hospital to the community, taking into account their unique and complex needs, is often fraught with complexities. Stroke patients either transition directly home, benefit from a period of inpatient rehabilitation, or access rehabilitation through Early Supported Discharge (ESD), which, by providing support in a community setting, has proved effective in accelerating discharge from hospital, and improving patient's quality of life (5, 6). However, while approximately 5,500 adults were admitted to Irish hospitals with stroke in 2019 (6, 7), only 7% of stroke survivors had access to ESD (8), compared to 39% in the UK(9).

After structured stroke services conclude, stroke patients and their families are frequently disappointed and frustrated as the concept of organised stroke care disappears (10). People with stroke often need continued rehabilitation and other supports. This requires a care transition from the acute hospital and ESD services to community services such as; primary care, social care, mental health, and health and wellbeing services. Un-coordinated care transitions are known to be a risk of substantial burden for patients and their family members, leading to risk for adverse events, rehospitalisation and dissatisfaction with services (11). The global epidemiological shift of disease burden towards long term conditions means understanding long-term outcomes. Stroke is no exception to this and understanding the long-term outcome needs of stroke survivors is becoming increasingly important. More people are surviving stroke to experience its long term consequences, but the outcomes and needs of people living with stroke in Ireland have not been described in detail.

The **Institute of Medicines analytical framework**(12) for quality health care will guide this project, which will review stroke survivor outcomes and survivor needs at hospital to home discharge, and at 3 and 6 months, will provide insight into the resource gaps for stroke survivors after their discharge from hospital or ESD. It will inform health care providers and policy makers in the development of stroke services nationally, that enhance transitions of care post-stroke, are timely, efficient, and equitable for all. This project is one of four PhD projects as part of a HRB funded Collaborative Doctoral

Award (CDA) at RCSI/UCD, 'iPASTAR: Improving Pathway for Acute STroke And Rehabilitation' led by Principle Investigators Prof David Williams and Prof Frances Horgan.

Patient and Public Involvement (PPI): This study recognises that the traditional "linear" model of knowledge generation is insufficient when addressing the complexity of care transitions. An iPASTAR PPI panel of stroke survivors, family members and a representative from a stroke support group (n=20), contributed to the development of the iPASTAR research questions and will work with the research team for the duration of the award (2020-2025). Six stroke survivors (PPI champions) have contributed to the methodological development of this project, we have discussed recruitment, timing of assessments, and data collection. I have taken on board ideas generated by the PPI panel in the development of the ethics documents (design of the study patient information leaflet (PIL); considerations for data protection); and around minimising participant burden and maximising response rates by allowing participants to specify preferences for data collection.

Aim: This study aims to explore and describe the outcomes, needs and healthcare utilisation, at discharge, and at 3 and 6 months, of people with stroke who have transitioned from hospital to home. This study will allow us to better understand the needs of the stroke population at the care transition from hospital and ESD services to home, and how those needs change over time.

Research Question: What are the outcomes and unmet needs of stroke survivors when transitioning to home, and at 3 and 6 months after discharge from structured services?

Research Objectives

1. To explore the outcomes of stroke survivors in the first 6 months after stroke, using standardised assessments of global health, function, quality of life and cognition.

2. To explore the unmet needs of stroke survivors living at home in the first 6 months after stroke, using a standardised needs assessment.

3. To explore healthcare utilisation of stroke survivors in the first 6 months after stroke, using a healthcare utilisation diary

Method:

Study design: An observational prospective cohort study of consecutive patients presenting with stroke will determine discharge, 3-, and 6-month, outcomes and needs of stroke survivors' post-

thrombectomy, stroke rehabilitation and ESD. The Strengthening and the Reporting of Observational Studies and Epidemiology (STROBE) guidelines(13) will be used to improve the quality of reporting (ensuring complete and adequate reporting) for my observational study.

Setting: The study will take place in collaboration with the stroke service at Beaumont Hospital, Regional Hospital Mullingar, and the ESD team in University College Hospital, Galway. A separate REC application was submitted, and approved by Beaumont Hospital, University College Hospital, Galway and Regional Hospital Mullingar.

Recruitment**:** Consecutive acute stroke patients will be recruited, between March 2022-December 2022, from the stroke services at the three participating hospital sites, in partnership with the director stroke services, stroke consultants, clinical nurse specialists and multi-disciplinary team members in stroke inpatient, off-site rehabilitation and ESD services.

Inclusion criteria:

- Consenting adults, over the age of 18, hospitalised after an acute stroke
- Only patients who are identified as being discharged home will be included.
- Patients must be cognitively competent to consent (as determined by clinical judgement); able to communicate; able to sign / give verbal consent.

Exclusion criteria:

-Patients who present with subarachnoid haemorrhage (SAH) or transient ischemic attack (TIA);
- Those that decline to provide informed consent;
- Those that are unwilling to be followed up.

Procedure: Patients will be screened for inclusion in the study by a gatekeeper, a member the stroke team at one of the three hospital sites (BH; UHG; RHM) - Details outlined in table 1. Eligible participants will be given, by the gatekeeper, a participant information leaflet (PIL) about the proposed study and a consent form, with directions to complete the consent form and return to the gatekeeper. Patients with communication difficulties can be supported by a family member / carer to partake in the study. The gatekeeper will inform the researcher (GOC) when consent has been obtained, and provide contact details for the participant (and support person), and some disease-related data (Table 2).

Data Collection: Baseline participant characteristics, disease related data and self-reported outcomes and needs of consenting participants will be collected by the primary researcher (GOC) within 7-10 days of discharge to home (T0) (Table 2). GOC will contact the participant (or support person) via telephone to arrange a suitable day, time and method for data collection. The researcher (GOC) will determine patient (and support person) preference for data collection (visit the participant in their home, telephone interview, or use videoconferencing platforms (Zoom/Microsoft Teams)), while adhering to relevant Covid-19 guidelines.

Participant characteristics

Patients will complete self-reported questionnaire that will gather information on patient's date of birth, gender, co-habiting status, employment, and pre-stroke homecare.

Disease-related data

Disease-related data including; date and type of stroke, stroke severity, reperfusion, and level of communication will be gathered from the patient chart and reported by the gatekeeper on transfer of participant contact details. Stroke severity on admission is measured using the National Institute of Health Stroke Severity Scale (NIHSS), a validated and reliable tool (14, 15), evaluating level of consciousness, vision and gaze, facial palsy, extremity weakness, limb ataxia, sensory loss, language, dysarthria, and neglect.

Self-reported **outcomes** (global health, function, cognition, quality of life), and **needs** will be gathered from the standardised self-reported questionnaires and surveys. Self-reported **healthcare utilisation** will be gathered from participant completion of a healthcare diary. **Table 2** includes an overview of the data collected, instruments and the time of collection

Outcomes:

PROMIS Global 10

The PROMIS Global-10 short form will be used to assess global health. It consists of 10 items that assess general domains of health and functioning including overall physical health, mental health, social health, pain, fatigue, and overall perceived quality of life. The scoring system allows each of the individual items to be examined separately, and be collated into 2 summary scores: Global Physical Health (GPH) and Global Mental Health (GMH). PROMIS Global-10 is recommended by the International Consortium for Health Outcomes Measurement (ICHOM) for use as part of a standard

set of outcome measures in stroke(16); and exhibits acceptable performance in validity and reliability testing (17, 18).

Simplified Modified Rankin Scale (smRS)

The Simplified Modified Rankin Scale (smRS**)** will used to assess the degree of disability caused by stroke (19). The smRS is scored on a six-point Likert scale ranging from 0 to 5 categorised as: 0) no symptoms; 1) no significant disability despite symptoms; 2) slight disability; 3) moderate disability; 4) moderate/severe disability; and 5) severe disability. It has been claimed to be reliable and valid to use for people with stroke (19, 20).

Telephone Montreal Cognitive Assessment Scale (T-MoCA)

The Telephone Montreal Cognitive Assessment Scale (T-MoCA) will be used to screen and identify mild cognitive impairment (21). The T-MoCA consists of six domains: short time/work memory, attention, abstraction concentration, language, and orientation to time. A total score ranging from 0-22 is calculated with lower scores indicating more severe cognitive impairment. The T-MoCA is a valid and reliable screening tool (21), allows flexibility of data collection and does not present the same barriers to access inherent to videoconferencing, as individuals can participate via landline or cell-phone, without requiring more advanced technological equipment or proficiency.

EuroQol 5 Dimenion-5L (EQ5D-5L)

The EuroQol 5 Dimenion-5L (EQ5D-5L) will be to assess health-related quality of life in participants. The EQ5D-5L consists of five dimensions (mobility, self-care, usual activities, pain and discomfort, anxiety & depression), each of which has five severity levels that are described by statements appropriate to that dimension (22). The EQ5D-5L has been found to valid for use as a generic health outcome measure in stroke (23).

Needs:

Stroke Survivor Needs Assessment

Self-reported needs will be assessed using the UK Stroke Survivor Needs Survey (10) which asks 44 closed questions incorporating health after stroke; everyday living; work and leisure; family, friends and use of support groups; personal and household finances; other needs and facilitators of recovery. An open ended question for additional comments is also included. *For 3- and 6-month time points the UK Stroke Association Needs Assessment will be used in its entirety but it is likely not all of this

form will be appropriate to stroke survivors immediately on discharge from hospital. PPI will be asked to review the form and advise/guide on the questions that are appropriate/ those that should be eliminated.

Healthcare utilisation

Participants' **self-reported healthcare utilisation** will be recorded contemporaneously. At the point of discharge home, participants will be provided with a diary. They will be requested to record all contacts with nursing, allied health, paramedical and medical professionals including hospital admissions over the 6-month follow-up period. At follow-up time points 3 and 6 months after discharge, participants will be asked for a copy of the diary.

At **3-month (T1),** and at **6-month (T2)** time periods, participants will be contacted by GOC to arrange to repeat the assessment battery (self-reported outcomes (global health, function, cognition, quality of life), and needs carried out at T0, and to determine healthcare utilisation over the previous 3 months.

Table 2 includes an overview of the data collected, instruments and the time of collection

Data collection will take approximately 15-20 mins at T(0) and 15-20 mins at T(1)&T(2). If the participant is fatigued in the course of data collection, the investigator (GOC) will arrange another time to complete assessment. For administration of the self-reported needs survey, participants can be given the option of completing as a google docs form or postal questionnaire. In the event of postal completion, eligible participants will be posted the questionnaire with a prepaid reply envelope and directions to complete and return their questionnaire to the study co-ordinating centre. Non-responders will be contacted by the researcher (via telephone/email/reminder letter as per participant preference) after approx 2 weeks to remind them to complete and return the questionnaire, or to arrange for the questionnaire to be completed over the phone, via video-conferencing or in a face-to-face interview.

<u>Sample size</u>

In 2020 Midlands Regional Hospital, Mullingar admitted approximately 150 strokes patients (8). Approximately 50% of all stroke patients are discharged home, so based on these figures, in a 6-month period we could expect to recruit between 25-35 participants. We will aim to recruit between 15 and 20 participants from RHM.

In 2019 Beaumont hospital admitted 470 strokes patients (7). Thirty nine patients from the Beaumont catchment area received a thrombectomy; with 50% discharged home, and 6% (28) of all stroke admissions were discharged with ESD. Based on 2019 figures, in a 6-month period we could expect to recruit approximately 15-20 participants who have experienced thrombectomy, and 15-20 who have experienced ESD. We could expect to recruit between 30-50 stroke survivors in a 6-month period.

University Hospital Galway was excluded from the 2019 NOCA Audit as their audit co-ordinator post was vacant (7). Collaboration with ESD coordinator (21/5/2021) reported 60 patients receiving ESD in 2019. Based on 2019 figures, in a 6-month period we could expect recruit approximately 15-20 participants who have experienced ESD.

We aim to recruit 60-90 participants in total from all sites.

Ethics

Ethics approval will be sought from RCSI; Midlands Regional Hospital, Mullingar; Beaumont; and University Hospital Galway research ethics committees (RECs). Covid-19 restrictions may impact on the presence of a researcher to carry out relevant measures so capacity for using telephone and online platforms has been built into the REC proposals to avoid time wastage making resubmissions at a later date.

Data Analysis:

All data will be collated in, and analysed using Stata V16. Categorical data will be coded and continuous data will be entered in numerical format.

Appropriate descriptive statistics (e.g. means, standard deviations, frequencies, percentages) will be used to report patient characteristics, levels and type of self-reported need, healthcare utilisation and outcome measures at each time point (Global Physical and Mental Health, Cognition, Function and Quality of life). All continuous variables will be assessed for normality using histograms and Shapiro-Wilk tests. Means and standard deviations will be calculated for normally distributed continuous variables, otherwise a median and interquartile range will be calculated.

The total number of unmet needs reported by each respondent will be calculated by summing the number of times a need was reported as “unmet” or “only partially met”. Needs within the same domain will be calculated as separate needs.

Health care utilisation including GP visits, hospitalisation and emergency care will be described across the full 6 months of data collection.

If possible, we will explore potential associations between unmet needs, type of intervention, gender, age group, time since stroke, co-habitation and the outcome measures using appropriate regression analyses and results reported as point estimates and 95% confidence intervals.

Dr Fiona Bolan has been consulted for statistical support.

Table 1: Recruitment and data collection plan

RECRUITMENT	Who	How	When
Tell participants about study and consents participants	Gatekeeper-member of inpatient / rehab (**and** ESD team if applicable)	1.Provide patient with Patient Information Leaflet (PIL) 2. Return to ask if patient is interested in participating in the research. 3. If they want to participate talk them through signing the consent form attached to the PIL, and encourage to add researcher number to phone (to optimise reach) 4. Inform the researcher (GOC) when patient has consented providing their details (or that of support), basic stroke details, and their expected discharge date to ESD (or acceptance to ESD for those recruited in ESD).	Before hospital discharge (or with 2-3 days of acceptance to ESD if applicable)
DATA COLLECTION	**Who**	**Format**	**When**
Gather baseline demographics and risk factor information	Researcher	Face to face, telephone or video-conferencing: **Participant response via self-reported questionnaire**	At T0, following consent. T0 = Within 7-10 days of arrival home from hospital
Collect outcome measures	Researcher	Face to face, telephone or video-conferencing: **Participant response via self-reported outcomes battery which will include:** PROMIS-10 Simplified Modified Rankin Scale (smRS) Telephone-Montreal Cognitive Screen (T-MoCA) EQ5D-5L	At T0 At T1 (90 days) At T2 (6 months)
Identify needs	Researcher	Face to face, telephone, video-conferencing, postal **Participant response via self-reported needs survey** Stroke Association Needs Survey	At T0 At T1 (90 days) At T2 (6 months)
Identify health-care utilisation	Researcher	Diary and self-reported use	At T1 (90 days) At T2 (6 months)

Table 2: Overview of the data collected, instruments and the time of collection

Data	Instrument / Source	Time of data collection		
		Baseline (TO)	3 months (T1)	6 months (T2)
Patient characteristics				
Date of birth (DOB)	Gatekeeper/ Questionnaire	●		
Sex	Questionnaire	●		
Cohabiting	Questionnaire	●		
Work status	Questionnaire	●		
Home care-pre stroke	Questionnaire	●		
Disease-related data				
Date of stroke	Gatekeeper	●		
Type of stroke	Gatekeeper	●		
Aphasia	Gatekeeper	●		
Reperfusion therapy	Gatekeeper	●		
Stroke severity (NIHSS)	Gatekeeper	●		
Outcomes				
Global health	PROMIS-10	●	●	●
Disability	smRS	●	●	●
Cognition	T-MoCA	●	●	●
Quality of life	EQ5D-5L	●	●	●
Needs				
Needs	Stroke Association Needs Survey	●*	●	●
Healthcare utilisation				
Date of hospital discharge (length of stay)	Questionnaire	●		
Healthcare utilisation	Diary	●	●	●

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