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COMprehensive Post-Acute Stroke Services (COMPASS) Study

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Patient-Centered Outcomes Research Institute (PCORI)

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Background

Stroke is the fifth-leading cause of death in the United States (US) and a major cause of long-term disability.[1] North Carolina (NC) is in the Stroke Belt, a region of the US with a very high stroke incidence. Eastern NC is the "buckle" of the Stroke Belt, where stroke mortality is 40% higher than the US average and hospital admission rates are the highest in NC.[2] African Americans, over 20% of the population in NC, are more likely than their white counterparts to die of stroke at relatively young ages.[2] There is also evidence that African-Americans are more likely to be readmitted after stroke.[3]

Stroke exemplifies a complex co-morbidity condition, with 85% of Medicare beneficiaries with stroke having four or more other chronic health conditions,[4] and their health care is costly. Stroke patients with congestive heart failure have per capita costs that are about five times higher than the average spending for Medicare fee-for-service beneficiaries.[4] In addition, stroke patients are frequently readmitted to the hospital.[5,6] A PCORI-funded study shows that 25% of stroke patients discharged home without post-acute care are readmitted within 90 days[7]. These data align with what stroke survivors and caregiver advocates from across NC have said that stroke patients need. One of our patient partners who started a support group for other stroke survivors stated:
"You can't just place an individual back in their home with a bottle of pills and a follow-up visit…There is a real need for assistance when patients get home…What is in place for the patient? Nothing… No visiting nurse, no one to answer questions, or help them get what they need. That is why people end up back in the hospital."

Roughly half of stroke patients in NC are discharged directly home, often with new disability. Around 44% cannot walk independently at discharge.[8] Complications from immobility account for up to 51% of deaths in the first 30 days after ischemic stroke.[9,10] Other complications are common early after stroke and include falls and fractures, aspiration pneumonia, deep vein thrombosis, infections, depression, and adverse events associated with warfarin therapy.[11–16] Even those with mild post-stroke disability can have physical and cognitive deficits which often go undetected during acute hospitalization. These mild disabilities interfere with function, and management of risk factors and medication.[17,18]

Fewer than 50% of individuals with stroke have their risk factors assessed, treated, or controlled. Of those overweight at initial evaluation, 90% remain overweight. Nearly half of hypertensive individuals do not have blood pressure controlled. Smokers do not quit and few participate in exercise programs.[19] At three months post-discharge, only 75% of stroke patients are still taking their preventive medications.[20] About 40% remain dependent on others.[20,21] Stroke also affects caregivers. Caregivers have poorer mental health, less social contact and activity, and are at increased risk for depression.[20,21]

Comprehensive post-acute services for stroke require bridging hospital-based acute care with expanded care teams for rehabilitation, primary care management, access to community resources, and caregiver support. Evidence-based reviews have concluded that stroke morbidity and mortality could be reduced through effective transitional care,[22–24] secondary prevention,[25] and rehabilitation early post-stroke.[26] Involvement with a stroke liaison worker or case manager is associated with more knowledge about stroke and satisfaction with services.[27,28] Caregiver-oriented, individualized discharge planning for stroke patients going home improves caregiver preparedness.[29]

Given the significant impact of stroke on public health, the high risk and complexity of these patients early after discharge, and the strain on caregivers, an effective post-acute care model is needed. A pragmatic trial is the ideal method to test a care model that can be readily disseminated and implemented.

Objectives & Specific Aims

The COMprehensive Post-Acute Stroke Services (COMPASS) Study will determine the effectiveness of a post-acute comprehensive intervention.

Primary Study Question:

Does implementation of the COMPASS for stroke patients discharged directly home, improve functional outcomes (measured by the Stroke Impact Scale-16) at 90 days post-stroke? Intention-to-treat principles will be used to determine all primary and secondary outcomes.

Primary Aim:

Comparative effectiveness of COMPASS verses usual care (Control) on stroke survivor functional status (measured by the Stroke Impact Scale) at 90 days post-stroke.

Secondary Aims:

1) Using responses from the 90 day caregiver survey, determine if the COMPASS intervention reduces caregiver strain (measured by the Modified Caregiver Strain Index) at 90 days post-stroke.
2) Using responses from the 90 day survey, we will measure self-rated general health; medication adherence (MMAS-4); self-monitoring of blood pressure; global disability; physical activity; depression (PHQ2); cognition (Mini MOCA); falls; fatigue; and satisfaction of care.
3) Using claims data from multiple payer sources up to 12 months after stroke hospitalization, we will measure effectiveness of COMPASS vs usual care for all-cause readmissions at 30 and 90 days and 1-year post-discharge.
4) Comparative effectiveness of the COMPASS vs usual care on: mortality; health care utilization; (emergency department visits, admissions to skilled nursing facilities/inpatient rehabilitation facilities); and use of transitional care management billing codes. We will use claims data from multiple payer sources up to 12 months after stroke hospitalization.
5) For all outcomes we will adjust analyses to account for race, sex, age, stroke severity, and insurance status.

Exploratory Aims:

1) Phase 2: The implementation sustainability objectives for Phase 2 of the COMPASS Study are to characterize whether rates of transitional care management (TCM) delivery and eCare plan delivery are sustained, worsen, or improve during the sustainability period of the COMPASS study for hospitals randomized to the intervention during Phase 1.
2) Phase 2: The effectiveness sustainability objective for Phase 2 of the COMPASS Study is to characterize whether patient outcomes are sustained, worsen, or improve during the sustainability period of the COMPASS study for hospitals randomized to the intervention during Phase 1.
3) Phase 2: The primary comparative effectiveness objective for Phase 2 of the COMPASS Study is to evaluate whether Stroke Impact Scale 16 (SIS-16) scores are improved during Phase 2 (i.e., the intervention phase) for hospitals randomized to usual care in Phase 1.
4) Phase 2: Using Claims, the Pre-Post analyses compared outcomes in hospitals randomized to provide UC in Phase 1 with outcomes among those that crossed over and delivered the INV in Phase 2 for mortality; health care utilization; (emergency department visits, admissions to skilled nursing facilities/inpatient rehabilitation facilities); and use of transitional care management billing codes. We will use claims data from multiple payer sources up to 12 months after stroke hospitalization.
5). Phase 2: Using Claims, the Sustainability analyses compared outcomes in hospitals randomized to deliver the INV in Phase 1 with outcomes among those that sustained the intervention (SUS) in Phase 2 for mortality; health care utilization; (emergency department visits, admissions to skilled nursing facilities/inpatient rehabilitation

facilities); and use of transitional care management billing codes. We will use claims data from multiple payer sources up to 12 months after stroke hospitalization.

Data Collected for Ancillary Studies:

1) Analysis of individual, organizational, and community factors affecting implementation of COMPASS through supplemental funding (CTSI Award lead by Co-I Dr. Gesell). This pilot project will contribute to a process evaluation of our Phase1, intervention-randomized health systems adopting COMPASS.
2) An exploratory analysis that compares patient clinic return rate and use of services to physical locations of patients and services (i.e. distance and drive times to/from clinics and community resources).
3) At the 90 day survey, we will also use the PROMIS Global-10 instrument that assesses general domains of health and functioning including overall physical health, mental health, social health, pain, fatigue, and perceived quality of life. These are similar in nature to our primary outcome, the SIS-16.

Hospital Performance Metrics (to support participating sites in delivery of the intervention):

1) Evaluate compliance with the new model of post-acute stroke care by exploring quality indicators among intervention hospitals, (e.g., proportion of patients called within 2 days after hospital discharge; proportion of patients seen by an advanced practice provider [MD/NP/PA] within 7 to 14 days from hospital discharge; and proportion of eligible patients receiving home or outpatient rehabilitation therapy).

Methods and Measures

Study Design

The COMPASS Study is a pragmatic, cluster-randomized trial of 41 hospitals in North Carolina designed to determine the effectiveness of a model of post-acute stroke care (i.e. the COMPASS Intervention) compared with usual care (Control).

Study Setting

The COMPASS intervention will be implemented in hospitals and communities in 2 phases over a 5-year period. We will recruit 41 hospitals that represent diverse geographic locations (i.e. rural vs urban), primary stroke center certification status, and stroke patient volumes. Included in this IRB Application (Appendix 1) is an attachment (Titled: COMPASS Hospital Characteristics) which provides a side-by-side comparison of hospitals expected to participate in the COMPASS trial with All North Carolina Hospitals. A list of our COMPASS Hospitals is also included. The data used to make the comparison is from CMS Hospital Compare[30]. COMPASS will ask participating hospitals to fill out a Hospital Survey (Appendix 2) at the start of the study to better understand the current state of transitional care at each hospital.

Study Population

In 2013, data from hospitals in the North Carolina Stroke Care Collaborative (NCSCC) indicated that 46% of patients were discharged directly home from the hospital after a stroke (our proposed study population). Using this data we anticipate an estimated sample of approximately 6,000 potentially eligible participants. In that population, the mean age was 65.0 years (SD 14.4), 25% were African American, and 48% were women. Stroke severity, measured by the NIH Stroke Severity score and ranging from 0 (no deficit) to 42 (maximum deficits), was on average 3.2 for those discharged home.

Randomization

Since individual stroke patients cannot easily be randomized to receive the COMPASS intervention, we determined that the optimal statistical design for this pragmatic trial utilizes a cluster randomized approach. Thus, 41 individual hospitals will be randomized to either receive the COMPASS intervention at the beginning of the study (Phase 1) or in Phase 2 (see Figure 1). Two of the participating 41 hospitals were randomized together, therefor we have 40 randomized units. Hospitals randomized to receive the intervention in Phase 2 will be referred to as the control group. Randomization per hospital will be stratified by volume of stroke patients and primary stroke center status. In this intention-to-treat design, all stroke patients who are discharged directly home from randomized acute care hospitals will be included in analyses. The analyses will be performed at the individual level with adjustment for lack of independence between hospitals. The primary analysis of patient-centered outcomes will occur at the end of Phase 1.

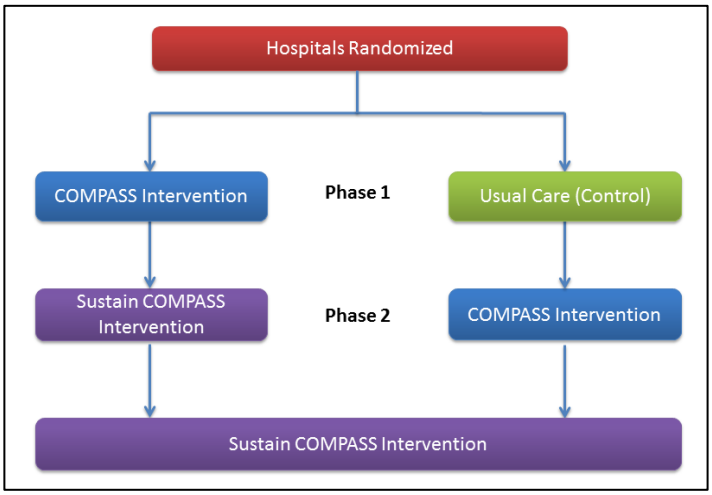

Figure 1: Hospital Randomization to the COMPASS Intervention in Phase 1 and Phase 2

Subjects Selection Criteria

Inclusion Criteria:

- Patients aged 18 years or older, discharged home from a participating COMPASS Study hospital with a diagnosis of ischemic or hemorrhagic stroke or transient ischemic attack (TIA).

Exclusion Criteria:

- Patients transferred to another short-term acute care hospital, skilled nursing facility, inpatient rehabilitation facility, or hospice.
- Patients with a diagnosis of subdural or aneurysmal subarachnoid hemorrhage.
- Patients who speak neither English nor Spanish.

Sample Size:

- Approximately 6,000 potentially eligible participants during Phase 1
- Approximately 6,000 potentially eligible participants during Phase 2

Intervention and Interactions

As described in the Methods section above, the trial has two Phases (see Figure 1).

- **Phase 1**: Patient enrollment for Phase 1 of the trial will run from June 2016 to March 2018. Phase 1 includes a control arm (Control Hospital) and an intervention arm (COMPASS-Intervention Hospitals). Details of these arms and interactions are described below. Figure 2 depicts the patient flow of activities for Phase 1 when there is a control arm and COMPASS intervention arm.
- **Phase 2**: Patient enrollment for Phase 2 of the trial will run from November 2017 – January 2019. Phase 2 includes an intervention arm (COMPASS-Intervention hospital) and the other arm is COMPASS Hospitals who will sustain the COMPASS intervention using their own hospital resources (COMPASS-Sustain hospital). Detail of these arms and interactions are described below.
- **Note, that there is some overlap between Phases 1 and 2.** The overlap is due to differences in the timing of hospital recruitment and enrollment (i.e. larger hospitals enrolled patients faster).

COMPASS will support hospitals in implementing structured post-acute stroke services consistent with CMS transitional care codes and management. Hospitals which participate are implementing COMPASS as the new standard of care. The goal of COMPASS is to structure and organize the processes of post-acute care to optimize patient recovery function, reduce caregiver stress, improve risk factor management, and facilitate self-management of risk factors.

Phase 1: Patients in Control Hospitals

Prior to hospital discharge, the Post-Acute Coordinator (PAC) will identify stroke and TIA patients for eligibility using the Eligibility Screening Form (Appendix 3). Determining eligibly will involve daily review of stroke admissions to the hospital by screening the electronic medical records. This will be done under Limited HIPAA Waiver.

If eligible, the patient will be enrolled, a COMPASS ID is assigned and the PAC will fill out the Enrollment Form (Appendix 4). For those not eligible, no further information is collected and a COMPASS Identification number is not assigned. Enrollment will be done under a Full HIPAA Waiver.

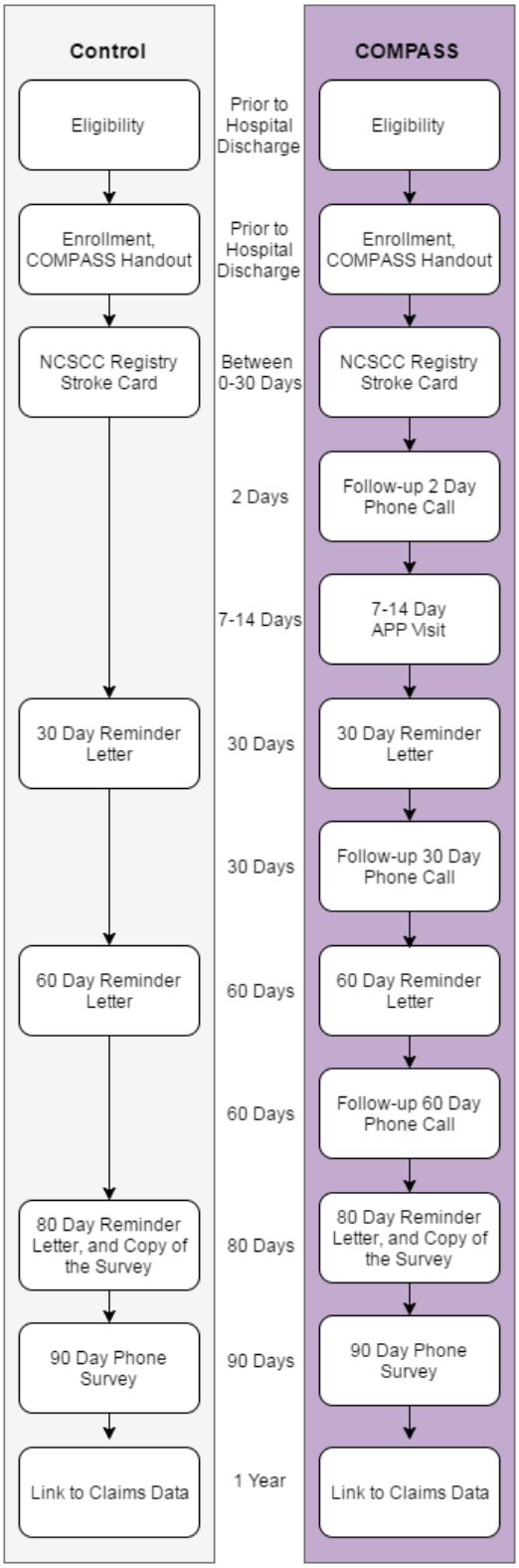

Figure 2: Flow of Intervention Activities for Phase 1, Control and COMPASS Participants

The PAC will visit eligible patients in the hospital, notify the patient that the hospital is participating in the COMPASS Study, and give the patient a handout with information on the COMPASS Study (Appendix 5). The information informs the patient that their hospital is participating in a state-wide study to evaluate best models of post-stroke care. The patient will be informed if their hospital is in the usual care group or in the COMPASS intervention group. The handout that patients receive in the control arm is tailored to the hospital. Each control arm hospital brochure will include the PAC name, the PAC contact information and a tailored description of the post-acute "standard care" that the patient will receive at that hospital. This information will equip patients with information to fully inform them of the COMPASS Study and how this will impact them and what to expect from the hospital. The PAC will also explain that the patient will get a phone call in about three months asking

them to participate in a telephone survey and that they will get three reminder letters in the mail to remind them about the survey (Appendix 6-8). The PAC will record patient and caregiver contact information on the COMPASS enrollment form. In the COMPASS analytical database, the PAC will record the date, time and method (i.e. in person or over the phone) of informing the patient of the COMPASS Study, and confirm that the patient was given the brochure. As a pragmatic study, we anticipate that PACs may miss a patient (for example a patient may be missed on the weekends) and the patient will need to be enrolled retrospectively and notified of the study and mailed the brochure. The PAC will attempt to reach the patient over the phone to follow-up on the mailed brochure. The brochure also has contact information for the patient to call the study if they would like additional information.

As part of case ascertainment and consistent with the North Carolina Stroke Care Collaborative (NCSCC) methodologies to characterize all stroke admissions and processes of acute stroke care the PAC will complete the NCSCC Stroke Care Card (Appendix 9).

Patients will receive three letters in the mail to remind them about the 90 day survey and to provide educational information and resources from the American Stroke Association (Appendix 6-8). Although the 90 day phone survey will be relying on a Full HIPAA Authorization Waiver, the letter mailed to the patient at 80 days includes a statement on HIPAA to inform the patient on how they have been identified for the study and that agreeing to participate in the phone survey will be authorizing the use of identifiable health information and how that information will be used in the study. The 80 day letter will also include $10 cash as a thank you gift for considering participation in the phone survey.

At 90 Days, stroke survivors will receive a phone call from the Carolina Survey Research Lab (CSRL). CSRL will follow a telephone script which includes consent (Appendix 10) and conduct blinded assessments (Appendix 23 and 24). If the patient prefers s/he can request that a proxy answer questions and provide verbal consent and HIPAA Authorization on her/his behalf. In the event contact is never made with the patient by phone or connection is lost (e.g. the number is not in service, no one answers the phone calls, call is answered but is disconnected prior to the researcher sharing the reason for calling, or there is loss of connection during the call) we will mail an abbreviated version of the survey with a letter explaining the survey purpose (Attachment 25). We will also include a self-addressed envelope with prepaid postage to the patient to gather responses via paper survey. This abbreviated survey contains the SIS-16, global health rating scale and blood pressure questions.

Approximately one year later the study will acquire claims data from Medicare, Medicaid, State Insurance Plan, and Blue Cross Blue Shield. We plan to use a HIPAA Waiver to acquire the data sets and along with this application we are asking for a waiver of signed consent to link all enrolled patients to the claims data sets.

Phase 1: Patients in COMPASS-Intervention Hospitals

In addition to the activities outlined in the Control Hospitals section above, patients who enter the study through a COMPASS Intervention hospital will receive: (1) a follow-up phone call 2 days after being discharged from the hospital, (2) a 7-14 day Advanced Practice Provider visit, (3) a follow-up 30 day phone call, and (4) a follow-up 60 day phone call. The structure and processes of this COMPASS intervention are consistent with the Center for Medicare and Medicaid (CMS) Transitional Care Management Codes. In essence the COMPASS study is an evaluation of the implementation of CMS recommendations for post hospital care coordination.

The process for determining Eligibility for COMPASS patients is identical to that of Control patients.

If the patient is eligible, they will be enrolled in a similar manner to that of the Control patients: The PAC will visit each patient in the hospital and give the patient a tailored handout about the COMPASS Study (Appendix 12). The information informs the patient that their hospital is participating in a state-wide study to evaluate best models of post stroke care. The patient will be informed if their hospital is in the usual care group or in the COMPASS intervention group. This brochure is tailored to the hospital. The PAC name and the PAC contact information will be provided on an appointment card. This information will equip patients with information to fully inform them of the COMPASS Study and how this will impact them and what to expect from the hospital. The PAC will also give an additional handout about COMPASS

intervention activities (Appendix 13), a Blood Pressure Log (Appendix 14) and Blood Pressure Handout (Appendix 15). The PAC will work with the patient to schedule follow-up visits with the patients Primary Care Physician (PCP) and the Advanced Practice Provider (APP) for the 7-14 day follow-up visit. The PAC will let the patient know they will be calling them in a couple of days for the 2-day follow-up phone call. The PAC will record patient and caregiver contact information on the COMPASS enrollment form. In the COMPASS analytical database, the PAC will record the date, time and method (i.e. in person or over the phone) of informing the patient of the COMPASS Study, and confirm that the patient was given the brochure. As a pragmatic study, we anticipate that PACs may miss a patient (for example a patient may be missed on the weekends) and the patient will need to be enrolled retrospectively and notified of the study and mailed the brochure. The PAC will attempt to reach the patient over the phone to follow-up on the mailed brochure. The brochure also has contact information for the patient to call the study if they would like additional information.

As part of case ascertainment and consistent with the North Carolina Stroke Care Collaborative methodologies to characterize all stroke admissions and processes of acute stroke care the PAC will complete the NC Stroke Care Card (Appendix 9). **(Note: this is identical to the Control group**).

At 2 days post- hospital discharge, the PAC will call the patient and discuss medication use, symptoms, and confirm (or schedule) follow-up appointments with the patients Primary Care Physician and the Advanced Practice Provider. The PAC will provide patient education to ensure they know about signs of a subsequent stroke. The script for the 2 day follow-up call is in Appendix 16.

Following the 2day call, the PAC will complete a disposition form (Appendix 34) to record if the call took place (yes/no) and if the call did not take place a categorical reason why the call did not take place. These questions are similar to what is acquired in claims data research. Use of data from this form will be done under a request for Full HIPAA Waiver for all patients who are enrolled in an intervention hospital.

Between 7 and 14 days, the patient will attend a follow-up visit with the advanced practice provider (APP). The PAC will also attend this visit. The goal of this visit is to create an individualized patient Care Plan and, if needed, make additional referrals for the patient. At this visit, the PAC will clinically assess the patient using the Post-stroke Functional Assessment (Appendix 17). Based on responses from this assessment, the PAC may also conduct the Caregiver Assessment (Appendix 18) with the patient's caregiver if the caregiver is present. The provider will assess the patient using the Post-stroke Advanced Practice Assessment (Appendix 19). Responses to these assessments will be used by the provider to develop an individualized patient Care Plan. These three assessments have been programmed into an electronic platform (eCare Application) to ease administration, assessments, data capture and development of the individualized patient Care Plan (eCare Plan) which will be conducted on an iPad. The tool will summarize the three assessments and make suggestions for the provider in creation of the individualized patient Care Plan (Appendix 20 is an example; the provider customizes these recommendations). As the decision-making authority in patient care, the final individualized patient Care Plan and any referrals are given by the provider. The PAC will review the Care Plan with the patient, establish preferences for care and coordinate referrals for services. A copy of the Care Plan will go forward to the patient’s primary care provider and rehabilitation providers. The APP will send a summary of the visit and the Care Plan to the patient’s primary care provider and rehabilitation providers. During this visit the patient will be asked for consent and HIPAA Authorization to use clinical data for future analyses (Appendix 21).

Following this clinic visit, the PAC will complete a clinic visit disposition form (Appendix 35) which records if the clinic visit was conducted (yes/no) and date of visit. This form also records which clinic forms were completed during the visit to determine to what extent the COMPASS intervention was implemented for quality improvement on processes and delivery of care. This form also summarizes care and community service recommendations, which were made for patient care and to record for quality improvement initiatives. This form includes yes/no and categorical responses similar to what is acquired in claims data. Use of data from this form will be done under a request for Full HIPAA Waiver for all patients who are enrolled in an intervention hospital.

At 30 and 60 days, patients will be called by the PAC to follow-up on their Care Plan. The PAC will ask the patient if they are having any challenges with implementing the care and treatment plans that their health providers have given them (Appendix 22).

Patients will also receive three letters in the mail to remind them about the 90 day survey and to provide educational information and resources from the American Stroke Association (Appendix 6-8). Although the 90 day phone survey will be relying on a Full HIPAA Authorization Waiver, the letter mailed to the patient at 80 days includes a statement on HIPAA to inform the patient on how they have been identified for the study and that agreeing to participate in the phone survey will be authorizing the use of identifiable health information and how that information will be used in the study. The 80 day letter will also include $10 cash as a thank you gift for considering participation in the phone survey. **(Note: this is identical to the Control group**).

At 90 Days, stroke survivors will receive a phone call from the Carolina Survey Research Lab (CSRL). CSRL will follow a telephone script which includes consent (Appendix 10) and conduct blinded assessments (Appendix 23 and 24). If the patient prefers s/he can request that a proxy answer questions and provide verbal consent and HIPAA Authorization on her/his behalf. In the event contact is never made with the patient by phone or connection is lost (e.g. the number is not in service, no one answers the phone calls, call is answered but is disconnected prior to the researcher sharing the reason for calling, or there is loss of connection during the call) we will mail an abbreviated version of the survey with a letter explaining the survey purpose (Attachment 25). We will also include a self-addressed envelope with prepaid postage to the patient to gather responses via paper survey. This abbreviated survey contains the SIS-16, global health rating scale and blood pressure questions. **(Note: this is identical to the Control group**)

Approximately one year later the study will acquire claims data from Medicare, Medicaid, State Insurance Plan, and Blue Cross Blue Shield. We plan to use a HIPAA Waiver to acquire the data sets and along with this application we are asking for a waiver of signed consent to link all enrolled patients to the claims data sets. **(Note: this is identical to the Control group**).

Phase 2: COMPASS-Intervention & COMPASS-Sustain Hospitals

Hospitals which were randomized to the control-arm in Phase 1 of the study will be encouraged to cross over to provide the COMPASS Intervention during Phase 2 of the study. Hospitals that were randomized to the COMPASS Intervention-arm during Phase 1 of the study will be encouraged to continue providing all of the COMPASS Intervention to eligible patients (Sustain Sites). Both the Intervention and the Sustain Sites will provide the same intervention as described in this section. This intervention is nearly identical to the Phase 1 Intervention. Minor changes were made in order to streamline some of the intervention activities based on lessons-learned from Phase 1. The structure, however, remains unchanged: Patients who enter the study through a participating hospital will receive: (1) a follow-up phone call 2 days after being discharged from the hospital, (2) a 7-14 day Advanced Practice Provider visit, (3) a follow-up 30 day phone call, and (4) a follow-up 60 day phone call.

The process for determining Eligibility for patients is identical to Phase 1 of the study: Prior to hospital discharge, the Post-Acute Coordinator (PAC) will identify stroke and TIA patients for eligibility using the Eligibility Screening Form to assist in determining eligibility (Appendix 3). Determining eligibly will involve daily review of stroke admissions to the hospital by screening the electronic medical records. This will be done under Limited HIPAA Waiver.

If eligible, the patient will be enrolled, a COMPASS ID is assigned and the PAC will fill out the Enrollment Form which has been streamlined for Phase 2 of the study (Appendix 38). For those not eligible, no further information is collected and a COMPASS Identification number is not assigned. Enrollment will be done under a Full HIPAA Waiver.

Once the patient is enrolled, the patient will be notified of the study. The PAC will visit each patient in the hospital and give the patient a tailored, Phase 2 handout about the COMPASS Study (Appendix 36 & Appendix 37). Like Phase 1 of the study, the information informs the patient that their hospital is participating in a state-wide study to evaluate best

models of post stroke care. The patient will be informed their hospital is providing the COMPASS intervention. The PAC name and the PAC contact information will be provided on an appointment card. This information will equip patients with information to fully inform them of the COMPASS Study and how this will impact them and what to expect from the hospital. The PAC will also give an additional handout about COMPASS intervention activities (Appendix 13), a Blood Pressure Handout and Log (Appendix 14). The PAC will work with the patient to schedule follow-up visits with the patients Primary Care Physician (PCP) and the Advanced Practice Provider (APP) for the 7-14 day follow-up visit. The PAC will let the patient know they will be calling them in a couple of days for the 2-day follow-up phone call. In the COMPASS data application, the PAC will record the date, time and method (i.e. in person or over the phone) of informing the patient of the COMPASS Study, and confirm that the patient was given the brochure. As a pragmatic study, we anticipate that PACs may miss a patient (for example a patient may be missed on the weekends) and the patient will need to be enrolled retrospectively and notified of the study and mailed the brochure. PACs are encouraged to notify patients over the phone as follow-up on the mailed brochure. The brochure also has a toll-free study phone number for patients to call the study if they would like additional information or to opt-out of the study.

In Phase 2, hospitals will not be *required* to complete the North Carolina Stroke Care card (Appendix 9), however, this card will be made available to hospitals if they find it beneficial.

At 2 days post- hospital discharge, the PAC will call the patient and discuss medication use, symptoms, and confirm (or schedule) follow-up appointments with the patients Primary Care Physician and the Advanced Practice Provider. The PAC will provide patient education to ensure they know about signs of a subsequent stroke. The script for the 2 day follow-up call is in Appendix 16. **(Note this is identical to Phase 1 Intervention)**

Following the 2day call, the PAC will complete a disposition form (Appendix 34) to record if the call took place (yes/no) and if the call did not take place a categorical reason why the call did not take place. These questions are similar to what is acquired in claims data research. Use of data from this form will be done under a request for Full HIPAA Waiver for all patients who are enrolled in an intervention hospital. **(Note this is identical to Phase 1 Intervention)**

Between 7 and 14 days, the patient will attend a follow-up visit with the advanced practice provider (APP). The PAC will also attend this visit. The goal of this visit is to create an individualized patient Care Plan and, if needed, make additional referrals for the patient. At this visit, the PAC will clinically assess the patient using the Post-stroke Functional Assessment (Appendix 17). Based on responses from this assessment, the PAC may also conduct the Caregiver Assessment (Appendix 18) with the patient's caregiver if the caregiver is present. The provider will assess the patient using the Post-stroke Advanced Practice Assessment (Appendix 19). Responses to these assessments will be used by the provider to develop an individualized patient Care Plan. These three assessments have been programmed into an electronic platform (eCare Application) to ease administration, assessments, data capture and development of the individualized patient Care Plan (eCare Plan) which will be conducted on an iPad. The tool will summarize the three assessments and make suggestions for the provider in creation of the individualized patient Care Plan (Appendix 20 is an example; the provider customizes these recommendations). As the decision-making authority in patient care, the final individualized patient Care Plan and any referrals are given by the provider. The PAC will review the Care Plan with the patient, establish preferences for care and coordinate referrals for services. A copy of the Care Plan will go forward to the patient's primary care provider and rehabilitation providers. The APP will send a summary of the visit and the Care Plan to the patient's primary care provider and rehabilitation providers. During this visit the patient will be asked for consent and HIPAA Authorization to use clinical data for future analyses (Appendix 21). **(Note this is identical to Phase 1 Intervention)**

Following this clinic visit, the PAC will complete a clinic visit disposition form (Appendix 35) which records if the clinic visit was conducted (yes/no) and date of visit. This form also records which clinic forms were completed during the visit to determine to what extent the COMPASS intervention was implemented for quality improvement on processes and delivery of care. This form also summarizes care and community service recommendations, which were made for patient care and to record for quality improvement initiatives. This form includes yes/no and categorical responses similar to what is acquired in claims data. Use of data from this form will be done under a request for Full HIPAA Waiver for all patients who are enrolled in an intervention hospital. **(Note this is identical to Phase 1 Intervention)**

At 30 and 60 days, patients will be called by the PAC to follow-up on their Care Plan. The PAC will ask the patient if they are having any challenges with implementing the care and treatment plans that their health providers have given them (Appendix 22). **(Note this is identical to Phase 1 Intervention)**

Patients will also receive three letters in the mail to remind them about the 90 day survey and to provide educational information and resources from the American Stroke Association (Appendix 6-8). Although the 90 day phone survey will be relying on a Full HIPAA Authorization Waiver, the letter mailed to the patient at 80 days includes a statement on HIPAA to inform the patient on how they have been identified for the study and that agreeing to participate in the phone survey will be authorizing the use of identifiable health information and how that information will be used in the study. The 80 day letter will also include $10 cash as a thank you gift for considering participation in the phone survey. **(Note this is identical to Phase 1)**

At 90 Days, stroke survivors will receive a phone call from the Carolina Survey Research Lab (CSRL). CSRL will follow a telephone script which includes consent (Appendix 10) and conduct blinded assessments (Appendix 23 and 24). If the patient prefers s/he can request that a proxy answer questions and provide verbal consent and HIPAA Authorization on her/his behalf. In the event contact is never made with the patient by phone or connection is lost (e.g. the number is not in service, no one answers the phone calls, call is answered but is disconnected prior to the researcher sharing the reason for calling, or there is loss of connection during the call) we will mail an abbreviated version of the survey with a letter explaining the survey purpose (Attachment 25). We will also include a self-addressed envelope with prepaid postage to the patient to gather responses via paper survey. This abbreviated survey contains the SIS-16, global health rating scale and blood pressure questions. **(Note this is identical to Phase 1)**

Approximately 6-months later the study will acquire claims data from Medicare, Medicaid, State Insurance Plan, and Blue Cross Blue Shield. We plan to use a HIPAA Waiver to acquire the data sets and along with this application we are asking for a waiver of signed consent to link all enrolled patients to the claims data sets. **(Note, this is identical to Phase 1 with the exception we are doing 6 months of claims data follow-up in Phase 2. As a reminder, in Phase 1, the study is doing 12 months of follow-up.)**

Phase 1 Only: Caregivers Outcomes Survey

COMPASS Study team will mail the patient's caregiver a letter (Appendix 26), and the Caregiver Survey (Appendix 27). Non-respondents will be mailed a second letter (Appendix 29) with the survey (Appendix 27). If the caregiver still does not respond they will receive a reminder telephone call from UNC Carolina Survey Research Lab. (**Note, Phase 2 will not include a Caregiver Outcomes Survey**)

Phase 1 & Phase 2: Community-Engagement

This is a community-engaged study. Patients, family caregivers, and others stakeholders will be involved in all phases of the research process. These community members will be engaged in non-research activities (e.g., revising study materials for clarity) as well as research activities (e.g., participating in focus groups). By design, community-engaged research requires decision making by many stakeholders and frequent IRB amendments. For clarity and oversight purposes we have submitted a separate IRB (PCORI Stakeholder Interviews: IRB00028495; Appendix 31) for research activities involving stakeholders.

Phase 1 Only: Implementation Analysis

We will be asking participating staff at implementing sites (approximately 20 PACs and COMPASS team members) to agree to have their responses on the Bi-weekly Implementation Calls and surveys recorded and transcribed and analyzed to better understand the process of implementing the COMPASS Care Model. We will be asking participating staff at implementing sites (approximately 40 therapy care providers and COMPASS team members) to agree to have their responses on the Bi-weekly Home Health and Outpatient Calls and surveys recorded and transcribed and analyzed to

better understand the process of implementing the COMPASS Care Model. We will also be asking study staff COMPASS Director of Implementation and members of the Implementation Committee for individual semi-structured interviews. Additional detail to this study activity is provided in Appendix 33.

Data Collection and Outcome Measures

Patient Participant Study Outcomes (Phase 1 and 2):

	Measure	Assessment(s)	When Collected	Appendix
Primary Outcome	Physical Function	Stroke Impact Scale (SIS-16)	@90 days, consenting patients asked by CSRL	23
Secondary Outcome	Self-rated General Health	A question rating health on a 5-point scale & a question on perception of health improvement	@90 days, consenting patients asked by CSRL	24
Secondary Outcome	Disability and Dependence	Modified Rankin Scale	@90 days, consenting patients asked by CSRL	24
Secondary Outcome	Physical Activity	Three questions which ask about time spent walking	@90 days, consenting patients asked by CSRL	24
Secondary Outcome	Depression	Patient Health Questionnaire (PHQ-2) Note: these items do not ask about suicidal thoughts or actions	@90 days, consenting patients asked by CSRL	24
Secondary Outcome	Cognition	MOntreal Cognitive Assessment (MOCA) Mini	@90 days, consenting patients asked by CSRL	24
Secondary Outcome	Medication Adherence	4-item Morisky Green-Levine Scale	@90 days, consenting patients asked by CSRL	24
Secondary Outcome	Secondary Prevention Self-Monitoring of BP	By asking: "Do you check your blood pressure at home?"	@90 days, consenting patients asked by CSRL	24
Secondary Outcome	Blood Pressure Management Effectiveness	For those who check BP at home, we ask: "Is your blood pressure less than 140/90 most of the time?"	@90 days, consenting patients asked by CSRL	24
Secondary Outcome	Falls and Hospitalization*	Questions to capture: Number of falls, injuries, and hospitalizations *Note: Note: Outcome is binary variable of Fall either Yes or No. Hospitalizations, injuries and number of falls were collected but were not used in the analyses	@90 days, consenting patients asked by CSRL	24

Secondary Outcome	Fatigue	PROMIS Fatigue Instrument – Adult Short Form 4A	@90 days, consenting patients asked by CSRL	24
Secondary Outcome	Satisfaction with care	Questions on how the patient felt about care and treatment from health care providers.	@90 days, consenting patients asked by CSRL	24
Exploratory Aim	Use of Community Resources	By asking: "Since discharge from the hospital, have you used services such as Senior Services, Meals on Wheels, in-home aides, or stroke survivor or caregiver support groups?"	@90 days, consenting patients asked by CSRL	24
Data collected to support the operations of the trial.	Initial Presentation Data	Hospital arrival and Mode of arrival, Ambulatory status prior to admission, Diagnosis at admission, NIHSS, Imaging performed, etc.	Entered into the COMPASS Database by the hospital	9
Data collected to support the operations of the trial.	Demographic Data	DOB, Race, Gender, Insurance, Medical History, Medication , etc.	Entered into the COMPASS Database by the hospital	9
Data collected to support the operations of the trial.	t-PA Data	Time t-PA was initiated, BP and Glucose levels, bleeding complications, etc.	Entered into the COMPASS Database by the hospital	9
Data collected to support the operations of the trial.	In-hospital Data	Admission data, secondary prevention counseling, treatment, lipid profile, medications, treatments, etc.	Entered into the COMPASS Database by the hospital	9
Data collected to support the operations of the trial.	Discharge Data	Resources and stroke education materials, assess for rehabilitation, ambulatory status, Rankin Score, final diagnosis, discharge disposition, ICD-10 data, etc.	Entered into the COMPASS Database by the hospital	9

Patient Participant Study Outcomes (Phase 2):

	Measure	Assessment(s)	When Collected	Appendix
Ancillary Study	General Heath and Function	PROMIS Global-10	@90 days, consenting patients asked by CSRL	23

Caregiver Participant Study Outcomes (Phase 1 only):

	Measure	Assessment(s)	When Collected	Appendix
Secondary Outcome	Caregiver Burden	Modified Caregiver Strain Index	@95 days, mailed to the caregiver	27
Data collected to support the operations of the trial.	Relation to stroke patient	Relation to stroke patient	@95 days, mailed to the caregiver	27
Data collected to support the operations of the trial.	Demographics	Age, Gender, Race	@95 days, mailed to the caregiver	27
Data collected to support the operations of the trial.	Primary Caregiver	Are you the primary caregiver	@95 days, mailed to the caregiver	27
Data collected to support the operations of the trial.	Length of Caregiving service	How long have you been providing care? How many hours per day do you spend providing care? Do others help provide care?	@95 days, mailed to the caregiver	27
Data collected to support the operations of the trial.	Type of caregiving activities	Type of caregiving activities	@95 days, mailed to the caregiver	27
Data collected to support the operations of the trial.	Awareness and use of Community Resources	Awareness and use of Community Resources	@95 days, mailed to the caregiver	27
Data collected to support the operations of the trial.	Self-rated General Health	Compared to others your age, how would you rate your health using a scale of 1 to 5, with 1 being “Poor” and 5 being “Excellent?”	@95 days, mailed to the caregiver	27
Data collected to support the operations of the trial.	Accessed the COMPASS Website	Have you explored the information on the COMPASS website	@95 days, mailed to the caregiver	27

Study outcomes collected and linked to insurance claims data (Phase 1 & Phase 2):

	Measure	Assessment(s)	When Collected	Appendix
Secondary Outcome	Readmissions	30-day, 90-day and 1-year all-cause readmission	Approximately 1 year post-stroke in Phase 1	This will be collected via Administrative Claims Data sets from Medicare, Medicaid, and Blue Cross Blue Shield
Secondary Outcome	Mortality	Mortality	Approximately 1 year post-stroke in Phase 1	This will be collected via Administrative Claims Data sets from Medicare, Medicaid, and Blue Cross Blue Shield
Secondary Outcome	Emergency Department (ED) Visits	Number of patient emergency department visits	Approximately 1 year post-stroke in Phase 1	This will be collected via Administrative Claims Data sets from Medicare, Medicaid, and Blue Cross Blue Shield
Secondary Outcome	Admissions to skilled nursing facilities and inpatient rehabilitation facilities	Number of patient admissions and number of days in to skilled nursing facilities, and number of patient admissions to inpatient rehabilitation facilities	Approximately 1 year post-stroke in Phase 1	This will be collected via Administrative Claims Data sets from Medicare, Medicaid, and Blue Cross Blue Shield
Secondary Outcome	Use of transitional billing codes	Use of Transitional Care Management (TCM) billing codes and Chronic Care Management (CCM) billing codes	Approximately 1 year post-stroke in Phase 1	This will be collected via Administrative Claims Data sets from Medicare, Medicaid, and Blue Cross Blue Shield

Clinical Data collection:

- We will collect clinical data to inform the patient's individualized care plan that will be routine for implementing transitional care, and would like to keep this data for future analyses:

	Measure	Assessment(s)	When Collected	Appendix
Data collected to support the operations of the trial.	Neurological Status and Deficits	Post Stroke Advanced Practice Assessment	7-14 Day Visit	19
Data collected to support the operations of the trial.	Stroke Complications	Post Stroke Advanced Practice Assessment	7-14 Day Visit	19
Data collected to support the operations of the trial.	Stroke Risk Factor Management	Post Stroke Advanced Practice Assessment	7-14 Day Visit	19
Data collected to support the operations of the trial.	Lifestyle Coaching	Post Stroke Advanced Practice Assessment	7-14 Day Visit	19
Data collected to support the operations of the trial.	Medication Access and Use	Post Stroke Functional Assessment	7-14 Day Visit	17
Data collected to support the operations of the trial.	Knowledge of Stroke Risk Factors	Post Stroke Functional Assessment	7-14 Day Visit	17
Data collected to support the operations of the trial.	Self-rated General Health	Post Stroke Functional Assessment	7-14 Day Visit	17
Data collected to support the operations of the trial.	Mobility	Post Stroke Functional Assessment	7-14 Day Visit	17
Data collected to support the operations of the trial.	Falls and Hospitalizations	Post Stroke Functional Assessment	7-14 Day Visit	17
Data collected to support the operations of the trial.	Social and Caregiver Support	Post Stroke Functional Assessment	7-14 Day Visit	17
Data collected to support the operations of the trial.	Activities of Daily Living	Post Stroke Functional Assessment	7-14 Day Visit	17
Data collected to support the operations of the trial.	Home Health, Outpatient services	Post Stroke Functional Assessment	7-14 Day Visit	17

Data collected to support the operations of the trial.	Durable Medical Equipment	Post Stroke Functional Assessment	7-14 Day Visit	17
Data collected to support the operations of the trial.	Living Will	Post Stroke Functional Assessment	7-14 Day Visit	17
Data collected to support the operations of the trial.	Relation	Caregiver Assessment	7-14 Day Visit	18
Data collected to support the operations of the trial.	Demographics	Caregiver Assessment	7-14 Day Visit	18
Data collected to support the operations of the trial.	Caregiving activities	Caregiver Assessment	7-14 Day Visit	18
Data collected to support the operations of the trial.	Self-rated General Health	Caregiver Assessment	7-14 Day Visit	18
Data collected to support the operations of the trial.	Stress	Caregiver Assessment	7-14 Day Visit	18
Data collected to support the operations of the trial.	Signs of a stroke	Caregiver Assessment	7-14 Day Visit	18

Analytical Plan

As described above, this pragmatic trial utilizes a cluster randomized design with 41 hospitals being randomized to receive the COMPASS intervention (N=20) or control (N=20) in Phase 1. In Phase 2, the control group hospitals will be rolled into the intervention (Figure 1). All stroke patients who are discharged directly home from one of the randomized hospitals will be included in the intention-to-treat analyses. Analyses will be performed at the individual (patient) level, with adjustments for hospital and/or patient level characteristics to control for possible correlations of patients within hospitals.

We used two stratification factors in randomization: annual stroke patient volume per hospital (3 levels: <100, 100-299, 300+ patients) and whether the hospital is a primary stroke center (Yes/No). Thus, there will be a total of 6 strata. We will use a random permuted block design with block size of two; within each stratum we will randomize an even number of hospitals. This will allow us to maintain balance between the treatment groups while also protecting the validity of the randomization process. Study team involved with site selection will not have access to the randomization schedule which will be held by Dr. Walter Ambrosius. Likewise, Dr. Ambrosius will not be involved in site selection. Although patients in the intervention cannot be blinded to their group assignment, interviewers gathering outcome data will be blinded. Our estimated sample size will permit pre-specified subgroup analyses by race, gender, age, stroke severity and insurance status.

For the primary aim, the primary endpoint is the Stroke Impact Scale (SIS-16) measured 90 days post-stroke. The secondary aims include the Modified Caregiver Strain Index at 90 days; 30- and 90-day all-cause readmissions; and mortality, health care utilization, continuity of care, utilization of transitional care, and medication adherence, all measured 1 year after index discharge. In addition, analyses by race, gender, age, stroke severity and insurance status will determine if there is evidence of heterogeneity of the intervention effect across any subgroups. Finally, for the two exploratory aims, we will (1) examine hospital-level measures of stroke care quality indicators in the COMPASS hospitals, and (2) compare administrative claims outcomes and post-acute stroke performance outcomes between COMPASS patients in Phase 1 (intervention phase) and Phase 2 (sustainability phase).

Since the primary endpoint (SIS-16) is measured on a continuous scale, we will use a mixed model to compare the COMPASS and control groups. Although the stratified randomization of hospitals should balance most important hospital-level characteristics between groups, since imbalances may exist between groups on patient-level characteristics, we propose to include both fixed and random effects in this mixed model. The first model will include two fixed effects: stratum (1 to 6) and the intervention effect (COMPASS vs. control) and one random effect: hospital. This additive model can be written as: $Y_{ijk} = \mu + \gamma_k + \alpha_j + \beta_{k(j)} + \varepsilon_{i(jk)}$, where Y_{ijk} is the outcome (i.e. SIS at 90 days) measured on the i^{th} patient, under the j^{th} intervention (j=1 (COMPASS), 2(Control) in the k^{th} hospital; μ is the grand mean; γ_k is the stratum (1 to 6) for hospital k; α_j is the fixed treatment effect for group j (COMPASS/CNT); $\beta_{k(j)}$ is the random effect of the k^{th} hospital nested within the exposure group; and $\varepsilon_{i(jk)}$ is the error term for the i^{th} patient nested within the treatment group and hospital. Other fixed effects can be added at the patient level (e.g. age, gender, race, stroke severity, or SES) for sensitivity analyses. The random hospital effect allows the possibility of correlated observations (patients) within hospitals. Of primary interest is the treatment effect (α_j), which indicates difference in the dependent variable (SIS-16) between groups.

After we fit our primary model, we will consider other models that may include more patient-level and hospital-level characteristics. For instance, since some patients may be transferred to a different hospital before being discharged home, we can include a yes/no variable on that point. Although hospitals will be stratified pre-randomization based on stroke volume, we can include a hospital-level covariate for the total number of stroke patients discharged home for each hospital. With 40 clusters (of the 41 hospitals, 2 were randomized together) included, we will be able to add other cluster-level covariates to the model if needed.

For secondary aims and outcomes measured on a continuous scale, we will use a similar approach as above (i.e. for the Modified CSI). For binary outcomes such as whether a patient is readmitted within 30 or 90 days (Secondary Aim 2), we will use mixed logit models to fit the relationship between the intervention and outcome measures. The mixed logit model is similar to the mixed model presented above but uses a logit link in a generalized linear mixed model. Software is

readily available (e.g., SAS PROC GLIMMIX) that can fit these models. The mixed logit model approach will also allow a mixture of fixed and random effects to be included as in the mixed model above. Other Secondary Aim 2 variables will be analyzed using a mixed model or alternatively generalized linear mixed models (e.g., Poisson regression [with overdispersion] for the number of inpatient days).

We will examine 1-year mortality rates as a binary outcome and use the methods described above to compare groups, but we will also consider mortality as a time-to-event outcome and compare groups using Cox proportional hazards models. In these survival analysis models, the treatment indicator will be included as the primary independent variable and the stratum included as stratification factor.

Human Subjects Protection

COMPASS is implementation of CMS recommendations for post hospital care coordination. COMPASS is using a pragmatic, randomized controlled trial approach because it facilitates consistent delivery in post-acute stroke care management. Hospitals are being asked to implement the COMPASS Intervention as a new standard of care for all stroke patients. Because specific informed consent would not typically be sought in a clinical setting, stroke patients at the participating hospitals will not have the option to consent to (or opt out of) the site intervention. It is unlikely that our study can seamlessly implement the new models of transitional care in routine clinical care delivery if the traditional informed-consent process for research participation is required. COMPASS will incorporate an Integrated Consent Model for Pragmatic Trials.[31] In this model, the "consent" will inform the patient that they are seeking care in a hospital that has been randomized to provide their usual standard of post hospital care or a hospital that is going to incorporate the COMPASS model of post hospital care. This integrated consent model simply incorporates information about the hospital randomization process and whether their hospital is randomized to usual standard of care or the COMPASS intervention.

A stroke coordinator (PAC), who is a hospital employee, will visit patients in the control sites and in the intervention sites prior to hospital discharge and provide patients with a tailored study brochure. The PAC will review the content of the informational brochure (Appendix 5 and Appendix 12) and inform patients that the hospital is participating in a statewide study to evaluate the best way to provide post-acute services after hospitalization for a stroke. The PAC will also inform the patient that there are many ways to care for patients after they leave the hospital and we are not sure which model is best.

The PAC can answer any questions that the patient has regarding this conversation and provide their contact information, the COMPASS toll-free phone number and website as a reference for additional information. For additional assurance, the study will ask PACs to document into the COMPASS Study data portal the date and time the patient was informed. The goal of this study is to capture all patients discharged directly home. In the event that a patient is discharged on a weekend or before the PAC is able to visit the patient, the PAC will make a call attempt to the patient to inform them of the hospital study and then the PAC will mail the brochure to the patient's preferred mailing address. The PAC will also document in the COMPASS Study data portal that the patient was called and the brochure was mailed to the patient.

Our protocol and process for consent reflects this integrated model. All enrolled stroke patients will be told that the hospital is enrolled in a state-wide initiative to evaluate and improve post-acute stroke care:

- Phase 1 & 2 - Consent for the Clinical Data (COMPASS Intervention Patients only at 7-14 Day APP Visit): A signed consent and HIPAA Authorization (collected on the iPad eCare Application or, if the PAC prefers, this can be conducted on paper) to use data collected from patient during clinical care for research purposes (i.e., to better understand recovery and factors that might influence response to the COMPASS intervention).
- Phase 1 & 2 - Consent for the 90 day phone survey for patients: A verbal consent over the phone, performed by the UNC Carolina Survey Research Laboratory. COMPASS will rely on the Full HIPAA Waiver for this phone survey, however we have included in the 80 day reminder letter, information on HIPAA for the patient to make an informed decision on if they would like to participating in the phone survey.
- Phase 1 only - Consent for the 95 day paper survey mailed to caregivers: A returned, completed survey constitutes consent.
- Phase 1 & 2 - Consent for the Claims Data Analysis: A waiver of consent is requested as this activity (1) is low risk, (2) does not affect the right and welfare of patients, and (3) cannot be practically carried out without this waiver.

Minimal/No Risk Intervention: Participation in the COMPASS study does not expose patients to any additional risks and therefor it is a minimal-risk or no-risk intervention. The COMPASS model and intervention activities are not experimental. COMPASS is evidence-based, and considered best practice for management of post-acute care. CMS supports the delivery of these types of post-acute services and has implemented billing codes (TCM and CCM) to actualize implementation of these services. Hospitals which participate in the COMPASS Study will be asked to implement at the hospital-level these evidence-based services into the systematic delivery of post-acute care to all stroke patients. The COMPASS Study will determine effectiveness of this model on self-reported functional outcomes.

In order to minimize potential differences in loss to follow-up between the control and intervention groups we will send reminder letters (as described in the intervention section) to both control and intervention groups. These letters will include resources from the American Stroke Association (ASA). We will include a refrigerator magnet to remind them that we will call stroke survivors and survey caregivers at 90 days to assess outcomes.

Informed Consent

As a pragmatic trial, our eligibility and outcomes assessment will include all patients discharged home from participating hospitals who are adopting the non-experimental, evidence-based intervention as the new model of care. Our approach has been to minimize patient risk and maximize participation by providing an informational brochure to patients and their families during the hospital stay (or informing by mail), and allow them to opt out of the follow-up phone call at 90 days.

Patients will not be asked for consent to participate at the hospital. It is unlikely that our study can seamlessly implement the new models of transitional care in routine clinical care delivery if the traditional informed-consent process for research participation is required. COMPASS will incorporate an Integrated Consent Model for Pragmatic Trials.[31] In addition, during focus groups, patient stakeholders informed us that this would not be the optimal time for informed consent. Patients are often overwhelmed during the hospital stay as they are introduced to a large amount of new information in addition to processing the recent health event (stroke). This was described during the focus group as an emotional and difficult time. Patient stakeholders reported that they are asked to sign a lot of paperwork during the stay and at discharge. According to our stakeholders, the process can be confusing. The COMPASS Study team did not want to add additional burden on the patients and study staff to gain informed consent at the hospital for this low/no risk study.

Figure 3 depicts the flow of Control (left and during Phase 1 only) and COMPASS Intervention (right during Phase 1 and 2) activities and how research activities are covered at each step (center).

A HIPAA Waiver which is included as a part of this application is used to confirm eligibility, enrollment, and collect NCSCC Registry Stroke Card data, contact the participants with letters and surveys.

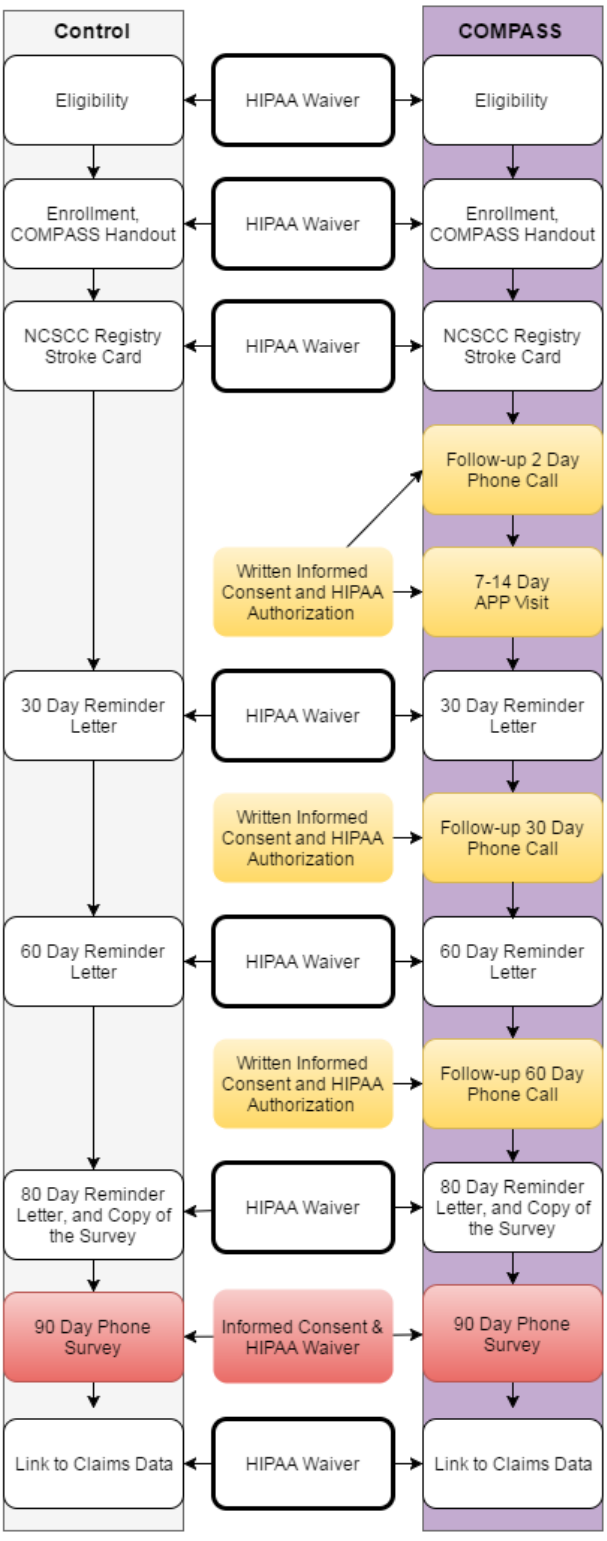

Figure 3: HIPAA Waiver and Consent of COMPASS

Consent for the Clinical Data (<u>COMPASS Intervention Arm only</u>): At the 7-14 day APP visit, COMPASS participants will be asked for written informed consent and HIPAA Authorization for the study to keep clinical data (2 day phone call, 7-14 day visit, 30 day phone call and 60 day phone call) for future analyses (e.g. follow-up with recommendations for care, demographic and clinical factors that predict follow up and outcomes in the intervention arm). The post-acute coordinator will ask for informed consent and will use the eCare Application on the iPad to capture signature. The abbreviated consent and HIPAA Authorization contains the following elements of informed consent: the purpose of the study; the types of clinical data that will be captured and analyzed; explaining how information the patient provides will be used; data will be kept confidential and secure and will abide to HIPAA regulations; a reminder that providing consent is voluntary; identification of funding agency, study PI, and institution; contact information should the patient want to withdraw

(Appendix 21). Patient will use his/her finger to sign and date on the iPad for capture of written signature. (A paper version of the consent form is also available.) The PAC who will be conducting the consent process will also sign and date. A hard copy of consent script will be printed out for the patient to take with them. If the patient declines consent, this will also be noted. In order to not disrupt the clinical work-flow, consent will be collected during the visit either in-between assessments or at the end of the visit.

Consent for the 90 Day Phone Survey for Patients (<u>All Patients</u>): All stroke patients (or representing proxies) will consent to (or decline) participation in the survey of outcomes. COMPASS will rely on the Full HIPAA Waiver for this phone survey, however we have included in the 80 day reminder letter, information on HIPAA for the patient to make an informed decision on if they would like to participating in the phone survey. Verbal consent at the introduction of the telephone survey should adequately protect the individuals' rights of patient participants. Study-eligible patients are discharged home, and thus proxy support is unlikely to be needed. If the patient prefers a proxy to complete the survey, the patient can ask the proxy to support them in responding. We will record whether the data are provided by the proxy or the patient.

Consent for the 95 Day Paper Survey Mailed to Caregivers (<u>All Caregivers</u>): Caregivers will be asked to respond to a paper survey questionnaire. This questionnaire does not have any questions about the patient, therefore we are not asking for permission from patients to send this survey to caregivers. Response to the questionnaire will be considered consent and HIPAA Authorization to participate in the study.

Consent for the Claims Data Analysis (<u>All Patients</u>): We will acquire claims data sets using a HIPAA waiver. We will link patient data collected at study enrollment (this data collected is under a HIPAA Waiver) to the claims data. A waiver of consent is requested and included in this application as this activity (1) is low risk, (2) does not affect the right and welfare of patients, and (3) cannot be practically carried out without this waiver.

Consent for Engagement Activities: Consent for research-related engagement activities (i.e. focus groups) will be covered under separate IRBs (PCORI Stakeholder Interviews: IRB00028495; Appendix 31).

Consent for Implementation Analysis (Phase 1 only): Additional detail to this study activity is provided in Appendix 33.
We will be asking participating staff at implementing sites (approximately 20 PACs, 40 therapy providers and COMPASS team members) to agree to have their responses on the Bi-weekly Implementation Calls and surveys recorded and transcribed and analyzed to better understand the process of implementing the COMPASS Care Model:

- Some of these calls and surveys have been previously recorded because our sites started launching in June 2016 and the funding for the CTSI Implementation Analysis will not start until April 2017. Retrospective recordings of the calls will be covered under a Waiver of Consent granted by the IRB as this is low-risk to the call participants, this data is needed to run this research analysis and because gaining consent would be difficult considering that there has been some staff turnover at some of our participating sites.
- For any future calls and surveys we will gain consent of participants by informing them that the (1) the call/survey is being recorded and (2) responses may be used for research to analyze implementation of COMPASS program, and (3) responses will be aggregated to maintain confidentiality (meaning any identifying information will be removed prior to publicly using any responses/data). This will require Waiver of Signature since by participating they are providing implicit consent.

We will also be asking study staff COMPASS Director of Implementation and members of the Implementation Committee for individual semi-structured interviews for which we will gain verbal approval. We estimate that we will interview her for 3 hours. For her time, we will offer compensation of $200 for her participation in this research.

Confidentiality and Privacy

Overview

The Principal Investigators and Co-Investigators will ensure the privacy and confidentiality of all study data. All COMPASS Study Investigators and team members are required to complete a yearly HIPAA training and will have research training from CITI (or its equivalent research training).

High-levels of security have been put in place to ensure confidential and secure collection, storage and transfer of data. Patient-level data will be stored on secure servers in four different locations, three of which are at UNC-CH and one at Wake Forest Baptist Health:

1. COMPASS Analytic Database housed by (UNC-CH) EMS Performance and Improvement Center (EMSPIC)
2. COMPASS eCare Plan Informatics Database housed by Wake Forest Baptist Medical Center (WFBMC)
3. Carolina Survey Research Lab (UNC-CH) will temporarily store data that is needed to conduct the phone surveys and send reminder letters.
4. Sheps Center (UNC-CH) will support COMPASS and house claims data.

The sections below describe the information technology protections put in place to ensure security of all patient-level data at all times in each database.

COMPASS Analytic Database at EMSPIC

All COMPASS participants will be assigned a unique participant ID that will be used to link participant records and identify participants within the database. Only key study investigators, team members and clinicians will have access to the identity of participants.

A comprehensive Data Use Agreement governs the use of the data collected and stored by the UNC EMS Performance and Improvement Center (EMSPIC) for research purposes.

Data security is achieved through storage in a secure data center (Peak10), data inspection and monitoring (StillSecure), and complex application security. Access to COMPASS data will require three levels of security: a badge and security code to enter EMSPIC, a badge and fingerprint scan to access the data center, and a security code for each data rack. All outside access to servers and databases must be accomplished through a Virtual Private Network (VPN). All EMSPIC applications use a strong and sophisticated security module, which restricts access based on entity assignments, and security rights monitored by EMSPIC staff. All applications are only accessible via Hypertext Transfer Protocol Secure (HTTPS). HTTPS is a layering of the standard internet protocol (HTTP) onto an SSL (Secure Sockets Layer) protocol. This results in bidirectional encryption of communications between the client and server and serves as reasonable security against eavesdropping on or tampering with the contents of that communication. The HTTPS protocol will be used for all application through SSL hardware encryption and signed by an accepted root certificate authority.

EMSPIC does not allow the use of portable storage devices and unencrypted data will never be stored on flash drives, external hard disks, or laptops. All applications developed at the EMSPIC prevent SQL Injection attacks from occurring by isolating all form data by escaping incoming string data.

Electronic Care (eCare) Plan Informatics Database

The COMPASS eCare Plan Application is a secure web-based application created by a HIPAA-trained programming team at Wake Forest Baptist Medical Center to capture intervention-related data. As described in the intervention section, the eCare Plan Application supports health care providers in efficiently and systematically evaluating patients and identifying next steps for referrals. Data collected into this application will be used to support providers in creation of an individualized care plan (eCare Plan) for patients and generate referral note(s) to other providers (if needed).

The eCare Plan Application is a secure application utilizing TLS level security (a more secure version of SSL). Communication and data transfer between the user's device (iPad, Desktop, Laptop) and eCare Plan Application are encrypted at all times. To access the eCare Plan Application, health care providers must user-authenticate into the COMPASS portal. The eCare Plan Application will employ role-based security which will limit users access to only information they were authorized to access. . Users will be asked to change their password regularly. Data will not be stored locally on any devices to minimize the risk associated with any lost or stolen devices.

The eCare Plan Informatics Database is part of a SQL Server relational data warehouse which is housed in the Wake Forest Health Sciences A1a data center on 3rd Street in Winston-Salem, NC. The webserver hosting the eCare Plan Application is also hosted in the A1a data center. The webserver is a virtual server so in the event of disaster or unexpected significant and lengthy interruption, we can migrate the server into a second data center on Miller St in Winston-Salem, NC. The servers are contained within a secure data center with environmental controls which detect abnormal conditions such as power outages, high heat or humidity, and loud sound. The A1a data center has several secure access points that are accessible only by a badge reader. Only authorized staff will have access to these areas. The building is surrounded by a 10-foot fence with a gate access through badge control. The outside building door is accessed through badge control. The data center room is housed in a locked computer room that is accessed through badge control. Each of these access controls is in place 24 hours a day and seven days a week. All servers have uninterruptible power supplies (UPS). The building has a backup generator that will automatically initiate in the event of a power failure. The computer room is equipped with fire suppression equipment. This equipment is tested on a scheduled timetable by the institution. The entire Data Center is fire- protected by a clean agent system which is backed up by a dry-pipe pre-action sprinkler system. The Data Center room is located on the second floor of the building in an area with no windows and has a raised floor to protect against flooding.

Carolina Survey Research Lab Database and Security

Staff at the CSRL must complete training on Human Subjects Protection, Conflict of Interest, and sign a Confidentiality Agreement. The team is provided a wide variety of computing resources for data collection, statistical computing, and office automation. Staff members and research assistants are provided with a Pentium class microcomputer running Windows 7 and Microsoft Office Professional, as well as SAS 9.3 and SUDAAN 10.0 for statistical analysis, virus detection software, and a wide variety of other standard microcomputer software.

CSRL computers communicate securely through the UNC- ITS systems for Internet communications and for access to secure files which have automatic back-up. All sensitive information is hosted on a server that meets the University Information Security policy (http://its.unc.edu/files/2014/08/Information-Security-Policy.pdf). This policy includes, but is not limited to, the following configurations: host based and network based firewalls, least functionality, least privileged, weekly vulnerability scans, secure backup (located in a separate location on campus), secured physical access, password enforcement policy, warning banner, incident management plan, monitored malware protection, and patch management.

CSRL manages information in a variety of forms including paper, diskettes, and electronic databases. The CSRL maintains a secure file room in an interior room within a suite for the storage of original paper forms and sensitive data on diskettes. This room is locked at all times and only select staff have access to it. For electronic databases, the CSRL employs two servers: (1) data collection machines, which may collect personal identifiers, are protected on a server behind a physical firewall that is cut-off from the Internet; and (2) data analysis machines have access to a server that stores de-identified data; that is, data collected through the calling room machines that have been stripped of any potential identifiers.

To facilitate surveys, patient and caregiver names, phone numbers and addresses, date of hospital discharge, preferred day and time of contact, as well as PAC information will be exported as a CSV file from the Analytic Database. This file will be stored on a secure server (\\cecil.schsr.unc.edu) and accessed by staff at CSRL for pre-loading into their phone system once per week. All access to this secure server will only be granted through UNC secure VPN.

Trained and approved staff at CSRL will have access to COMPASS Analytic Database to record responses and avoid storing patient level-data in a database outside of the primary COMPASS database.

Sheps Center Data Security

The Sheps Center will be housing administrative claims data and the server to which EMSPIC and CSRL will post their shared files. Claims data files at the Sheps Center are placed on a secure dataset server configured specifically to handle large-scale health utilization data. Each data file has access restricted to those users authorized by the relevant DUA. The primary dataset directories on the dataset server provide one inventory of our current claims data files. Disk-to-disk backups of claims data files on our dedicated dataset server are made nightly to two separate backup servers at two different Data Center locations on the UNC campus.

Claims data files are housed on a dedicated secure dataset server configured specifically for sensitive health utilization data. The server is physically located in a Tier II data center at 440 W Franklin St, Chapel Hill as part of the UNC campus. These facilities have 24x7 surveillance, multiple power sources and backup power sources, climate control, etc. Our systems administrators get access via electronic pass cards. Each card entry gets recorded with time/date stamps in facility access logs. The dataset server is behind a firewall, accessible only to Sheps Center IP addresses and UNC Secure VPN addresses. There is no printer attached to the dataset server. Only aggregated (anonymized) data and SAS output are taken off the server and onto local computers.

The server is a Linux (RedHat enterprise) server with all unneeded services disabled. Access to the claims data on the Sheps Dataset Server will be restricted to users authorized by the PI. The server is routinely patched with system updates and receives twice-weekly vulnerability scans using Qualys. Identified vulnerabilities are addressed according to UNC Security Policy. Access to the server is via SSH. Off campus access is restricted to UNC VPN connections requiring a user to authenticate with VPN before server login. VPN also provides an encrypted tunnel. SAS and Stata are typical data programs used.

The Sheps Center makes two daily disk-to-disk backups of the secure dataset server. One backup goes to a dedicated backup server within the same Tier II data center at 440 W Franklin. The second goes to a second dedicated backup server at a second Tier II data center located across town at 211 Manning Drive, Chapel Hill. The backup data travel via an SSH tunnel over the same VLAN within the UNC campus firewalls. Both backup servers are behind a firewall denying the ability of other computers or servers to initiate a connection to the backup servers. Instead, the backup servers reach out to the secure dataset server and “pull” the backup data over.

The hard drives and CDs on which data have been delivered will be stored in a locked cabinet at the Sheps Center. Only authorized staff will have keys to the cabinet. The office will be locked when not occupied. In addition, the Sheps Center is locked 24 hours a day.

User level access to claims data files is restricted based on authorized roles. Unix groups are leveraged to provide layered controls. Users may access the data in the following ways:

1. Using a computer that is on the UNC Active Directory domain and is managed by UNC ITS security tools that perform required scans for viruses and malware and force updated software and operating system patches. Users with this type of computer (desktop or laptop) can access the server directly from campus or via a remote VPN using SSH.
2. Using a computer not managed by UNC ITS security tools via a specifically designated secured UNC Virtual Computer (virtual computing lab), which connects to the server. This virtual desktop is setup, maintained, and managed by Sheps Center sys admins. At the end of a working session, the virtual computer is destroyed along with any data that may have been used locally in the virtual computer instance.

Logical access is safeguarded at multiple levels:

1. The claims data files will be housed on a dedicated secure dataset server configured specifically for sensitive health utilization data. The server is physically located in a Tier II data center at 440 W Franklin St, Chapel Hill,

an extension of the UNC campus. These facilities are governed by the UNC ITS Data Center Operations policies and procedures. They have 24x7 surveillance, required visitor sign-in with escorts, multiple power sources and backup power sources, climate control, etc. Our systems administrators get access via electronic pass cards. Each card entry gets recorded with time/date stamps in facility access logs. While other sys admins of ITS have access to the same physical space where our server racks are housed, these are trusted people governed by central campus ITS policies and procedures. Also, the Data Center space has logged entry of individuals and is under constant surveillance where any unauthorized physical access would be monitored and recorded. Significant sanctions are known and apply, up to and including job termination and possible criminal prosecution.

2. The designated server is firewalled allowing only SSH port 22 to be open. All unnecessary ports are closed and all unnecessary services are disabled. User level access to files is restricted based on authorized roles. SSH connections are limited to UNC subnets and UNC VPN addresses. Access to the designated secure dataset server is restricted to computers within the UNC network domain. Connections originating outside the UNC network are restricted to UNC VPN authentication first and then system-level user/pw authentication. Users may only connect using SSH and Kerberos authentication leveraging the UNC Single Sign-on policies and procedures.
3. Nightly secure backups are performed to two dedicated backup servers – one backup within the same data center within the firewalled subnet and the second backup in another data center across town via the same VLAN. The original CMS data is not backed up to tape but instead the delivery media is kept for backup, if needed. In case of (a) data center disaster, or (b) backup failure, a second backup computer is housed in a second campus data center. Two system administrator computers are allowed to connect to backup servers to control them. Firewall prevents all other computers from reaching backup servers. Backup computers initiate the network connections to the server. It is not possible for any user to initiate a connection to a backup server from the main server or from any other computer except for those owned by two system administrators. All network connections are encrypted.
4. The designated server is kept up-to-date with recommended operating system patches and patches for applications. The server is scanned twice weekly for vulnerabilities using the UNC licensed QualysGuard SaaS software. System administrators monitor event logs, security logs, and system logs. UNC uses Snort for intrusion detection and Tipping Point for intrusion prevention. These systems/appliances are monitored and handled centrally by the UNC ITS Security Office. Suspicious activity is reported to the Sheps Center's Security Liaison for investigation and handling with assistance from the central ITS Security Office. If these data will be delivered via CD or hard drive, the media will be kept in a locked storage location provided by the project, with key access only to research team members.
5. Project staff at the Sheps Center will access the secure dataset server via SSH using computers physically in the Sheps Center Building. The Sheps Center Building's exterior doors are locked 24x7. Individual offices inside the Sheps Center are also locked. Staff enter using an authorized key. Visitors must be buzzed in using a video intercom system and then must report to the receptionist and sign in. There are no servers physically located in the Sheps Center Building.

Description of the Secure Data Transfers

Secure Data Transfer between the COMPASS DB and eCare Plan Informatics (eCPI) DB
Data transfer between the COMPASS Database and the eCPI Database will be via RESTful web services designed specifically for the limited datasets being exchanged. Secure data transfer protocols will be in place to provide fully encrypted transmissions. The eCare Application may retrieve and update patient data from the COMPASS Database (the database of record for patient data) for use during a patient visit in order to foster the use of that data in creating an eCare Plan. Patient data is requested based on key identifiers and the resulting match reflected in the eCare application. The web service will allow for the transmission of data stored in the eCPI database to the COMPASS Database for use in analysis as well as patient status updates and notifications to appropriate study personnel. The eCare database remains the database of record for those intervention data while making the COMPASS DB and associated application aware of the analytical data needed for the study. The eCare application will contain the logic necessary during the flow of its data collection to validate data with the patient as well as prevent implausible and/or out-of-range responses.

Secure Data Transfer between COMPASS DB and CSRL
As described above, to facilitate surveys, patient and caregiver names, phone numbers and addresses, date of hospital discharge, preferred day and time of contact, as well as PAC information will be exported as a CSV file from the Analytic Database. This file will be stored on a secure server (\\cecil.schsr.unc.edu) and accessed by staff at CSRL for pre-loading into their phone system once per week.

Data Access for Analysis

We have in place secure operations for sharing SAS datasets between investigators to ensure safety and confidentiality of patients. Datasets will be stored on a secure server that is accessed through a virtual network. Study investigators will be granted access to this server for running data reports and analyses of the study data. These internal datasets will contain the COMPASS Unique participant IDs to link data in different files together. PHI (including date of birth, medical record number, names, addresses, phone numbers, and email addresses) will be removed from datasets prior to export of these SAS datasets from the COMPASS Database. Data sharing with investigators outside of UNC will occur through data transfers using secure File Transfer Protocols.

REDCap (Research Electronic Data Capture)

COMPASS Study will use REDCap at Wake Forest Baptist Medical Center to store responses from hospital stakeholders and track stakeholder engagement activities.

Vanderbilt University, with collaboration from a consortium of institutional partners, has developed a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. REDCap (Research Electronic Data Capture) is hosted at Wake Forest Baptist Medical Center through the Biomedical Informatics program of the Translational Science Institute. REDCap servers are located within the Wake Forest Baptist Health firewall and all web-based information transmission is SSL (Secure Socket Layer) encrypted; the databases are backed up nightly through the institution's enterprise backup system. Users are granted access to the system using their unique medical center username and password with specific access rights setup for each study. REDCap was developed specifically around HIPAA-Security guidelines and is used by 1,000+ academic/non-profit consortium partners on six continents with over 195,000 research end-users (www.project-redcap.org).

Data and Safety Monitoring

The COMPASS Data and Safety Monitoring Board (DSMB) will serve to support as an independent review board of the study and study activities to protect patients. Adverse events among this patient population are likely; however because COMPASS is a minimal/no risk study, COMPASS will not be tracking adverse events. Therefore the COMPASS DSMB will provide thrice-annual review of study activities providing external review and assurance on the performance of the study. This thrice-annual review will include case ascertainment and enrollment; expected versus observed outcomes; review of percentage of participants in the intervention receiving the 2-day call, the 7-14 day visit, the eCare Plan; and review of protocol deviations.

To avoid any appearance of conflict of interest, it is critical that DSMB members not be involved in the study, have no vested interest in its outcome, have no ties to the study investigators (e.g., not from the same institution and no history of extensive collaboration), and have no financial ties to any commercial concerns likely to be affected by the study's outcome. If at any time a DSMB member perceives that he/she or another member of the Board has a potential conflict of interest, he/she is obligated to bring the issue to the attention of the full DSMB for open discussion and resolution.

Responsibilities

1. COMPASS DSMB members will be responsible for assuring study participants are not exposed to unnecessary, unreasonable or unexpected risk, and is charged with ensuring that the study is conducted according to the highest scientific and ethical standards.
2. Specifically, oversight will include the following areas:
    - Review of the COMPASS Manual of Operations and Procedures (MOP), the analysis plan, and implementation of the study procedures at the first DSMB meeting.
    - Review of study protocol including our informed consent processes.
    - The DSMB may recommend modifications or request clarifications of the protocol.
    - Review of the study outcomes and their clear definition, study procedures, informed consent documents, data security, and investigator responsibilities.
    - In subsequent meetings, the DSMB will focus on case ascertainment and enrollment; expected versus observed outcomes; review of percentage of participants in the intervention receiving the 2-day call, the 7-14 day visit, the eCare Plan; and review of protocol deviations.
    - Any other areas the DSMB considers oversight to be necessary.

Frequency of Meetings and Communication between DSMB and COMPASS

COMPASS DSMB members will meet annually. The first meeting will take place in person, in early 2016. Subsequent meetings will take place remotely over webinar. Meetings will be closed to the public. Only DSMB members and members of the COMPASS Executive Leadership Committee will attend. ELC members will prepare in advance a DSMB report for review (Appendix 32). Each meeting will start with discussion between COMPASS Executive Leadership Team and DSMB and then the DSMB will meet privately without study personnel.

At the end of each annual meeting, the DSMB will provide a verbal report to the Executive Leadership Team noting any areas of concern in study performance and/or operations. Care will be exercised to ensure no information will be conveyed that could compromise the study or its outcomes. Within two weeks, the DSMB Chair will provide a written report to PCORI and the Executive Leadership Team, which includes the DSMB recommendation for continuing, discontinuing, amending, or suspending the study. This written report will cover data reviewed, recommendations, and date of the next scheduled review. This report will be forwarded by the PIs to the Central IRB at Wake Forest Medical Center and the Data Coordination IRB at the University of North Carolina and PCORI.

Membership

The process for identifying the DSMB included feedback from PCORI, recommendations from the Steering Committee and vetting by the Executive Leadership Committee (ELC). The ELC reviewed each recommendation and consulted with PCORI for additional guidance and input on the final selection of DSMB members. Once DSBM members were

approved by the ELC, the Project Manager sent out a formal letter to the proposed DSMB members inviting them to serve. COMPASS DSMB members include:

DSMB Chair:

1. Jason Conner, PhD – Director and Senior Statistical Scientist for Berry Consultants. Dr. Connor has expertise in Bayesian statistics and designing adaptive clinical trials. He serves on the Clinical Trials Advisory Panel (CTAP) for PCORI. Dr. Connor has accepted to serve as a DSMB member.

DSMB Members:

2. Judy Lichtman, PhD, MPH – Chair, Chronic Disease Epidemiology, Yale University. Dr. Lichtman focuses on stroke research and is experienced in outcomes research, quality improvement and CMS data linkage. Dr. Lichtman has accepted to serve as a DSMB member.
3. Brett Kissela, MD – Chair of Department of Neurology and Rehabilitation Medicine at the University of Cincinnati (UC) College of Medicine and UC Health. Dr. Kissela is a stroke neurologist and stroke researcher. Dr. Kissela has accepted to serve as a DSMB member.
4. Theresa Damush, PhD – Associate Research Professor of Medicine, Indiana University School of Medicine. Dr. Damush is a research health psychologist focusing on implementing evidence-based practices for stroke survivors and caregivers. She specializes in the design and evaluation of patient centered programs. Dr. Damush has accepted to serve as a DSMB member.

Reporting of Unanticipated Problems or Deviations

Any unanticipated problems, deviations or protocol changes will be promptly (within 10 days) reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

This study is not collecting or reporting adverse events.

System-Level Protocol Deviations include:

- Loss of participating site (i.e. a hospital drops out of the study).
- Change of personnel or study staff at the hospital without notifying the COMPASS Team of change of study personnel.

Patient-level Protocol Deviations include:

- Not notifying enrolled patients that the hospital is participating in the COMPASS Study by either (1) providing the COMPASS brochure packet to the patient prior to discharge or (2) mailing the patient brochure (if the patient is discharged before study staff can inform the patient).
- *For Intervention-randomized sites conducting the consent:* Consent needs to be conducted by research trained study staff or clinicians.

Study-Level Deviations include:

- Including any patient participants in analysis (for research purposes) if they have not provided consent and authorization according to our outlined protocols and our "consent matrix" (Appendix 39).

References

1. American Heart Assosiation. Heart Disease and Stroke Statistics—2015 Update. *Circulation*. 2015;131:e29–e322.
2. Bertoni AG, Ensley D, Goff DC. 30,000 fewer heart attacks and strokes in North Carolina: a challenge to prioritize prevention. *N. C. Med. J.* 2012;73:449–456.
3. Kennedy BS. Does race predict stroke readmission? An analysis using the truncated negative binomial model. *J. Natl. Med. Assoc.* 2005;97:699–713.
4. Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries. Baltimore, MD: 2012.
5. Olson DM, Cox M, Pan W, Sacco RL, Fonarow GC, Zorowitz R, LaBresh KA, Schwamm LH, Williams L, Goldstein LB, Bushnell CD, Peterson ED. Death and Rehospitalization after Transient Ischemic Attack or Acute Ischemic Stroke: One-year Outcomes from the Adherence Evaluation of Acute Ischemic Stroke–Longitudinal Registry. *J. Stroke Cerebrovasc. Dis.* 2013;22:e181–e188.
6. Fonarow G, Smith E, Reeves M, Pan W, Olson D, Hernandez A, Peterson E, Schwamm L. Hospital-level variation in mortality and rehospitalization for Medicare beneficiaries with acute ischemic stroke. *Stroke*. 2011;42:159–166.
7. Rosamond W, Johnson A, Bennett P, O'Brien E, Mettam L, Jones S, Coleman S. Monitoring and improving acute stroke care: The North Carolina Stroke Care Collaborative. *N. C. Med. J.* 2012;73:494–498.
8. Bernhardt J, Dewey H, Thrift A, Donnan G. Inactive and Alone Physical Activity Within the First 14 Days of Acute Stroke Unit Care. *Stroke*. 2004;35:1005–1009.
9. Bamford J, Dennis M, Sandercock P, Burn J, Warlow C. The frequency, causes and timing of death within 30 days of a first stroke: the Oxfordshire Community Stroke Project. *J. Neurol. Neurosurg. Psychiatry*. 1990;53:824–829.
10. Johnston KC, Li JY, Lyden PD, Hanson SK, Feasby TE, Adams RJ, Faught RE, Haley EC. Medical and Neurological Complications of Ischemic Stroke Experience From the RANTTAS Trial. *Stroke*. 1998;29:447–453.
11. Whitson HE, Pieper CF, Sanders L, Horner RD, Duncan PW, Lyles KW. Adding injury to insult: fracture risk after stroke in veterans. *J. Am. Geriatr. Soc.* 2006;54:1082–1088.
12. Davenport RJ, Dennis MS, Wellwood I, Warlow CP. Complications after acute stroke. *Stroke J. Cereb. Circ.* 1996;27:415–420.
13. White JH, Attia J, Sturm J, Carter G, Magin P. Predictors of depression and anxiety in community dwelling stroke survivors: a cohort study. *Disabil. Rehabil.* 2014;:1–8.
14. Husseini NE, Goldstein LB, Peterson ED, Zhao X, Pan W, Olson DM, Zimmer LO, Williams JW, Bushnell C, Laskowitz DT. Depression and Antidepressant Use After Stroke and Transient Ischemic Attack. *Stroke*. 2012;43:1609–1616.
15. Kelly J, Rudd A, Lewis RR, Coshall C, Moody A, Hunt BJ. Venous Thromboembolism After Acute Ischemic Stroke A Prospective Study Using Magnetic Resonance Direct Thrombus Imaging. *Stroke*. 2004;35:2320–2325.
16. Lai S-M, Studenski S, Duncan PW, Perera S. Persisting Consequences of Stroke Measured by the Stroke Impact Scale. *Stroke*. 2002;33:1840–1844.
17. Bushnell CD, Zimmer LO, Pan W, et al. Persistence with stroke prevention medications 3 months after hospitalization. *Arch. Neurol.* 2010;67:1456–1463.
18. Kopunek SP, Michael KM, Shaughnessy M, Resnick B, Nahm E-S, Whitall J, Goldberg A, Macko RF. Cardiovascular Risk in Survivors of Stroke. *Am. J. Prev. Med.* 2007;32:408–412.
19. Rigby H, Gubitz G, Eskes G, Reidy Y, Christian C, Grover V, Phillips S. Caring for stroke survivors: baseline and 1-year determinants of caregiver burden. *Int. J. Stroke Off. J. Int. Stroke Soc.* 2009;4:152–158.
20. Rigby H, Gubitz G, Phillips S. A systematic review of caregiver burden following stroke. *Int. J. Stroke*. 2009;4:285–292.
21. Prvu Bettger J, Alexander KP, Dolor RJ, Olson DM, Kendrick AS, Wing L, Coeytaux RR, Graffagnino C, Duncan PW. Transitional Care After Hospitalization for Acute Stroke or Myocardial InfarctionA Systematic Review. *Ann. Intern. Med.* 2012;157:407–416.
22. Fearon P, Langhorne P, Early Supported Discharge Trialists. Services for reducing duration of hospital care for acute stroke patients. *Cochrane Database Syst. Rev.* 2012;9:CD000443.

23. Langhorne P, Taylor G, Murray G, Dennis M, Anderson C, Bautz-Holter E, Dey P, Indredavik B, Mayo N, Power M, Rodgers H, Morten Ronning O, Rudd A, Suwanwela N, Widen-Holmqvist L, Wolfe C. Early supported discharge services for stroke patients: a meta-analysis of individual patients' data. *Lancet*. 2005;365:501–506.
24. Kernan WN, Ovbiagele B, Black HR, Bravata DM, Chimowitz MI, Ezekowitz MD, Fang MC, Fisher M, Furie KL, Heck DV, Johnston SC (Clay), Kasner SE, Kittner SJ, Mitchell PH, Rich MW, Richardson D, Schwamm LH, Wilson JA. Guidelines for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke*. 2014;:STR.0000000000000024.
25. Teasell R. Evidence-Based Review of Stroke Rehabilitation [Internet]. [cited 2014 Jun 14];Available from: http://www.ebrsr.com/
26. Legg LA, Quinn TJ, Mahmood F, Weir CJ, Tierney J, Stott DJ, Smith LN, Langhorne P. Non-pharmacological interventions for caregivers of stroke survivors. *Cochrane Database Syst. Rev.* 2011;:CD008179.
27. Forster A, Brown L, Smith J, House A, Knapp P, Wright JJ, Young J. Information provision for stroke patients and their caregivers. *Cochrane Database Syst. Rev.* 2012;11:CD001919.
28. Salter K, Allen L, Richardson M, Teasell R. Community Reintegration [Internet]. EBRSR.COM; 2013. Available from: http://www.ebrsr.com/sites/default/files/Chapter19_Community-reintegration_FINAL_16ed.pdf
29. Tu J, Willison D, Silver F, Fang J, Richards J, Laupacis A, Kapral M. Impracticability of informed consent in the Registry of the Canadian Stroke Network. *New Engl J Med*. 2004;350:1414–1421.
30. Centers for Medicare & Medicaid Services. Hospital Compare Datasets. [https://data.medicare.gov/data/hospital-compare]
31. Kim, SYH and Miller FG. Informed Consent for Pragmatic Trials — The Integrated Consent Model. N Engl J Med 2014; 370:769-772

Appendices

Appendix 1 - COMPASS Hospital Characteristics

In order to provide additional details on hospitals that the COMPASS Study is recruiting to participate, we have prepared a side-by-side comparison of the COMPASS Hospitals we expect to randomize with All North Carolina Hospitals (Table 1). We gathered the comparison data from the publicly reported CMS Hospital Compare Information (CMS. Hospital Compare Datasets: https://data.medicare.gov/data/hospital-compare).

For each of the hospitals that we expect to randomize, we have generated Table 2 which provides additional details on the percentage of hospitals that are a Primary Stroke Center (PSC) or a Certified Stroke Center (CSC) and annual stroke volume. This data comes from our North Carolina Stroke Care Collaborative (NCSCC) Data.

Table 3, is the list of hospitals participating in the study. This list was updated in December 2016.

**Table 1. Comparison of Anticipated Participating Hospitals with All NC Hospitals **

	COMPASS (N=47*)	All NC Hospitals (N=85)
30-day Mortality Rate for Stroke Patients	15.6 (14.2 - 16.7)	15.4 (14.1 - 16.6)
30-day Unplanned Readmission Rate for Stroke Patients	12.6 (11.8 - 13.4)	12.8 (12.1 - 13.6)
CMS HCAHPS 5-Star Quality Rating, median score		
Overall summary score	3 (3 - 4)	3 (3 - 4)
Care transition score	3 (3 - 4)	3 (2 - 4)
Stroke quality measures, % of patients that received measure		
Venous Thromboembolism (VTE) Prophylaxis	98 (96 - 100)	99 (96 - 100)
Discharged on Antithrombotic Therapy	100 (99 - 100)	100 (99 - 100)
Anticoagulation Therapy for Atrial Fibrillation/Flutter	100 (96 - 100)	100 (96 - 100)
Thrombolytic Therapy	95 (91 - 100)	93 (84 - 99)
Antithrombotic Therapy by End of Hospital Day 2	100 (98 - 100)	100 (98 - 100)
Discharged on Statin Medication	98 (96 - 100)	99 (96 - 100)
Stroke Education	97 (92 - 100)	97 (90 - 100)
Assessed for Rehabilitation	100 (99 - 100)	100 (98 - 100)

*Data from Murphy Medical Center are not available from Hospital Compare.

Notes: Values are presented as median (25th, 75th percentile). HCAHPS represents Hospital Consumer Assessment of Healthcare Providers and Systems.

**This Table was last Updated in Jan 2016

**Table 2. Characteristics of Anticipated Hospitals (N=48)

	N	Percent
Teaching hospital	2	4%
Joint Commission stroke certified sites (PSC or CSC)	22	46%
Geographic region		
Piedmont	26	54%
Western	11	23%
Eastern	11	23%
Annual stroke volume		
<100 discharges	12	25%
100-299 discharges	23	48%
300+ discharges	13	27%

**This Table was last Updated in Jan 2016

Table 3. List of Participating Hospitals (Table Updated December 2016)

#	Hospital	Wave	Arm	Stroke Center	2013 Stroke Discharges
1	Cape Fear Valley Medical Center	1	Usual Care	PSC	300+
2	FirstHealth Moore Regional	1	Intervention	PSC	300+
3	Onslow Memorial Hospital	1	Usual Care	PSC	100-299
4	Carteret County General Hospital	1	Intervention	PSC	100-299
5	WFBH Lexington Medical Center	1	Usual Care	PSC	100-299
6	Hugh Chatham Memorial Hospital	1	Intervention	PSC	100-299
7	Pardee Health	1	Usual Care	No	100-299
8	Lenoir Memorial Hospital	1	Intervention	No	100-299
9	CHS NorthEast	2	Intervention	PSC	300+
10	Novant Health Presbyterian Medical Center	2	Usual Care	PSC	300+
11	New Hanover Regional MC	2	Usual Care	PSC	300+
12	Mission Hospital	2	Intervention	PSC	300+
13	Novant Health Huntersville Medical Center	2	Intervention	PSC	100-299
14	Novant Health Matthews Medical Center	2	Usual Care	PSC	100-299
15	CHS University	2	Intervention	No	100-299
16	CHS Blue Ridge	2	Usual Care	No	100-299
17	CHS Union	2	Intervention	PSC	100-299
18	CHS Cleveland	2	Usual Care	PSC	100-299
19	CHS Kings Mountain	2	Usual Care	No	<100
20	Wilkes Regional Medical Center	2	Intervention	No	100-299
21	Northern Hospital of Surry County	2	Usual Care	PSC	<100
22	Frye Regional Medical Center	2	Intervention	PSC	300+
23 a	Carolinas Medical Center	3	Intervention	PSC	300+
23 b	CHS Mercy (randomized with CMC as a single unit)	3	Intervention	PSC	<100
24	WakeMed Health & Hospitals	3	Usual Care	PSC	300+
25	Duke Raleigh Hospital	3	Usual Care	PSC	100-299
26	CHS Stanly	3	Intervention	PSC	100-299
27	Ashe Memorial Hospital	3	Intervention	No	<100
28	Alleghany	3	Usual Care	No	<100
29	Betsy Johnson Hospital	3	Usual Care	No	100-299
30	Morehead Memorial Hospital	3	Intervention	No	<100
31	UNC Hospital	3	Usual Care	CSC	300+
32	Rex Healthcare	3	Intervention	PSC	300+
33	CHS Lincoln	3	Usual Care	No	<100
34	Caldwell Memorial Hospital	3	Intervention	No	100-299
35	Vidant Duplin Hospital	3	Intervention	PSC	<100
36	Blue Ridge Regional	3	Usual Care	No	<100
37	Vidant Edgecombe Hospital	3	Usual Care	No	100-299
38	Angel Medical Center	3	Intervention	No	<100
39	Washington County Hospital	3	Intervention	No	<100
40	SouthEastern Regional Medical Center	3	TBD	No	300+

Appendix 2 - COMPASS Hospital Survey

Confidential

COMPASS Study Hospital Survey

The goal of this survey is to understand your hospital's current practice for stroke care from the acute setting through post-discharge management. We also wish to capture information about how your hospital identifies stroke cases and whether you would be willing to consider participation in the Comprehensive Post-Acute Stroke Services (COMPASS) trial.

We appreciate your time and attention to the survey. If you have any questions, please contact Sara Jones (sara.jones@unc.edu).

Thank you!

The COMPASS Team

RESPONDENT INFORMATION

Title _____

Full Name: _____

Email address: _____

Hospital Name: _____

Hospital City: _____

Hospital Zip Code: _____

Please check the description that best defines your position:

◯ Director of care coordination and/or case management
◯ Director of translational care clinic
◯ Quality improvement director
◯ Stroke care coordinator
◯ Other

If other, please specify _____

ACUTE STROKE CARE

1 How many patients with ischemic or hemorrhagic stroke or TIA meeting the ICD-9/10 criteria below were treated at your hospital in 2015 or the last calendar year for which you have data? Click below to view the ICD table.

_____

[Attachment: "ICD table.PNG"]

Enter the most recent calendar year for which you have data _____

2 In the last calendar year, how many stroke and TIA patients were discharged directly home from your hospital? _____

3 How frequently are patients with presumptive stroke/TIA diagnosis (stroke-like symptoms) identified in your hospital?

- ◯ Daily
- ◯ Two or more times per week
- ◯ One time per week
- ◯ One time every 2 weeks
- ◯ One time per month

4 Are patients who are admitted with a presumptive stroke/TIA diagnosis during the weekend entered into a daily patient list during that same weekend?

◯ Yes ◯ No

5 What information is used to develop a roster of patients admitted with a presumptive stroke/TIA diagnosis? (check all that apply)

- ☐ Diagnosis (ICD-10 codes)
- ☐ Census for selected units (ICU or dedicated neurology units)
- ☐ Hospital problem list - principle problems
- ☐ Hospital problem list - other problems
- ☐ Census for the entire hospital
- ☐ Review of daily admissions/arrivals for admitting diagnosis or stroke-like symptoms
- ☐ Use of stroke admission order sets
- ☐ Code stroke logs
- ☐ Neurology consult orders
- ☐ Stroke rounds by attending and/or residents
- ☐ Shared "stroke patient" lists
- ☐ Other

Please specify what other information is used

_____

6 Who in your hospital is responsible for developing a list of patients admitted with a presumptive stroke/TIA diagnosis?

- ◯ Stroke care coordinator
- ◯ Direct care nurse
- ◯ Stroke care provider (MD, NP, PA)
- ◯ Nursing operations supervisors
- ◯ Nursing unit managers
- ◯ Nursing unit team leaders
- ◯ Other

Please specify other responsible party

_____

Confidential

7 Who in your hospital abstracts stroke patient information into the NCSCC Stroke Care Card or Get-With-The-Guidelines-Stroke PMT?

- ◯ Stroke care coordinator
- ◯ Data abstractor other than stroke coordinator
- ◯ NA, data captured electronically with no manual abstraction
- ◯ NA, do not participate in NCSCC or GWTG-Stroke
- ◯ Other

Please specify other hospital abstractor

_____

8 Who in your hospital is responsible for compliance with CMS Medicare and Medicaid Performance Metrics for acute stroke care?

- ◯ Stroke care coordinator
- ◯ Quality performance manager
- ◯ Other

Please specify other responsible party

_____

9 Can patients who are admitted to your hospital with a presumptive stroke/TIA be identified concurrent with practice?

◯ Yes ◯ No

9a If no, what are the barriers to concurrent identification of stroke/TIA patients? (check all that apply)

- ☐ Missed potential stroke/TIA in the ED
- ☐ Patients cared for outside of ICU or dedicated neuro-unit
- ☐ Atypical presentation of stroke/TIA
- ☐ Admission by off-service providers (non-neurologists or non-hospitalists)
- ☐ Short length of stay (less than 1-2 days)
- ☐ Lack of updated hospital problem list
- ☐ Uncertain terms in Discharge summary ("probable", "possible")
- ☐ Diagnostic testing not final before discharge
- ☐ Other

Please specify other barrier to identification

_____

10 For questions 10a-10i Indicate the frequency with which each provider type (includes MDs, NP/PA) admits patients with a presumptive stroke/TIA

_____

10a Hospitalists

- ◯ All of the time
- ◯ Mostly
- ◯ Occasionally
- ◯ Rarely
- ◯ Never

10b Intensivists

- ◯ All of the time
- ◯ Mostly
- ◯ Occasionally
- ◯ Rarely
- ◯ Never

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10c Neurologists

- ◯ All of the time
- ◯ Mostly
- ◯ Occasionally
- ◯ Rarely
- ◯ Never

10d Neurosurgeons

- ◯ All of the time
- ◯ Mostly
- ◯ Occasionally
- ◯ Rarely
- ◯ Never

10e Nephrologists

- ◯ All of the time
- ◯ Mostly
- ◯ Occasionally
- ◯ Rarely
- ◯ Never

10f Oncologists

- ◯ All of the time
- ◯ Mostly
- ◯ Occasionally
- ◯ Rarely
- ◯ Never

10g Cardiologists

- ◯ All of the time
- ◯ Mostly
- ◯ Occasionally
- ◯ Rarely
- ◯ Never

10h Internal medicine (non-hospitalists)

- ◯ All of the time
- ◯ Mostly
- ◯ Occasionally
- ◯ Rarely
- ◯ Never

10i Other

- ◯ All of the time
- ◯ Mostly
- ◯ Occasionally
- ◯ Rarely
- ◯ Never

Please specify type of other

_____

11 Is information on patients discharged following stroke/TIA (e.g. name, address, telephone) available at your hospital?

◯ Yes ◯ No

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12 Is information on the patient's post-acute caregiver (e.g. name, address, telephone) available at your hospital?

◯ Yes ◯ No

13 Does your hospital have a dedicated stroke team?

◯ Yes ◯ No

13a Select the actively involved (i.e. participating in at least 75% of meetings each year) members of the stroke team by their role. (check all that apply)

☐ Neurologist
☐ Hospitalist
☐ Nurse practitioner
☐ Unit charge nurse
☐ Case manager (e.g. RN)
☐ Pharmacist
☐ Physical Therapist
☐ Occupational Therapist
☐ Speech therapist
☐ Nutritionist
☐ Behavioral or mental health specialist
☐ Social worker (e.g. MSW)
☐ Other

Please describe the other role _____

14 Does your hospital have a stroke unit or dedicated beds in a specific unit for stroke patients?

◯ Yes ◯ No

15 Does your hospital use telestroke for acute care (i.e. access to acute stroke experts via two-way live video and audio consultation and image sharing technology)?

◯ Yes - as a hub hospital
◯ Yes - as a spoke hospital (supported by telestroke service)
◯ No

15a Please provide name of the hub hospital

_____

16 Does your hospital have a patient navigator for your stroke patients? [The patient navigator is someone who helps with coordination of healthcare services and offers assistance in reducing barriers to receiving care and treatment; for example, arranging for financial support, arranging transportation services, coordination of visits across providers.]

◯ Yes - supporting acute care only
◯ Yes - supporting post-acute care only
◯ Yes - supporting both acute and post-acute care
◯ No

17 Does your hospital have an inpatient peer/mentor support program for your stroke patients?

◯ Yes ◯ No

DISCHARGE PLANNING FOR PATIENTS GOING HOME

1 Do you have a multidisciplinary discharge planning team for stroke patients? [By multidisciplinary discharge planning team, we mean a team of physicians, nurses, and key ancillary service specialists involved in managing a patient's discharge]

◯ Yes ◯ No ◯ Do not know

1a Please identify members of your discharge planning team. (check all that apply)

☐ Neurologist
☐ Hospitalist
☐ Nurse practitioner
☐ Unit charge nurse
☐ Case manager (e.g., RN, BSN, or MSN)
☐ Pharmacist
☐ Physical therapist
☐ Occupational therapist
☐ Speech therapist
☐ Nutritionist
☐ Behavioral or mental health specialist
☐ Social worker (e.g. MSW)
☐ Other

Specify type of other member

_____

2 Does your hospital conduct an assessment of stroke patient's and family's transitions needs prior to discharge?

◯ Yes ◯ No ◯ Do not known

2a What areas are assessed and documented in the patient's medical record? (Check all that apply)

☐ Caregiver availability after discharge for supervision and assistance
☐ Activities of Daily Living
☐ Physical Mobility (Balance, Strength, Endurance, and Walking)
☐ History of Falls
☐ Assessment of cognitive function using standardized assessments (e.g. Mini Mental Status Exam, MOntreal Cognitive Assessment -MOCA)
☐ Home environment assessment for safety and mobility
☐ Need for assistive equipment
☐ Availability of transportation for follow-up appointments
☐ Confirmation of primary care provider
☐ Appointment made for follow-up with primary care provider
☐ Depression and need for follow-up care
☐ Advanced directives and end of life planning
☐ Need and referral for other follow-up: home visit by RN, NP/PA or MD, home health, outpatient rehabilitation, other outpatient specialty care
☐ Knowledge and need for community services, e.g., meals on wheels, support groups, etc.
☐ Other

Describe other areas

3 Does your hospital assess the stroke patient/family's understanding of their discharge instructions and transition home (e.g. teach-back)?

◯ Yes ◯ No ◯ Do not know

3a What areas are assessed for patient/family understanding? (check all that apply)

- ☐ Risk factors for stroke
- ☐ Management of risk factors following discharge
- ☐ Medications and plan for medication management
- ☐ Follow up appointments, procedures and services
- ☐ Stroke signs and symptoms
- ☐ Expected level of recovery within 90 days
- ☐ Other

List other areas that are assessed

4 Does your hospital include a transition of care plan in the discharge summary for the stroke patient/family?

◯ Yes ◯ No ◯ Do not know

5 Is an appointment made with a primary care provider prior to discharge?

◯ Yes ◯ No

5a What are the challenges with getting a primary care appointment within 14 days of discharge? (check all that apply)

- ☐ None
- ☐ Insurance type
- ☐ Patient does not have insurance
- ☐ Patient does not have a primary care provider
- ☐ Unable to reach the primary care provider's office to make the appointment
- ☐ Availability of primary care appointments within 7 to 14 days post-stroke
- ☐ Patient refusal
- ☐ Other

Specify other challenge

_____

5b For what proportion (percentage) of your stroke patients are you able to make a follow-up appointment with a primary care provider within 14 days?

_____

5c Is a hospital discharge summary sent to the patients' primary care provider when an appointment is made?

◯ Yes ◯ No ◯ Do not know

6 Is a patient specific transitional care plan sent to the primary care provider and/or rehab providers?

◯ Yes ◯ No ◯ Do not know

POST-DISCHARGE PATIENT MANAGEMENT AND FOLLOW-UP

(For stroke/TIA patients discharged home)

1 Does the hospital perform follow-up telephone calls for stroke patients after discharge?

- ◯ No - there is no patient follow-up by telephone
- ◯ Yes - within 48-72 hours of discharge
- ◯ Yes - within 7 days
- ◯ Yes - within 14 days
- ◯ Yes - other time point (enter time below)

Enter the number of days after discharge

_____

Specify other provider

_____

1a Who usually makes this follow-up call?

- ◯ Stroke care coordinator
- ◯ Stroke care nurse
- ◯ Designated transitional care coordinator
- ◯ Other

5a Specify other

2 How would you best describe the setting in which stroke patient's follow-up care is delivered?

- ◯ Neurology Clinic
- ◯ Hospitalist Clinic
- ◯ Paramedicine Program
- ◯ Stroke Follow-up Clinic
- ◯ General Follow-up Clinic (not stroke-specific)
- ◯ Primary Care Practitioner's Clinic
- ◯ Chronic disease Transitional Care Clinic
- ◯ Other

Specify other setting

_____

3 Does your hospital/health system provide in-person specialty follow-up with neurology to all stroke patients?

- ◯ No clinic or outpatient follow-up with neurology
- ◯ Yes - clinic or outpatient visit within 14 days of hospital discharge
- ◯ Yes - clinic or outpatient visit within 30 days of hospital discharge
- ◯ Yes - clinic or outpatient visit within 60 days of hospital discharge
- ◯ Other in-person follow-up arrangement
- ◯ In-person home visit (please indicate days after hospital discharge below)

Describe other follow-up arrangement

_____

Enter the number of days after discharge

_____

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4 If there is follow-up that occurs within 14 days of hospital discharge (either with a general primary care provider or neurology specialist), who is the health care professional primarily responsible for the in-person follow-up?

- ◯ No in-person follow-up is performed within 14 days
- ◯ Nurse Practitioner only
- ◯ Physician Assistant only
- ◯ Physician only
- ◯ Either Nurse Practitioner or Physician Assistant
- ◯ Nurse Practitioner or Physician Assistant and a Physician
- ◯ Other

Specify other type of health professional

_____

4a Please indicate what are the objectives of the in-person follow-up appointment/visit or neurology specialty follow up. Select all that apply.

- ◯ Conduct a thorough neurological examination
- ◯ Review medication use, access, and adherence, and reconcile as needed
- ◯ Assess risk factor levels
- ◯ Coordinate access to primary care
- ◯ Coordinate use of home health services, outpatient physical therapy, occupational therapy, or speech therapy (as needed)
- ◯ Provide referral to community services
- ◯ Other

Specify other objectives of the in-person follow-up

5 Does your hospital have an electronic patient care plan for post-acute management accessible to the patient and all of his or her providers (e.g. primary care, rehabilitation teams, home health) caring for stroke patients after hospital discharge?

- ◯ Yes - available to the patient and all post-acute providers
- ◯ Yes - available to all post-acute providers (no direct patient access)
- ◯ Yes - available to select post-acute providers only
- ◯ No

Please describe the select providers

6 Does your hospital share electronic medical record information with any of the following non-hospital services for stroke patients following discharge home? Select all that apply.

- ☐ No, information is not shared with non-hospital services
- ☐ Primary care practices
- ☐ Home health agencies
- ☐ Outpatient therapy practices
- ☐ Mental health providers
- ☐ Outpatient neurology care
- ☐ Outpatient specialty care
- ☐ Telehealth sites and care providers after hospital discharge
- ☐ EMS after hospital discharge
- ☐ Hospital or health system sponsored stroke support group
- ☐ Community resources for stroke (e.g., external stroke support groups, caregiver support groups, AAA, community exercise programs, senior centers)
- ☐ Other

Specify other

_____

Confidential

7 Does your hospital have integrated patient care plans and supported coordination and communication for stroke patients with any of the following. Select all that apply.

- ☐ No, integrated care plans with non-hospital providers are not in place
- ☐ Primary care practices
- ☐ Home health agencies
- ☐ Outpatient therapy practices
- ☐ Mental health
- ☐ Outpatient neurology care
- ☐ Outpatient specialty care
- ☐ Telehealth after hospital discharge
- ☐ EMS after hospital discharge
- ☐ Hospital or health system sponsored stroke support group
- ☐ Community resources for stroke (e.g., external stroke support groups, caregiver support groups, AAA, community exercise programs, senior centers)
- ☐ Other

Specify other plans

_____

8 Does your hospital or affiliated providers use the transitional care management (TCM) billing codes for stroke patients? (The TCM codes are CPT codes 99495 and 99496, covering communication with patient and/or caregiver within two business days of discharge)

◯ Yes ◯ No ◯ Not Sure

9 Does your hospital or affiliated primary care providers use the chronic care management (CCM) billing codes for stroke patients? (The CCM code is CPT code 99490, covering non-encounter care provided to patients with two or more chronic conditions)

◯ Yes ◯ No ◯ Not Sure

10 Does the hospital measure patient outcomes by telephone for stroke patients after discharge (e.g., medication adherence, function and disability, etc.)?

- ◯ No outcome assessment by telephone
- ◯ Yes, calls made 30 days after discharge
- ◯ Yes, calls made 60 days after discharge
- ◯ Yes, calls made 90 days after discharge
- ◯ Yes, calls made 180 days after discharge
- ◯ Other

Describe other timing of calls

_____

10a Please indicate what outcomes are assessed. Select all that apply.

- ☐ Physical function/disability
- ☐ Cognitive function
- ☐ Mental health or depression
- ☐ Medication adherence
- ☐ Risk factor knowledge
- ☐ Caregiver strain
- ☐ Other

Specify other outcomes

_____

11 Does you hospital use metrics to assess the quality of care transitions?

◯ Yes ◯ No ◯ Do not know

11a List metrics used

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12 Does your hospital have any other programs or strategies not already described that specifically focus on reducing readmissions for stroke patients?

◯ Yes ◯ No ◯ Do not know

12a Describe programs or strategies

13 Does your hospital have any other transitional care management programs or efforts to improve care transitions and reduce readmissions for diagnoses other than stroke?

◯ Yes ◯ No ◯ Do not know

13a Describe these programs and patient population targeted.

14 Please add anything else you would like to share about the transitional care services available at your hospital.

DESCRIPTIVE DATA

1 What was the 30-day all-cause readmission rate for stroke patients last calendar year (enter a %)? [If unknown, enter 99]

_____

2 What was the 90-day all-cause readmission rate for stroke patients last calendar year (enter a %)? [If unknown, enter 99]

_____

Appendix 3 - Eligibility Screening Form

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Participant Eligibility Screening Form

ID Number: ☐☐☐☐☐ Form Code: E L G ☐ Date: 10OCT2016 Version 1.2

ADMINISTRATIVE INFORMATION (0a-0d and 0f are auto-populated)

0a. Completion Date: ☐☐ / ☐☐ / ☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐☐☐

0c. NCSCC ID: ☐☐☐☐☐☐☐☐☐☐ 0d. Hospital ID: ☐☐☐☐

0e. Medical Record #: ☐☐☐☐☐☐☐☐☐☐ 0f. Form Status: ☐

ELIGIBILITY CRITERIA

1. Patient date of birth ☐☐ / ☐☐ / ☐☐☐☐ (Month / Day / Year)

2. What is the patient's primary language? ☐ English ☐ Spanish ☐ Other _____

3. Was the patient admitted for the sole purpose of elective carotid endarterectomy? ☐ Yes ☐ No

4. What is the final hospital diagnosis (see clinical algorithm for assistance)?

☐ Ischemic stroke
Stroke symptoms persisting >1 hour with at least 1 of the following: 1) MRI confirmation of infarct/ischemia; 2) receipt of tPA; or 3) high suspicion of cerebrovascular cause OR transient stroke symptoms with MRI confirmation of infarct/ischemia. Exclude suspected stroke mimics.
ICD-10 code examples: I63.0, I63.1, I63.2, I63.3, I63.4, 163.50, I63.6, I63.8, I63.9, 166.19, 166.29, 166.9, I67.89, H34.1 [retinal vascular occlusion], H34.23 [retinal artery branch occlusion]

☐ Non-traumatic intraparenchymal hemorrhage
Stroke symptoms with CT and/or MRI confirmation of IPH. ICD-10 code example: I61.0-I61.4, I61.8-I61.9

☐ Other non-aneurysmal intraventricular hemorrhage
Intraventricular blood suspected to have originated from brain (e.g. thalamus) and with no evidence of aneurysm.

☐ Ischemic stroke with hemorrhage
Hemorrhagic conversion noted within an ischemic stroke (would be coded similar to IS above)

☐ Stroke not otherwise specified
Stroke symptoms without MRI confirmation (e.g. patients who cannot receive MRI due to pacemaker) and stroke cannot be seen on CT scan.

☐ Transient ischemic attack (TIA) → **Go to Question 4a**
Transient episode of neurological dysfunction without infarction. Exclude diagnosis of TIA vs. complicated migraine, syncope, infection, reactivation of old stroke symptoms, medication reaction, delirium
ICD-10 code examples: all G45 except G45.3 [amaurosis fugax]

☐ Aneurysmal subarachnoid hemorrhage
Headache or stroke symptoms with CT and/or MRI confirmation of SAH and aneurysm. ICD-10 code example: 160.0-I61-9

☐ No stroke-related diagnosis

Eligibility Screening Form Page 1 of 2

4a. Was a brain MRI performed? ☐ Yes → **Go to Question 4b** ☐ No

4b. Did MRI show evidence of an acute infarct? ☐ Yes ☐ No

5. What is the patient's discharge disposition?

- ☐ Home with self-care
- ☐ Home with home health
- ☐ Hospice – home
- ☐ Hospice – health care facility
- ☐ Acute care facility
- ☐ Other health care facility → **Go to Question 5a**
- ☐ Expired
- ☐ Left against medical advice
- ☐ Jail, prison, or other detention facility
- ☐ Not documented or unable to determine

5a. If 'OTHER HEALTH CARE FACILITY, specify the type:

- ☐ Skilled nursing facility
- ☐ Inpatient rehabilitation
- ☐ Long-term care
- ☐ Intermediate care facility
- ☐ Other

END OF PARTICIPANT ELIGIBILITY SCREENING FORM

Appendix 4 - Enrollment Form

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Participant Enrollment Form

ID Number: ☐☐☐☐☐ Form Code: E N R ☐ Date: 06JUN2016 Version 1.0

ADMINISTRATIVE INFORMATION (auto-populated)

0a. Completion Date: ☐☐ / ☐☐ / ☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐☐☐

0c. NCSCC ID: ☐☐☐☐☐☐☐☐☐☐ 0d. Hospital ID: ☐☐☐ 0f. Form Status: ☐

A. PATIENT CONTACT INFORMATION

1. Patient full name _____ (First) _____ (Middle) _____ (Last)

2. Telephone number(s)

a. Primary number: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

Best time to call: ☐ Weekday daytime ☐ Weekday evening ☐ Weekend ☐ Anytime

b. Alternate 1: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

Best time to call: ☐ Weekday daytime ☐ Weekday evening ☐ Weekend ☐ Anytime

c. Alternate 2: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

Best time to call: ☐ Weekday daytime ☐ Weekday evening ☐ Weekend ☐ Anytime

3. Email address _____

4. Home address _____ (Address line 1)

_____ (Address line 2)

_____ (City) (State) (Zip) (County)

B. CAREGIVER CONTACT INFORMATION

☐ Patient does not have a caregiver (i.e., a family member or friend who will help them with their recovery, for example, in preparing meals, shopping, getting or taking medications, scheduling or transporting to doctor appointments) → **Go to Question 12**

5. Caregiver full name _____ (First) _____ (Middle) _____ (Last)

6. Caregiver gender: ☐ Male ☐ Female

7. Telephone number(s)

a. Primary number: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

b. Alternate 1: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

8. Email address _____

9. Caregiver home address ☐ Same as patient address

_____
Address line 1

_____
Address line 2

_____
City State Zip

10. What is the caregiver's primary language?

☐ English
☐ Spanish
☐ Other _____

11. Caregiver relationship to the patient?

☐ Spouse (husband or wife)
☐ Sibling
☐ Son or daughter
☐ Friend or neighbor
☐ Parent or legal guardian
☐ Other, specify: _____

C. ADDITIONAL CONTACT INFORMATION

☐ Patient unable or unwilling to provide an additional contact / not documented → **Go to Question 16**

12. Full name

First _____ Middle _____ Last _____

13. Telephone numbers

a. Primary number: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

b. Alternate 1: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

14. Email address: _____

15. Relationship to patient?

- ☐ Spouse (husband or wife)
- ☐ Sibling
- ☐ Son or daughter
- ☐ Friend or neighbor
- ☐ Parent or legal guardian
- ☐ Other, specify: _____

D. DEMOGRAPHIC AND IN-HOSPITAL DATA

16. Patient gender: ☐ Male ☐ Female

17. Patient race (*check all that apply*):

- ☐ White
- ☐ Black / African American
- ☐ Asian
- ☐ American Indian / Alaska Native
- ☐ Native HI / Other Pacific Islander
- ☐ Unknown
- ☐ Other: _____

18. Hispanic ethnicity: ☐ Yes ☐ No

19. Insurance *(check all that apply)*:

- ☐ Medicare (traditional fee-for-service)
- ☐ Medicare Advantage
- ☐ Medicare Supplemental Insurance / Medigap
- ☐ Medicaid
- ☐ Private insurance
- ☐ VA / Champus / other
- ☐ Uninsured / self-pay

20. Does the patient have documented past medical history of the following *(check all that apply)*:

- ☐ Stroke
- ☐ Transient ischemic attack
- ☐ Atrial Fibrillation or Flutter
- ☐ Myocardial infarction or CAD
- ☐ Congestive heart failure
- ☐ Carotid stenosis
- ☐ Peripheral arterial disease
- ☐ Hypertension
- ☐ Dyslipidemia
- ☐ Smoking
- ☐ Depression
- ☐ Drug/alcohol abuse
- ☐ Family history of stroke
- ☐ Migraines
- ☐ Chronic renal insufficiency
- ☐ Heart Valve
- ☐ Current pregnancy or within 6 weeks post-partum
- ☐ Hormone replacement therapy
- ☐ Sickle cell
- ☐ Sleep apnea
- ☐ Diabetes mellitus

21. Please enter the body mass index (BMI). _____ kg/m^2 ☐ Not documented

22. What was the patient's ambulatory status <u>prior to admission</u>?

- ☐ Able to ambulate independently (with or without a device)
- ☐ With assistance (from person)
- ☐ Unable to ambulate
- ☐ Not documented

23. NIH Stroke Scale Score (00-42) ☐ Not documented

_____

24. Has this patient been admitted within the past 90 days for a TIA or stroke?

- ☐ Yes → **Fill in date and ICD code below**

Date of Admission: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

Discharge ICD code: _____

- ☐ No
- ☐ Not documented

25. Did the initial exam show aphasia? ☐ Yes ☐ No / not documented

26. Hospital admission date for this event: ☐☐ / ☐☐ / ☐☐☐☐

☐ No admission date; patient was not admitted as an inpatient (select reason below)

- ☐ Discharged directly from ED to home
- ☐ Discharged from observation status without inpatient admission
- ☐ Other reason

27. Was the patient referred for rehabilitation services after discharge? ☐ Yes → **Go to 27a** ☐ No → **Go to 27b**

27a. If YES, check all that apply:

- ☐ Home health Physical Therapy
- ☐ Home health Occupational Therapy
- ☐ Home health Speech Therapy
- ☐ Outpatient Physical Therapy
- ☐ Outpatient Occupational Therapy
- ☐ Outpatient Speech Therapy

27b. If NO, indicate why not

- ☐ Patient not evaluated for need of rehab services
- ☐ Patient not in need of rehab services
- ☐ Patient / family refused
- ☐ Other reason

28. What was the patient's ambulatory status <u>at discharge</u>?

- ☐ Able to ambulate independently (with or without a device)
- ☐ With assistance (from person)
- ☐ Unable to ambulate
- ☐ Not documented

29. Modified Rankin Score at discharge (0-6) _____ ☐ Not performed / not documented

30. Hospital discharge date: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

31. Was a follow-up clinic visit with a nurse, nurse practitioner, or physician assistant (i.e. primary care, transitional care clinic, neurologist, or other doctor visit) scheduled prior to discharge?

- ☐ Yes → **Fill in date below**
- ☐ No

If YES, enter visit date: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

32. Name of patient's primary care provider: _____ ☐ Not known

33. Phone number of patient's primary care provider:

(☐☐☐) ☐☐☐ - ☐☐☐☐ ☐ Not known

34. Did the PAC notify the patient of the COMPASS study and distribute the brochure?

- ☐ Yes, discussed in person and distributed brochure → **Fill in date below**
- ☐ Yes, discussed over the phone and mailed brochure to patient → **Fill in date below**
- ☐ No

If YES, enter date of notification or mailing: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

END OF PARTICIPANT ENROLLMENT FORM

Appendix 5 - Control-Arm Patient Handout –COMPASS Study

Your recent hospital visit means that you are eligible for the COMPASS Study. Will you help us?

Your hospital is participating in a statewide study called the Comprehensive Post-Acute Stroke Services (COMPASS) Study. This study includes people who have had a stroke or transient ischemic attack (TIA), sometimes referred to as a mini-stroke. The purpose of the COMPASS Study is to determine the best ways to care for patients after they go home – to help survivors find their way forward to recovery.

In the COMPASS Study, North Carolina hospitals have been randomly assigned into two groups (similar to flipping a coin). One group of hospitals is providing patients with their usual standard of care after the patient goes home. The other group of hospitals is providing their usual care with the addition of an evaluation by a nurse practitioner, physician assistant or doctor within two weeks of hospital discharge, during which patients will receive a plan of care that will be shared with their other doctors, therapists and nurses.

Our hospital is providing the usual standard of post-acute care which includes:

- A hospital discharge summary that will go to the doctor that cares for you
- A discharge plan of care provided to you
- [insert other post-acute stroke transitional care services provided by the hospital]

We are committed to finding the best way to improve health and recovery after experiencing this health episode. The COMPASS study will not interfere with the usual standard of care at our hospital or your usual and planned follow up visits with your primary care doctors.

After you have left the hospital, the COMPASS team would like to learn about your overall experience. They will:

- Call you in 3 months to ask questions about your recovery and satisfaction with your care.
- Mail you 3 reminder letters before you are called. The last letter will include a small gift to thank you for your time, so be sure to open it.
- Mail a survey to the family member, friend, or neighbor whom you identify as helping you in your recovery *(care helper)*.

Whether or not you choose to participate in the survey, our hospital is committed to providing you with high-quality care for you during your recovery. All information you and your *care helper* provide will be kept strictly confidential and secure.

If you have any questions about the COMPASS Study, or prefer not to participate, feel free to ask the stroke coordinator, or you can call the COMPASS Study team using the toll-free number below.

Hospital Stroke Coordinator: [insert stroke coordinators name and phone number]
COMPASS toll-free number: 1-844-501-7668
COMPASS Study website: www.nccompass-study.org

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Appendix 6 - Letter to the Patient at 30 Days and Magnet

Dear <NAME>, <DATE>

Greetings from the COMPASS Study! We are contacting you on behalf of <HOSPITAL>, which is participating in our study. You may remember your nurse gave you a brochure about our study purpose while in the hospital. As a reminder, our goal is to improve healthcare and the lives of North Carolinians who had a transient ischemic attack (TIA), mini-stroke, stroke, or related episode.

What to expect:

In a couple months you will receive a call from a team member at the Carolina Survey Research Lab to ask you to take part in a phone survey. During this call, we would like to talk with you about how you have been doing since your hospital visit. The survey is brief, and is completely voluntary and confidential. **Your participation will be very valuable in helping other patients and their families find their way forward to recovery.**

How you can participate:

[-] Your call is tentatively scheduled for the week of **<DATE >**

[-] We will call you at **<PHONE #>**

[-] We have enclosed a COMPASS Study refrigerator magnet and will send a gift to you in a future letter so be sure to open it!

If the phone number above is incorrect or if you would like to opt-out of this call and future letters, please contact us as soon as you can at the toll-free number: 1-844-501-7668.

Find out more about the COMPASS Study:

[-] To learn more about the COMPASS Study please visit our website: www.nccompass-study.org

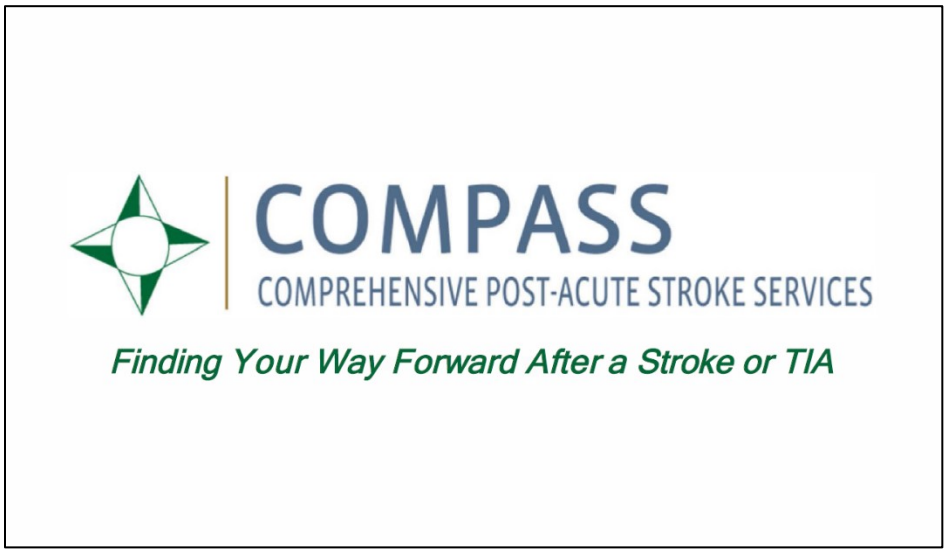
[-] If you would like to speak with a team member about the study, call us at: 1-844-501-7668

Thank you very much for your time and we look forward to speaking with you soon!

Best regards,

The COMPASS Study Team

P.S Don't forget to mark your calendar. Your response matters!


COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES
Finding Your Way Forward After a Stroke or TIA

Appendix 7 - Letter to the Patient at 60 Days

Dear <NAME>, <DATE>

Greetings from the COMPASS Study team! This is another reminder that you will be receiving a call from a team member at the UNC Carolina Survey Research Lab. They will ask you to take part in a phone survey. The survey is brief, completely voluntary and confidential. **Your participation will be very valuable in helping other North Carolinians and their families.**

How you can participate:

[-] Your call is tentatively scheduled for the week of <DATE>

[-] We will call you at <PHONE #>

[-] We will send you one more reminder letter a week before the call. That letter will include a copy of the survey questions and our thank you gift – so be sure to open it!

Please contact us at the toll-free number 1-844-501-7668 if any of the information above is incorrect or you would like to opt out of the phone call and future letters.

We encourage you to explore resources provided by the American Heart/ American Stroke Associations. The free *Stroke Family Warmline* connects you to other individuals and their families who have had experiences similar to yours (1-888-4-STROKE). The *Stroke Connection Magazine* is also an excellent resource. You can read a digital copy and subscribe by visiting: http://strokeconnection.strokeassociaton.org

Find out more about the COMPASS Study:

[-] To learn more about the COMPASS Study and to find other useful information about care after stroke or mini-stroke, please visit our website: www.nccompass-study.org

[-] If you would like to speak with a team member about the study, call us at: 1-844-501-7668

Best regards,

The COMPASS Study Team

Appendix 8 - Letter to the Patient at 80 Days

Dear <NAME>, <DATE>

Greetings from the COMPASS Study team! As you know, we are working to determine the best ways to care for individuals after they go home from the hospital. <HOSPITAL NAME> and your doctor have identified you as a participant in this study.

A team member at the UNC Carolina Survey Research Lab is planning to call. We want to hear how you've been doing since your hospital visit a few months ago. Attached is a copy of the survey questions if you would like to review them before the call. **We appreciate your help in improving healthcare in North Carolina!**

How you can participate:

[-] We have enclosed $10 to say THANK YOU in advance!

[-] Your call is scheduled for the week of <DATE >

[-] We will call you at <PHONE #>

[-] Our records show your preferred call window is: <BEST TIME TO CALL>

Please contact us as soon as you can at the toll-free number 1-844-501-7668 if any of the information above has changed.

At the beginning of the call, you will be asked if you wish to participate. Participation is completely voluntary and confidential and any information you provide will be held securely. We hope that you will provide your input.

Find out more about the COMPASS Study:

[-] To learn more about the COMPASS Study please visit our website: www.nccompass-study.org

[-] If you would like to speak with a team member about the study, call us at: 1-844-501-7668

We look forward to speaking with you soon!

Best regards,

The COMPASS Study Team

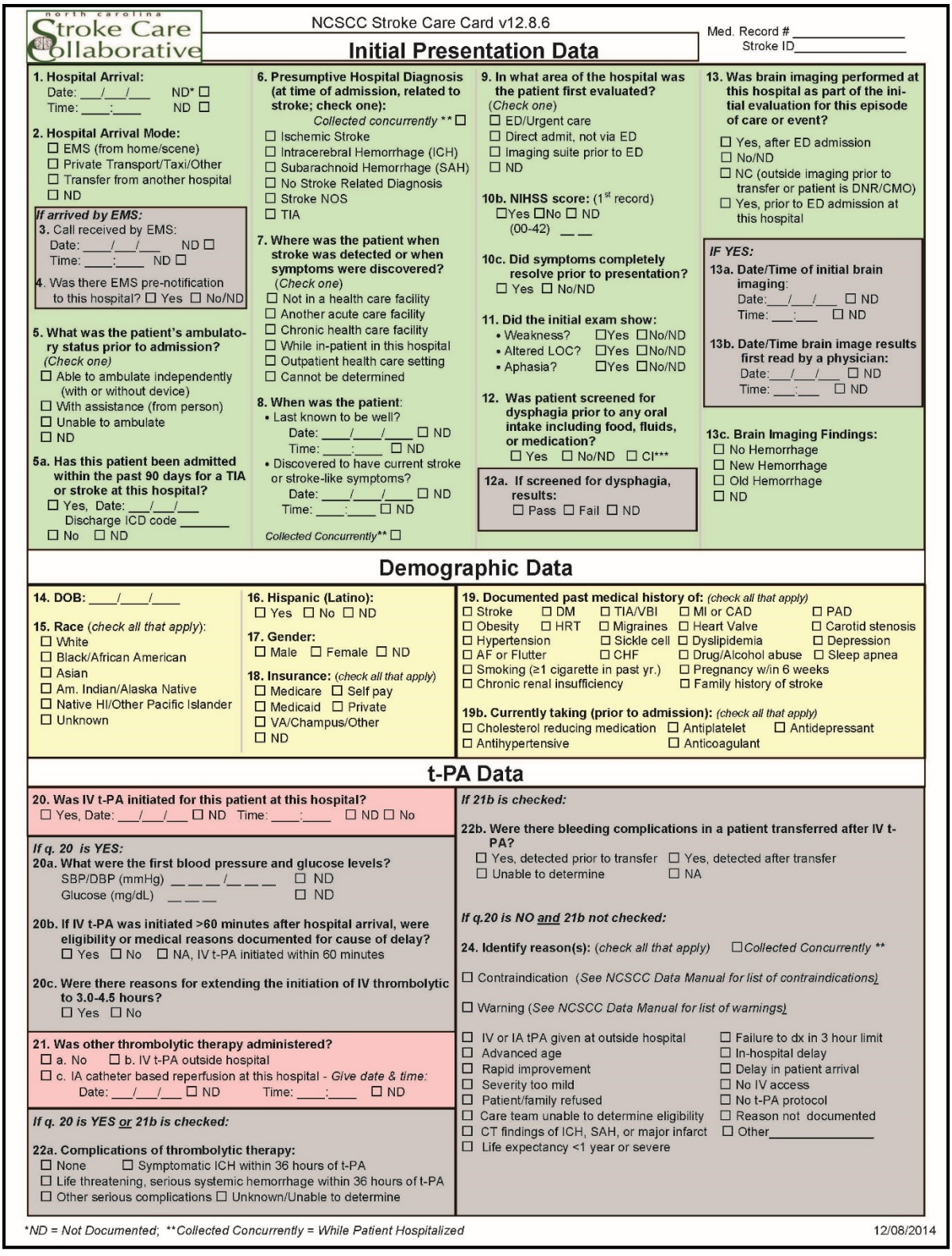
[pg 2]

HIPAA Authorization Note: The COMPASS Study team has worked with your hospital and doctor to identify you as a potential participant for this research study. The Carolina Survey Research Lab (CSRL) will ask for your consent to participate when they call you next week. We do hope that you will agree to participate in the survey but this is voluntary and optional. Any responses you provide will be held confidential and securely.

By agreeing to participate in the phone survey, you will be giving permission to CSRL to use or disclose your identifiable health information for the COMPASS research study. The health information that we may use or disclose for this research includes information from your recent hospital visit, visits to your doctor, medications, and other information about your insurance claims. The health information listed above may be used by and/or disclosed to the study investigators at this site and others, study management centers, the study sponsor, and other groups, including federal agencies, which have a responsibility to assist in the oversight and management of the research study.

Please note that <HOSPITAL NAME> may not refuse to treat you if you do not provide consent for this Authorization and phone survey. Once you have agreed, you may change your mind and take back the Authorization at any time. Even if you take back this Authorization, the organization may still use information that was previously collected about you. To take back the Authorization, you must call 1-844-501-7668 or email thecompassstudy@gmail.com. Authorization does not have an expiration date.

Appendix 9 - NCSCC Stroke Care Card



north carolina Stroke Care Collaborative

NCSCC Stroke Care Card v12.8.6

Med. Record # _____
Stroke ID_____

Initial Presentation Data

1. Hospital Arrival:
Date: ___/___/___ ND* ☐
Time: ____:____ ND ☐

2. Hospital Arrival Mode:
☐ EMS (from home/scene)
☐ Private Transport/Taxi/Other
☐ Transfer from another hospital
☐ ND

If arrived by EMS:
3. Call received by EMS:
Date: ____/____/____ ND ☐
Time: ____:____ ND ☐
4. Was there EMS pre-notification to this hospital? ☐ Yes ☐ No/ND

5. What was the patient's ambulatory status prior to admission?
(Check one)
☐ Able to ambulate independently (with or without device)
☐ With assistance (from person)
☐ Unable to ambulate
☐ ND

5a. Has this patient been admitted within the past 90 days for a TIA or stroke at this hospital?
☐ Yes, Date: ___/___/___
Discharge ICD code _____
☐ No ☐ ND

6. Presumptive Hospital Diagnosis (at time of admission, related to stroke; check one):
*Collected concurrently *** ☐
☐ Ischemic Stroke
☐ Intracerebral Hemorrhage (ICH)
☐ Subarachnoid Hemorrhage (SAH)
☐ No Stroke Related Diagnosis
☐ Stroke NOS
☐ TIA

7. Where was the patient when stroke was detected or when symptoms were discovered?
(Check one)
☐ Not in a health care facility
☐ Another acute care facility
☐ Chronic health care facility
☐ While in-patient in this hospital
☐ Outpatient health care setting
☐ Cannot be determined

8. When was the patient:
• Last known to be well?
Date: ____/____/____ ☐ ND
Time: ____:____ ☐ ND
• Discovered to have current stroke or stroke-like symptoms?
Date: ____/____/____ ☐ ND
Time: ____:____ ☐ ND

*Collected Concurrently*** ☐

9. In what area of the hospital was the patient first evaluated?
(Check one)
☐ ED/Urgent care
☐ Direct admit, not via ED
☐ Imaging suite prior to ED
☐ ND

10b. NIHSS score: (1st record)
☐Yes ☐No ☐ ND
(00-42) __ __

10c. Did symptoms completely resolve prior to presentation?
☐ Yes ☐ No/ND

11. Did the initial exam show:
• Weakness? ☐Yes ☐No/ND
• Altered LOC? ☐Yes ☐No/ND
• Aphasia? ☐Yes ☐No/ND

12. Was patient screened for dysphagia prior to any oral intake including food, fluids, or medication?
☐ Yes ☐ No/ND ☐ CI***

12a. If screened for dysphagia, results:
☐ Pass ☐ Fail ☐ ND

13. Was brain imaging performed at this hospital as part of the initial evaluation for this episode of care or event?
☐ Yes, after ED admission
☐ No/ND
☐ NC (outside imaging prior to transfer or patient is DNR/CMO)
☐ Yes, prior to ED admission at this hospital

IF YES:
13a. Date/Time of initial brain imaging:
Date:___/___/___ ☐ ND
Time: ___:___ ☐ ND

13b. Date/Time brain image results first read by a physician:
Date:___/___/___ ☐ ND
Time: ___:___ ☐ ND

13c. Brain Imaging Findings:
☐ No Hemorrhage
☐ New Hemorrhage
☐ Old Hemorrhage
☐ ND

Demographic Data

14. DOB: ____/____/____

15. Race *(check all that apply)*:
☐ White
☐ Black/African American
☐ Asian
☐ Am. Indian/Alaska Native
☐ Native HI/Other Pacific Islander
☐ Unknown

16. Hispanic (Latino):
☐ Yes ☐ No ☐ ND

17. Gender:
☐ Male ☐ Female ☐ ND

18. Insurance: *(check all that apply)*
☐ Medicare ☐ Self pay
☐ Medicaid ☐ Private
☐ VA/Champus/Other
☐ ND

19. Documented past medical history of: *(check all that apply)*
☐ Stroke ☐ DM ☐ TIA/VBI ☐ MI or CAD ☐ PAD
☐ Obesity ☐ HRT ☐ Migraines ☐ Heart Valve ☐ Carotid stenosis
☐ Hypertension ☐ Sickle cell ☐ Dyslipidemia ☐ Depression
☐ AF or Flutter ☐ CHF ☐ Drug/Alcohol abuse ☐ Sleep apnea
☐ Smoking (≥1 cigarette in past yr.) ☐ Pregnancy w/in 6 weeks
☐ Chronic renal insufficiency ☐ Family history of stroke

19b. Currently taking (prior to admission): *(check all that apply)*
☐ Cholesterol reducing medication ☐ Antiplatelet ☐ Antidepressant
☐ Antihypertensive ☐ Anticoagulant

t-PA Data

20. Was IV t-PA initiated for this patient at this hospital?
☐ Yes, Date: ___/___/___ ☐ ND Time: ____:____ ☐ ND ☐ No

If q. 20 is YES:
20a. What were the first blood pressure and glucose levels?
SBP/DBP (mmHg) __ __ __/__ __ __ ☐ ND
Glucose (mg/dL) __ __ __ ☐ ND

20b. If IV t-PA was initiated >60 minutes after hospital arrival, were eligibility or medical reasons documented for cause of delay?
☐ Yes ☐ No ☐ NA, IV t-PA initiated within 60 minutes

20c. Were there reasons for extending the initiation of IV thrombolytic to 3.0-4.5 hours?
☐ Yes ☐ No

21. Was other thrombolytic therapy administered?
☐ a. No ☐ b. IV t-PA outside hospital
☐ c. IA catheter based reperfusion at this hospital - *Give date & time:*
Date: ___/___/___ ☐ ND Time: ____:____ ☐ ND

If q. 20 is YES or 21b is checked:

22a. Complications of thrombolytic therapy:
☐ None ☐ Symptomatic ICH within 36 hours of t-PA
☐ Life threatening, serious systemic hemorrhage within 36 hours of t-PA
☐ Other serious complications ☐ Unknown/Unable to determine

If 21b is checked:

22b. Were there bleeding complications in a patient transferred after IV t-PA?
☐ Yes, detected prior to transfer ☐ Yes, detected after transfer
☐ Unable to determine ☐ NA

If q.20 is NO and 21b not checked:

24. Identify reason(s): *(check all that apply)* ☐*Collected Concurrently ***

☐ Contraindication *(See NCSCC Data Manual for list of contraindications)*

☐ Warning *(See NCSCC Data Manual for list of warnings)*

☐ IV or IA tPA given at outside hospital
☐ Advanced age
☐ Rapid improvement
☐ Severity too mild
☐ Patient/family refused
☐ Care team unable to determine eligibility
☐ CT findings of ICH, SAH, or major infarct
☐ Life expectancy <1 year or severe
☐ Failure to dx in 3 hour limit
☐ In-hospital delay
☐ Delay in patient arrival
☐ No IV access
☐ No t-PA protocol
☐ Reason not documented
☐ Other_____

**ND = Not Documented; **Collected Concurrently = While Patient Hospitalized*

12/08/2014

In-Hospital Data

25. Was the patient:
- ☐ Admitted only for carotid endarterectomy? → **STOP, patient ineligible**
- ☐ Part of stroke clinical trial? → **STOP, patient ineligible**

Hospital Admission:
- ☐ **Admission date:** ____/____/____
- ☐ **Not admitted (Select reason below)** → **SKIP to Q49**
  - ☐ Discharged home or to other non-acute care location
  - ☐ Transferred to another acute care hospital
  - ☐ Died in ED
  - ☐ Left ED against medical advice
  - ☐ Discharged from observation status without admission
  - ☐ Other reason

26. Where was this patient cared for and by whom?

In stroke unit	☐ Yes ☐ No/ND	Neurology admit	☐ Yes ☐ No/ND
Stroke consult	☐ Yes ☐ No/ND	Other service admit	☐ Yes ☐ No/ND

27. Was patient NPO throughout the entire hospital stay?
☐ Yes ☐ No/ND*

29a. Did patient die on the day of arrival or the 1st day after arrival?
☐ No ☐ Yes → **Skip to Q49**

30. Was patient restricted to comfort measures only by physician, APN, or PA?
- ☐ Yes, day of arrival or 1st day after arrival → **Skip to Q33 (Omit Q34-41 & 46-47)**
- ☐ Yes, 2nd day after arrival or later
- ☐ Yes, timing unclear → **Proceed to Q31, (Omit Q34-41 & 46-47)**
- ☐ No ☐ ND

31. Was VTE prophylaxis administered (check all types that apply)?

☐ Low dose unfract. heparin (LDUH)	☐ Low molec. weight heparin (LMWH)
☐ Factor Xa Inhibitor	☐ Warfarin
☐ Venous foot pumps	☐ Intermittent pneumatic
☐ Oral factor Xa Inhibitor	☐ Graduated compression stockings
☐ Aspirin	☐ **No**, none of the above, or ND

Date of initial administration: ____/___/___ ☐ Date ND

IF 'Oral factor Xa Inhibitor' is checked: Is there a documented reason for using Oral Factor Xa Inhibitor for VTE? ☐ Yes ☐ No

IF 'No, none of the above, or ND' is checked: Is there a documented reason why VTE prophylaxis was not given? ☐ Yes ☐ No/ND

32. Was antithrombotic therapy received by the end of day after ARRIVAL?
☐ Yes ☐ No/ND ☐ CI

33a. Did patient die on the 2nd day after arrival or later?
☐ No ☐ Yes → **Skip to Q49**

34. Was the patient or caregiver provided smoking cessation counseling?
☐ Yes ☐ No/ND ☐ N/A ☐ CI

35. Was patient prescribed antihypertensive medication at discharge?
☐ Yes ☐ No/ND ☐ CI

36. Was antithrombotic medication prescribed at discharge?
☐ Yes ☐ No/ND ☐ CI ☐ *Collected Concurrently***

IF YES:
36a. Which antithrombotic(s) were prescribed? (Check all that apply)
☐ Antiplatelet ☐ Anticoagulant

37. Lipid profile: *Units:* ☐ mg/dl ☐mmol/liter
HDL __ __ __ .__ __ ☐ ND Triglycerides __ __ __ __.__ __ ☐ ND
LDL __ __ __.__ __ ☐ ND HgB A1c __ __. __% ☐ ND
Total __ __ __.__ __ ☐ ND

38a. Were statins prescribed at discharge? ☐ Yes ☐ No/ND

IF NO/ND:
38b. Is there a documented reason why statins were not prescribed?
☐ Yes ☐ No/ND

IF YES: Statin Medication Name & Dose
38e. Statin medication: _____ **Dose:** _____ **mg /day**

39a. Was the patient prescribed antidepressant medication at discharge?
☐ Yes ☐ No/ND

40. Was atrial fibrillation/flutter (AF) or paroxysmal AF documented during this episode of care?
☐ Yes ☐ No/ND

(IF Q19 or Q40 YES)
41. If history of AF or PAF or dx this admission, was anticoagulation med. prescribed upon discharge (e.g. Warfarin, unfractionated heparin IV, LMW heparin)? ☐ Yes ☐ No/ND ☐ CI

42. Was patient treated for a UTI during this admission?
☐ Yes ☐ No/ND

IF YES:
43. Did patient have a foley catheter during this admission?
☐ Yes, in place on arrival ☐ No
☐ Yes, after admission ☐ Unable to determine

44. Did patient experience a DVT or PE during this admission?
☐ Yes ☐ No/ND

45. Was patient treated for hospital-acquired pneumonia during this admission?
☐ Yes ☐ No/ ND ☐ CI

Discharge Data

46. Did the patient and/or caregiver receive stroke education and/or resource materials? *(check all that apply)*

Personal modifiable risk factors	☐ Yes ☐ No/ND
Stroke warning signs and symptoms	☐ Yes ☐ No/ND
How to activate EMS for stroke	☐ Yes ☐ No/ND
Follow-up after discharge	☐ Yes ☐ No/ND
Medications prescribed	☐ Yes ☐ No/ND

47. Was the patient assessed for or received rehabilitation services?
☐ Yes ☐ No/ND

If YES, Check all that apply:
- ☐ Received rehab services during hospitalization
- ☐ Transferred to rehab facility
- ☐ Ineligible to receive rehab services
- ☐ Referred to rehab services after discharge
- ☐ Patient/family refused rehab services

48. What was the patient's ambulatory status at discharge? *(check one)*
- ☐ Able to ambulate independently (with or without device)
- ☐ With assistance (from person)
- ☐ Unable to ambulate
- ☐ ND

48b. Modified Rankin Score at discharge: _____ (0-6)
☐ Not performed / ND

49. Date of Discharge/Death:
_____/_____/_____

50. Final Hospital Diagnosis *(check only one)* **:**
- ☐ Ischemic Stroke
- ☐ Intracerebral Hemorrhage (ICH)
- ☐ Subarachnoid Hemorrhage (SAH)
- ☐ No stroke related diagnosis
- ☐ Stroke NOS
- ☐ TIA

51. Was a stroke order set used for this admission?
☐ ED only ☐ Both ED and In-patient
☐ In-patient only ☐ None

52. Discharge disposition: *(check one)*
- ☐ Home, self-care
- ☐ Home with home health care
- ☐ Hospice - Home
- ☐ Hospice - Health care facility
- ☐ Acute care facility
- ☐ Other health care facility (*please specify*)
  - ☐ SNF
  - ☐ Inpatient rehabilitation
  - ☐ Long-term care
  - ☐ Intermediate care facility
  - ☐ Other
- ☐ Expired
- ☐ Left against medical advice/AMA
- ☐ ND / unable to determine

ICD-9 / ICD-10 Data

54. ICD-9 discharge dx	ICD-10 discharge dx
___ ___ ___ . ___ ___	___ ___ ___ . ___ ___ ___ ___

*ND = Not Documented; **Collected Concurrently = While Patient Hospitalized; ***CI = Documented Contraindication 11/12/2014

Appendix 10 - Screener and Consent (At 90 Days)

CONSENT LANGUAGE PULLED OUT OF THE SCREENER

PURPOSE:

We are calling to follow up on his/her/your recent hospital stay at [HOSPITAL]. This hospital is participating in the COMPASS study which is a research study looking at how patients are doing after their stroke.

EXPLAIN [IF IRB_MON=1]:

[….] During this survey, you have the right to refuse to answer any questions you don't want to answer and you can stop participating at any time. [….]

SECURITY:

We wanted to also let you know that by participating you are giving us permission to keep a record of your responses to the survey. All of your responses and data will be strictly confidential and will be kept in a secure location.

RISKBENEFIT:

We do not anticipate that participation in this survey involves any risks. There is also no direct benefit to you for participating.

PARTICIPATE/CONSENT:

Do I have your permission to continue with the survey?

THANK YOU:

Thank you for agreeing to participate in the COMPASS Study.

IF IRB_OFFER NUM:

If you have any additional questions about the study, I can provide the numbers of the Wake Forest and UNC Chapel Hill Institutional Review Boards. Their job is to protect your rights and welfare as a research participant. They have reviewed and approved this study. Would you like those numbers?

The survey also has a link to the COMPASS website.

IRB_PI NUMBER [IF [IF IRB_OFFER NUM=1]:

If you have any questions, comments or concerns about the study, please contact, anonymously if you wish, the Wake Forest IRB at 336-716-4542 or the UNC Chapel Hill Institution Review Board. You can reach them at 919-966-3113 or by email to IRB_subjects@unc.edu. This information is also at the bottom of the survey that was mailed to you.

Information about how to reach the COMPASS project manager, the UNC Institutional Review Board, as well as the link to the COMPASS website, are at the bottom of the survey that was mailed to you.

Screener

LABEL	VALUE	TEXT	INSTRUCTIONS
DID ANSWER	**0-1** **0=NO** **1=YES**	INTERVIEWER: DIAL ###-###-####. DID A PERSON ANSWER? IF NO, HANG UP AFTER 12 RINGS.	
UNKNOWN HELLO [IF DID ANSWER=1]	**1=PERSON NAMED ON PHONE OR COMING TO PHONE (GO TO SEL_HELLO)** **2= PERSON NAMED NOT AVAILABLE (GO TO SCHEDULE_CB1)** **3= PERSON NAMED ON PHONE IS IN THE HOSPITAL, INPATIENT REHAB OR A NURSING HOME(GO TO IN_FACILITY)** **4= PATIENT UNABLE TO TALK ON PHONE DUE TO THEIR STROKE (GO TO MED_SPECIFY)** **5= PERSON NAMED ON PHONE IS DECEASED (GO TO DECEASED)** **6= PERSON NAMED NO LONGER AT THIS NUMBER, BUT NOT IN A FACILITY (GO TO ASK_NEW#)** **7=NO ONE BY THAT NAME KNOWN (GO TO MISMATCH)** **99=HANG UP OR PERSON NAMED REFUSES TO COME TO PHONE**	Hello, my name is [FULL NAME] and I'm calling on behalf of [HOSPITAL NAME] and the COMPASS STUDY. May I please speak with [FIRST NAME LAST NAME]?	PRELOAD NAME
ASK_NEW#	**0=NO, GK WILL NOT PROVIDE NUMBER (GO TO END INTERVIEW AND CODE REV1** **1=YES, GK WILL PROVIDE NUMBER (GO TO GET_NEW#)**	Does [Mr/Ms LAST NAME] have a new personal or residential number where I could reach [him/her] regarding this study? IN: IF GK SAYS R IS DECEASED, IN A	

		FACILITY OR MEDICALLY INCAPABLE, GO BACK TO UNKNOWN_HELLO AND CHOOSE APPROPRIATE RESPONSE. IF NEEDED: For the purposes of this study, we are not able to speak with those in nursing homes or other facilities, but we might be able to speak with a family member or friend.	
GET_NEW#	**ENTER NUMBER**	Thank you. What is that number?	
GET_ALT#	**ENTER NUMBER (GO TO END_INTERVIEW, THEN APPOINTMENT TAB)**	Is there another number in case we don't reach [him/her] at that number? IN: IF NO OTHER NUMBER, LEAVE EMPTY AND HIT ENTER TO CONTINUE	
SCHEDULE_CB1	**1=PREFERRED CB TIME PROVIDED (GO TO THANK_CB)** **2= PERSON NAMED ON PHONE IS IN THE HOSPITAL, INPATIENT REHAB OR A NURSING HOME (GO TO IN_FACILITY)** **3= PATIENT UNABLE TO TALK ON PHONE DUE TO THEIR STROKE (GO TO MED_SPECIFY)** **4= PERSON NAMED ON PHONE IS DECEASED (GO TO DECEASED)** **9=REFUSE (GO TO RESP_REF)**	I am calling in regard to a phone survey we would like you/[MR/MS LAST NAME] to complete. You/she/he should have received some letters about this survey. When would be a good time to call back? IN: IF R IS NO LONGER AT THIS NUMBER BUT NOT IN A FACILITY, GO BACK TO UNKNOWN_HELLO AND CHOOSE #6	
IN_FACILITY	**0=NO (GO TO FACILITY_SPECIFY)** **1=YES (GO TO SCHEDULE_CB2)** **8=DON'T KNOW (GO TO SCHEDULE_CB2)**	Do you think s/he will be available and able to do a phone survey before [EXPIRATION DATE MINUS 2DAYS?] IF 'DON'T KNOW':	PRELOAD EXPIRATION DATE

	9=REFUSE (GO TO FACILITY_SPECIFY)	OK, I'll plan to try to call back before then to see if they are available.	
FACILITY_SPECIFY	**1=the hospital (GO TO PROXY)** **2=an in-patient rehabilitation facility, or (GO TO PROXY)** **3=a nursing home? (GO TO PROXY)** **4=OTHER (GO TO SPEC_OTHER)**	Could you please tell me, is s/he currently in . . . IN: IF GK HAS ALREADY SPECIFIED FACILITY, CONFIRM INFORMATION HERE	
SPEC_OTHER	**OPEN TEXT (250 CHARACTERS)**	SPECIFY OTHER	
MED_SPECIFY	**1=DIFFICULTY TALKING** **2=DIFFICULTY UNDERSTANDING** **3=TOO SICK** **4=OTHER (GO TO OTHER_MED)** **8=DON'T KNOW (GO TO PROXY)** **9=REFUSE (GO TO PROXY)**	For our records, would you mind telling me: Is [Mr./Ms. LAST NAME] unable to do the survey because [he/she] has difficulty talking, difficulty understanding, is too sick or is there some other reason [he/she] is unable to do the survey? IN: IF GK INFORMS YOU THAT R IS IN A FACILITY, GO BACK TO UNKNOWN_HELLO AND CODE APPROPRIATELY BEFORE CONTINUING	ALL GO TO PROXY
OTHER_MED	**OPEN TEXT** **50 CHARACTERS**	What other reason is that?	
PROXY	**1= YES, WILLING PROXY ON PHONE (GO TO RCV_INFO, THEN PROXY NAME, THEN PROXY_REL, THEN EXPLAIN)** **2= YES, WILLING PROXY COMING TO PHONE (GO TO SELECTED_HELLO, RCV INFO, PROXY NAME, PROXY REL)** **3= YES, PROXY IS UNAVAILABLE (GO TO PROXY NAME, THEN SCHEDULE_CB2)** **4= NO, THERE IS NO PROXY (GO TO INEL)**	I'm sorry to hear that. I would like to complete the survey with someone else if possible. Does Mr/Ms [LAST NAME] have an adult relative or health care power of attorney who can be reached at this number and who has regular contact with him/her and knows about his/her health and could take the survey on his/her behalf?	IF UNK_HELLO=3,4 OR 5 OR SCHEDULE_CB1=2 ,3 OR 4AND IN_FACILITY=0 AND PROXY=0, GO TO INEL AND CODE PRE1 (IN FACILITY) IF UNK_HELLO=6 OR SCHEDULE_CB1=5 AND PROXY=0, GO TO INEL AND CODE MEDX

	5= PROXY REFUSAL (GO TO RESP_REF)		
SEL_HELLO [IF UNKNOWN HELLO=1]	**0-3** **0=NO** **1=YES (GO TO RCV_INFO AND/OR PROXY_NAME, THEN EXPLAIN)** **2=UNKNOWN UNAVAILABLE** **3=UNKNOWN REFUSAL (GO TO RESP_REF)**	IF PARTICIPANT OR PROXY **IS ALREADY ON THE PHONE**, ENTER "YES" IF PARTICIPANT **JUST CAME TO THE PHONE**, SAY: Hello, my name is [FULL NAME]. I'm calling on behalf of the COMPASS study. Am I speaking with [FILL IF PROXY=1 OR 2: an adult relative or health care power of attorney for] [FIRST NAME LAST NAME]?	IF PROXY=3 OR 4, GO TO RCV_INFO THEN PROXY NAME
RCV_INFO [IF SELECTED HELLO = 1]	**0-3** **1=CONTINUE (GO TO EXPLAIN)** **2=R UNAVAILABLE (GO TO SCHEDULE_CB2)** **3=R REFUSAL (GO TO RESP_REF)**	We are calling to follow up on his/her/your recent hospital stay at [HOSPITAL]. This hospital is participating in the COMPASS study which is a research study looking at how patients are doing after their stroke. We recently sent him/her/you a description of the study and some reminder letters about this call. . Today I'm calling to ask you some questions about how you are feeling and about your health in general. IF PROXY=2: We were informed earlier that Mr./Ms. [LAST NAME] would be unable to participate in a phone survey due to his/her health	PRELOAD GENDER

		but that you would be able to answer our questions on his/her behalf. INTERVIEWER: IF R CLAIMS HE IS UNAWARE OF THE STUDY, PROMPT BY DESCRIBING. IF STILL UNFAMILIAR, CODE FINAL REFUSAL. IN: THE LETTER IS NOT REQUIRED TO DO THE PHONE SURVEY	
PROXY_NAME	**OPEN TEXT** **(10 CHARACTERS)** **GO TO PROXY RELATION**	Could you please tell me your first name so that I can refer to you personally? IN: THIS IS A REQUIRED FIELD. IF PROXY IS UNWILLING TO PROVIDE A NAME, EXPLAIN THAT YOU NEED INITIALS OR A NICKNAME SO THAT IF YOU MUST CALL BACK YOU CAN BE SURE TO REACH THEM AND NOT SOME OTHER FRIEND OR FAMILY MEMBER.	PROGRAMMING: THIS IS A REQUIRED FIELD
PROXY_RELATION	1=Legal guardian? 2=Health care agent named under a health care power of attorney? 3=Spouse? 4=Adult son and/or daughter? 5=Parent? 6=Adult brother and/or sister? 7=Uncle and/or aunt? 8=Other adult relative (GO TO OTHER_REL)? 88=DON'T KNOW (GO TO 99=REFUSED (GO TO RESP REF	For our records, can you tell us your relationship to [R NAME]? IN: IF NOT ONE OF THESE RELATIONSHIPS, R MUST COMPLETE ELIGIBILITY AND CONSENT HIM/HERSELF BEFORE ALLOWING PROXY TO COMPLETE; GO BACK TO UNK_HELLO AND CHOOSE APPROPRIATE RESPONSE TO SPEAK TO R OR GO BACK TO PROXY AND CHOOSE #4, NO PROXY	
OTHER_REL	**OPEN TEXT** **50 CHARACTERS**	SPECIFY OTHER RELATIONSHIP	

PROXY_AGE	**1=YES (GO TO HOSP_INFO)**	And I need to confirm, are you at least 18 years old? IN: IF NO, GO BACK AND RE-ASK PROXY AND CODE APPROPRIATELY.	DON'T ALLOW REF OR DK
MISMATCH [IF UNKNOWN HELLO=8]	**0-2** **0=NO** **1=YES** **2=HANG UP BEFORE NUMBER VERIFICATION**	Let me just confirm that I dialed correctly. Did I reach you at ###-###-####?	
MISDIAL [IF MISMATCH=0]	**EMPTY**	I'm sorry. I must have misdialed. Thank you for your time.	REDIAL
DECEASED	**ENTER DATE (GO TO END INTERVIEW AND CODE DECX)** **DON'T KNOW(GO TO END INTERVIEW AND CODE DECX)** **REFUSE(GO TO END INTERVIEW AND CODE DECX)**	I'm very sorry to hear that. Would you mind telling me when s/he passed away so that I can record that information and we do not call again?..	END CALL AND CODE DECX
END INTERVIEW [IF ASK_NEW#=0 OR 1 OR MISMATCH=1]	**EMPTY**	Thank you for your time.	END CALL

HOSP_INFO **[IF IRB_CONF=1]**	**1=INFO ON RECORD IS CORRECT (GO TO EXPLAIN)** **2=HOSPITAL IS WRONG (GO TO NEW HOSP)** **3=DISCHARGE DATE IS WRONG (GO TO NEW DISCHARGE)** **4=R SAYS NOT HOSPITALIZED FOR STROKE (GO TO NEW ADMIT)** **8=DON'T KNOW (GO TO EXPLAIN)** **9=REFUSE (GO TO EXPLAIN)**	Our records show that he/she/you was/were hospitalized for a stroke or TIA at [HOSPITAL] and that he/she/you was/were sent home on [DschrgD]. Is that correct? IF NEEDED: TIA stands for transient ischemic attack and is sometimes referred to as a mini-stroke or warning stroke. IN: R MAY HAVE BEEN HOSPITALIZED ON OTHER DATES, BUT WE ARE NOT ASKING ABOUT THOSE. IT IS OKAY TO CONTINUE EVEN IF R DOES NOT REMEMBER HOSPITAL AND DATE INFORMATION.	PRELOAD HOSPITAL AND DISCHARGE DATE
NEW_HOSP	**OPEN TEXT**	What was the name of the hospital where you were hospitalized for your stroke?	
NEW DISCHARGE	**MM/DD/YYYY**	What was the date of your discharge?	
NEW ADMIT	**OPEN TEXT**	What were you hospitalized for?	
EXPLAIN **[IF IRB_MON=1]**	**1-3** **1=CONTINUE (GO TO HOSP_INFO)** **2=R UNAVAILABLE** **3=R REFUSAL (GO TO RESP_REF)**	Before I continue, I need to let you know that for quality control purposes, this call may be monitored by my supervisor. During this survey, you have the right to refuse to answer any questions you don't want to answer and you can stop participating at any time.	
INELIGIBLE		I'm sorry, but that means we won't be able to do the survey. Thank you very much for your time. I	

		appreciate your talking with me.	
ELIGIBLE	**1-3 1=CONTINUE (GO TO PURPOSE)**	INTERVIEWER: CASE IS NOW ELIGIBLE, ENTER 1 TO CONTINUE	
LENGTH	**1-3 1=CONTINUE (GO TO SECURITY) 2=R UNAVAILABLE 3=R REFUSAL (GO TO RESP_REF)**	The survey should take about 20 minutes to complete.	
SECURITY	**1-3 1=CONTINUE (GO TO RISKBENEFIT) 2=R UNAVAILABLE 3=R REFUSAL (GO TO RESP_REF)**	We wanted to also let you know that by participating you are giving us permission to keep a record of your responses to the survey. All of your responses and data will be strictly confidential and will be kept in a secure location.	
RISKBENEFIT	**1-3 1=CONTINUE (GO TO INCENTIVE) 2=R UNAVAILABLE 3=R REFUSAL (GO TO RESP_REF)**	We do not anticipate that participation in this research survey involves any risks. There is also no direct benefit to you for participating.	
IRB_OFFER NUM	**0-1 0=NO 1=YES (GO TO IRB_PI NUMBER)**	If you have any additional questions about the study, I can provide the numbers of the Wake Forest and UNC Chapel Hill Institutional Review Boards. Their job is to protect your rights and welfare as a research participant. They have reviewed and approved this study. Would you like those numbers? The survey also has a link to the COMPASS website.	
IRB_PI NUMBER [IF [IF IRB_OFFER NUM=1]	**EMPTY**	If you have any questions, comments or concerns about the study, please contact,	

		anonymously if you wish, the Wake Forest IRB at 336-716-4542or the UNC Chapel Hill Institutional Review Board. You can reach them at 919-966-3113 or by email to IRB_subjects@unc.edu. Information about how to reach the COMPASS project manager, the UNC Institutional Review Board, as well as the link to the COMPASS website, are at the bottom of the survey that was mailed to you.	
BEGIN SURVEY [IF IRB MON=1]	**1-3** **1=YES, CONTINUE** **2=YES, RESPONDENT UNAVAILABLE** **3=NO, RESPONDENT REFUSAL**	Do I have your permission to continue with the survey? INTERVIEWER: ANSWER ANY RESPONDENT QUESTIONS, AND THEN CONTINUE.	
THANK_YOU	**GO TO INTRO**	Thank you for agreeing to participate in the COMPASS study.	
WHO_DO	**1=PATIENT** **2=PROXY, WITH PATIENT CONSENT (GO TO NON-LAR NAME)** **3=PROXY AS LEGAL AUTHORIZED REPRESENTATIVE**	WHO IS COMPLETING THIS SURVEY? IN: A NON-LAR PROXY IS ALLOWED **ONLY** IF THE PATIENT CONSENTED HIM/HERSELF. PROXIES MUST BE AT LEAST 18 YEARS OLD.	
NON-LAR NAME	**OPEN TEXT** ENTER NON-LAR NAME	ONCE NON-LAR PROXY IS ON THE PHONE: Hello, my name is [FULL NAME] and I'm calling regarding the COMPASS Study, which is a research study looking at how patients are doing after their stroke.	

		Mr./Ms. [LAST NAME] has already given his/her consent to participate in the study but would like for you to answer the questions on his/her behalf. Could you please tell me your first name so that I can refer to you personally?	
NON-LAR AGE	1=YES (GO TO SURVEY INTRO)	Are you at least 18 years old? IN: IF NO, GO BACK TO BEGIN_SURVEY AND CODE APPROPRIATELY.	
SCHEDULE CB_2 []	**OPEN TEXT** **[200 CHAR]**	When would be a better time for me to speak with him/her/you?	SCHEDULE CALLBACK THEN END CALL
RESP REF	**OPEN TEXT** **[200 CHAR]**	To help us understand how to improve our study, may I ask why you don't want to participate?	END CALL
REF SPEC	**OPEN TEXT** **[200 CHAR]**	ENTER SPECIFICALLY WHAT WAS SAID ABOUT REASON FOR REFUSAL	ONLY COMES UP IF REFUSAL IS FINAL (2ND SOFT REFUSAL OR 1ST HARD REFUSAL)
THANK_CB		Thank you. We will try back another time.	
ANSWERING MACHINE MESSAGE [IF DID ANSWER=0 AND ANSWERING MACHINE PICKS UP]	**EMPTY**	Hello, my name is (FULL NAME) and I am calling from the University of North Carolina on behalf of [HOSPITAL NAME]. We are trying to get in touch with [PARTICIPANT FIRST AND LAST NAME]. We'll try you back again later or you may also call us, toll-free, at 1-866-862-4636 and leave a message letting us know the best time to call.	LEAVE A MESSAGE THE FIRST TIME AN ANSWERING MACHINE IS REACHED. WAIT UNTIL THE 4TH CALL ATTEMPT TO LEAVE A SECOND MESSAGE.

Appendix 11 – Sustain-Arm Patient Handout –COMPASS Study Brochure

Appendix 12 - Intervention-Arm Patient Handout –COMPASS Study Brochure

Your recent hospital visit means that you are eligible for the COMPASS Study. Will you help us?

Your hospital is participating in a statewide study called the Comprehensive Post-Acute Stroke Services (COMPASS) Study. This study includes people who have had a stroke or transient ischemic attack (TIA), sometimes referred to as a mini-stroke. The purpose of the COMPASS Study is to determine the best ways to care for patients after they go home – to help survivors find their way forward to recovery.

In the COMPASS Study, North Carolina hospitals have been randomly assigned into two groups (similar to flipping a coin). One group of hospitals is providing patients with their usual standard of care after the patient goes home. The other group of hospitals is providing their usual care with the addition of an evaluation by a nurse practitioner, physician assistant or doctor within two weeks of hospital discharge, during which patients will receive a plan of care that will be shared with their other doctors, therapists and nurses.

Our hospital is providing the COMPASS model of post-acute care, which includes:

- A follow-up phone call 2 days after discharge
- A visit with a nurse practitioner, physician assistant, or doctor 7-14 days after discharge
- A plan of care that will be shared with your other health care providers
- Additional follow-up phone calls 30 and 60 days after discharge

We are committed to finding the best way to improve health and recovery after experiencing this health episode. In addition to the COMPASS care, you will continue to receive high-quality care at our hospital and at your usual follow-up visits with your primary care doctors.

After you have left the hospital, the COMPASS team would like to learn about your overall experience. They will:

- Call you in 3 months to ask questions about your recovery and satisfaction with your care.
- Mail you 3 reminder letters before you are called. The last letter will include a small gift to thank you for your time, so be sure to open it.
- Mail a survey to the family member, friend, or neighbor whom you identify as helping you in your recovery (*care helper*).

Whether or not you choose to participate in the survey, our hospital is committed to providing you with high-quality care for you during your recovery. All information you and your *care helper* provide will be kept strictly confidential and secure.

If you have any questions about the COMPASS Study, or prefer not to participate, feel free to ask the stroke coordinator, or you can call the COMPASS Study team using the toll-free number below.

COMPASS toll-free number: 1-844-501-7668
COMPASS Study website: www.nccompass-study.org

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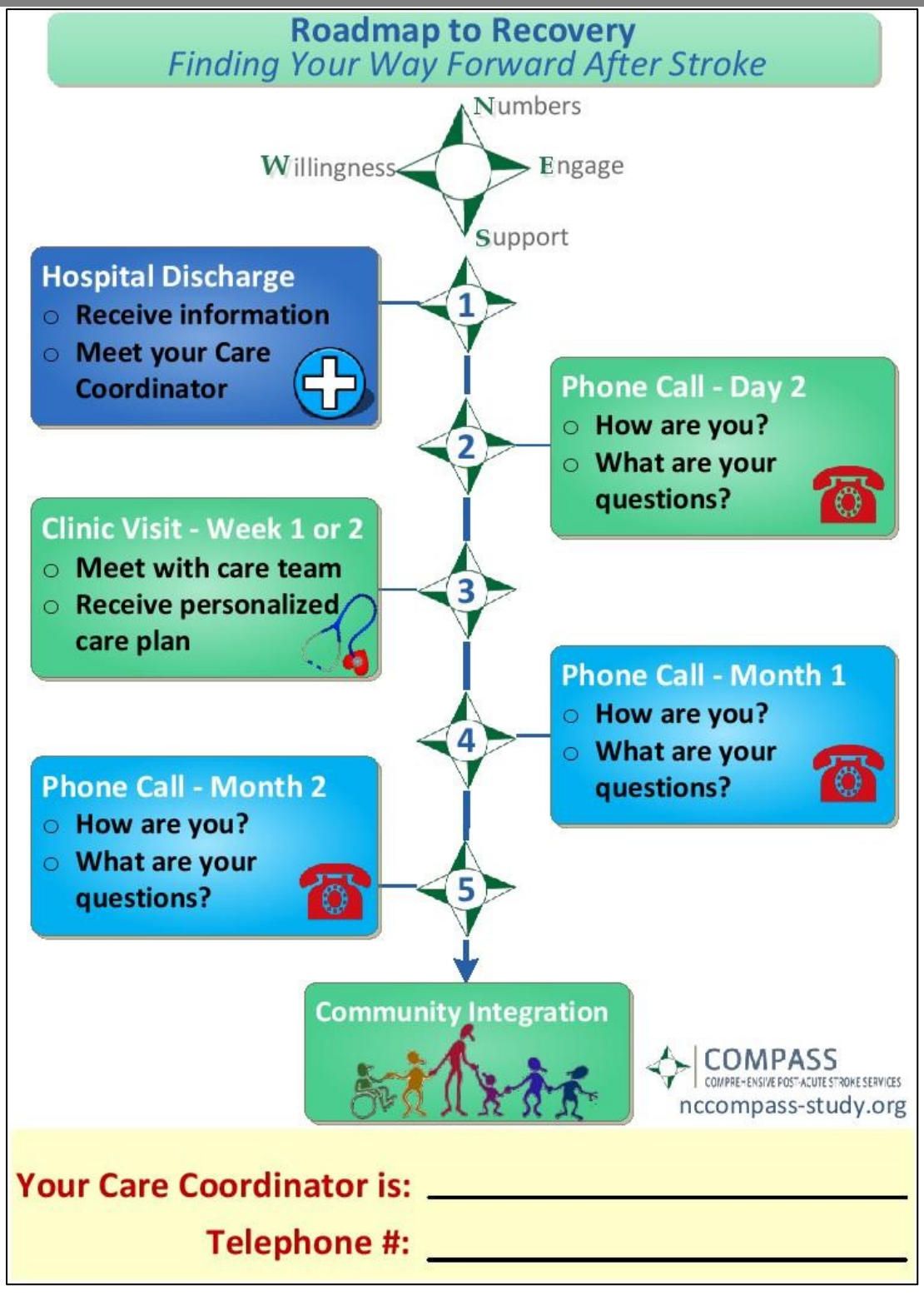
Appendix 13 - Intervention- Arm Patient Handout –COMPASS Roadmap



Appendix 14 - COMPASS Blood Pressure Log

Know Your Numbers

Prevent stroke by monitoring your blood pressure

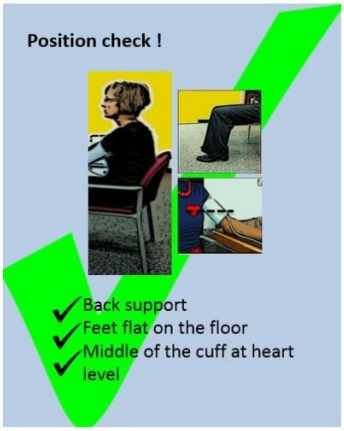
COMPASS Blood Pressure Log

Name:_____

My Home Blood Pressure Goal Is: _____/_____

- ☐ Arm monitor
- ☐ Wrist monitor

My blood pressure is taken by placing the cuff on my Left arm / Right arm *(circle one)*



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Things to remember about your home blood pressure monitor:

- Take your blood pressure (BP) at least 3 times per week. COMPASS recommends taking BP once a day. Take some BP's first thing in the morning before you take any of your medicines & take some BP's later in the day or evening.
- It is VERY important to bring your home BP log book to every doctor's visit.
- It is VERY important to take your BP while seated, after 5 minutes of rest, with your back supported and your feel flat around the ground. The **position matters** as otherwise you can get falsely high or low numbers.

  (see quick video to review the correct position at: http://tinyurl.com/BPinstructions)
- Remind your provider that you are in the COMPASS Study.

Alert values when your numbers may be too high/low

Some healthcare providers tell patients to call them if their blood pressure gets too high or too low. Only you and your providers can come up with those exact "alert" values, but here is some general guidance.

While monitoring your blood pressure, if you get an upper number (systolic) reading of 180 mm Hg or higher OR a lower number (diastolic) reading of 110 mm HG or higher, wait a couple of minutes and take it again.

If the reading is still at or above that level, you should call your provider immediately and possibly seek immediate emergency medical treatment. If you cannot access the emergency medical services (EMS), have someone drive you to the hospital right away.*

*This text is modified from: http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/AboutHighBloodPressure/Understanding-Blood-Pressure-Readings_UCM_301764_Article.jsp

Reading 1		Reading 2		Reading 3		Notes (from you or your provider)
Date & BP	Heart Rate (pulse)	Date & BP	Heart Rate (pulse)	Date & BP	Heart Rate (pulse)	
3/1/2016 @ 2PM 132/85	81	3/3/2016 @ 8 AM 130/80	70	3/5/2016 @ 10 PM 126/80	72	Medication changed to 100 mg, 2 times/day

Reading 1		Reading 2		Reading 3		Notes (from you or your provider)
Date & BP	Heart Rate (pulse)	Date & BP	Heart Rate (pulse)	Date & BP	Heart Rate (pulse)	
3/1/2016 @ 2PM 132/85	81	3/3/2016 @ 8 AM 130/80	70	3/5/2016 @ 10 PM 126/80	72	Medication changed to 100 mg, 2 times/day

Reading 1		Reading 2		Reading 3		Notes (from you or your provider)
Date & BP	Heart Rate (pulse)	Date & BP	Heart Rate (pulse)	Date & BP	Heart Rate (pulse)	
3/1/2016 @ 2PM 132/85	81	3/3/2016 @ 8 AM 130/80	70	3/5/2016 @ 10 PM 126/80	72	Medication changed to 100 mg, 2 times/day

Appendix 15 - COMPASS Blood Pressure Educational Handout

Know Your Numbers

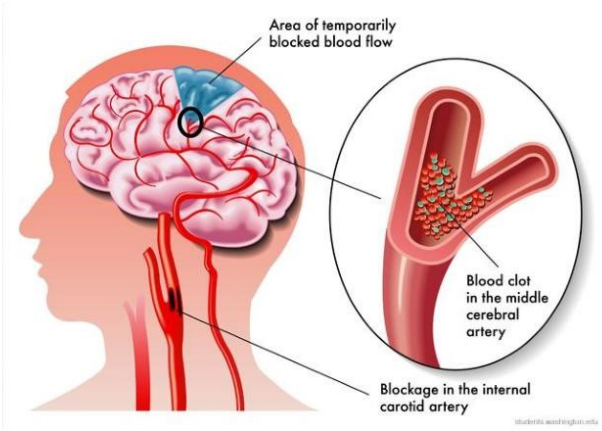
Prevent stroke by monitoring your blood pressure

What is blood pressure?

The heart pumps the blood through the body through channels called blood vessels. **The pressure of the blood in these vessels is the "blood pressure".**

If the blood pressure is too high, then the vessels can get damaged, clogged or even rupture that can cause strokes, heart attacks, damage to your kidney as other organs.

1. Keeping your blood pressure down can reduce the risk of having another stroke!



NOTES:

- High blood pressure is also called hypertension, but that does not mean you are "hyper," or nervous.
- A calm person can have high blood pressure and have no idea they have it unless it is checked using a blood pressure monitor. This is why high blood pressure is called the "silent killer".

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2. The best way to make sure your blood pressure is not too high is to check your blood pressure often using a blood pressure monitor AND
   - Keep a log of these numbers (using your COMPASS BP log)
   - Discuss your numbers with your healthcare team!

Date/Time	Reading 1		Reading 2		Reading 3		Notes (from you or your provider)
	BP	Heart Rate (pulse)	BP	Heart Rate (pulse)	BP	Heart Rate (pulse)	
Example: 8/8/11, 8pm	132/85	81	130/80	70	126/80	72	Medication changed to 100 mg, 2 times/day

NOTES:
Other things you can do to keep your blood pressure down:
- Take your medicines right (see chapter 2)
- Eat healthier (learn about the DASH or Mediterranean Diet)
- Be more active
- Don't add salt to your food at the table (find other ways to make food taste great.

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3. Other important things!

- Know your goal Blood Pressure numbers
- ASK YOUR DOCTOR to tell you what your goal Upper ("systolic") and Lower (diastolic") numbers should be and write them in the Target boxes below. 🎯
- Work with your Care Coordinator to understand your blood pressure numbers, how the numbers normally change from minute to minute and when to call your doctor.

Your Target Blood Pressure	Upper number (Systolic)
	Lower number (Diastolic)

NOTES:

- You may hear that "normal" blood pressure is when the upper number is under 120 and the lower number is under 80.
- You will also here that better blood pressure "control" is when the upper number is under 150 or 140 and lower number under 90.
- **But** since everyone is a little different, find out what your "target" numbers are and write them in the target box.

Questions or concerns

If you have any questions or concerns about any symptoms you have, or your medicines, talk with your health care provider or contact your Post-Acute Care Coordinator _____ at _____.

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More about High Blood Pressure and ways to keep your blood pressure numbers in your target range:

What causes high blood pressure?
The exact causes are unknown. Possible causes we cannot change are age, race, sex, and family history of high blood pressure. Lifestyle factors that can cause high blood pressure are:

- Smoking
- Using too much salt
- Being overweight or obese
- Drinking too much alcohol (more than 2 drinks for men, 1 drink for women per day)
- Using birth control pills (women)
- Being physically inactive

More information about else can be done to reduce high blood pressure?
High blood pressure can be treated in one or more of these ways.

- **Low Salt Diet** – Too much salt may be part of the cause of high blood pressure for many people. Prepared foods, such as TV dinners and packaged meals, have a lot of salt. Find out the amount of salt your doctor thinks you should have each day. Read food labels on processed foods to see how much salt (sodium) is in each serving. Don't add salt at the table to foods.
- **Follow a "Mediterranean-like**" diet. The Mediterranean-type diet emphasizes vegetables, fruits, and whole grains and includes low-fat dairy products, poultry, fish, legumes, olive oil, and nuts. It suggests limited intake of sweets and red meats. Learn more at http://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/mediterranean-diet/art-20047801.
- **Follow the DASH Diet**. The DASH plan is a diet rich in fruits, vegetables, low fat or nonfat dairy. It includes grains, especially whole grains; lean meats, fish and poultry; nuts and beans. It is high fiber and low to moderate in fat and rich in potassium, magnesium, and calcium. It is a plan that follows US guidelines for sodium content. The DASH eating plan lowers cholesterol and makes it easy to lose weight. It is a healthy way of eating, designed to be flexible enough to meet the lifestyle and food preferences of most people.
- **Other lifestyle changes** – Stopping smoking, losing weight, cutting down on or not drinking alcohol and exercising regularly may be things your doctor suggests to help lower your blood pressure. If your doctor has told you to make these changes, your COMPASS Program folder will have information about each of these. If your doctor did not mention these, but you are interested in having more information, let your COMPASS post-acute coordinator know when he/she calls you for your follow-up phone calls and he/she can send you more information.

High Blood Pressure Medicines

Medicines – Your doctor may want you to take medicine to help lower high blood pressure. These may be used alone or with other medicines.

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There are several types of high blood pressure medicines. Each works in a different way to lower blood pressure or help your heart. Which medicines may be best for you and your high blood pressure?

This depends on:

- The causes of your high blood pressure
- How high your blood pressure is
- How your body responds to each medicine
- Any other health problems you have

Your doctor will look at your risk factors that may be causing your high blood pressure to find out which medicine or medicines may work best for you.

The types of medicines most often used are:

- **Angiotensin-converting enzyme (ACE) inhibitors** – These keep your body from making angiotensin II. It is a hormone that makes blood vessels tighten. ACE inhibitors lower the amount of this hormone so your blood vessels remain relaxed. Blood flows more easily, lowering your overall blood pressure.
- **Angiotensin II receptor blockers (ARBs)** - ARBs block the action of angiotensin II. This also relaxes blood vessels so that blood can flow more easily.
- **Diuretics** – Often called "water pills," these will make you urinate (pass water) and help your kidneys get rid of salt and water. Less water means you have less blood volume in your blood vessels. This leads to lower blood pressure. Taking a diuretic also means less fluid collects in your feet, ankles, legs and abdomen.
- **Beta-blockers** –Beta-blockers slow the heartbeat and keep the heart from pumping so hard. The blood then goes through your blood vessels with less force and the pressure inside the vessels goes down.
- **Calcium channel blocker (CCB)** – Also called a calcium antagonist. Some CCBs keep blood vessels from tightening so much. They do this by preventing calcium from entering the muscle cells in your heart and blood vessels. Others slow your heart rate. As a result, blood can flow more easily through the vessels. This lowers your blood pressure.
- **Alpha-blockers** – These reduce the nerve impulses that tell your blood vessels to tighten. Your blood vessels remain relaxed, lowering your blood pressure.
- **Alpha-agonists** – These target receptors in your brain to help lower blood pressure.
- **Renin inhibitors** – Renin inhibitors block the enzyme renin from triggering a process that helps regulate blood pressure. Blood vessels relax and widen, making it easier for blood to flow through the vessels. This lowers blood pressure.
- **Combination medications** –There are single tablets that have two heart-related or blood pressure medicines to make it easier to take the medicines.

If one drug does not work for your or you do not like the way it makes you feel, others are available. Work with your doctor to find which ones are best for you. Many people need more than one type of blood pressure medicine to get the best results.

Resources for this information include: National Heart, Lung and Blood Institute, NIH – nhlbi.nih.gov/health/health-topics/topics/hbp; *Your Guide to Lowering High Blood Pressure* – nhlbi.nih.gov/hbp/; mayoclinic.com/health/high-blood-pressure/DS00100; The DASH Diet - /

Appendix 16 - Two-Day Post-Discharge Follow-up

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Two-Day Post-Discharge Follow-Up

ID Number: | | | | | | Form Code: | 2 | D | A | Y | | Date: 7JUN2016 Version 1.0

ADMINISTRATIVE INFORMATION (0a-0b are auto-populated)

0a. Completion Date: | | | / | | | / | | | | | (Month / Day / Year) 0b. Staff ID: | | | | | |

A. Hi. My name is _____, and I am calling on behalf of the stroke team of (name of hospital from which patient was discharged). May I speak to (patient name)?

- ☐ Yes, patient is available → **Go to Question 1**
- ☐ No, patient is not currently available → **Go to Section B**
- ☐ No, patient is deceased → **End Two-Day Post-Discharge Follow-Up**
- ☐ No, patient is hospitalized → **End Two-Day Post-Discharge Follow-Up**
- ☐ No, patient is in a skilled nursing facility → **End Two-Day Post-Discharge Follow-Up**

B. May I please speak to (patient name)'s primary caregiver?

☐ Yes → **Go to Section D** ☐ No → **Go to Section C**

C. May I please get the primary caregiver's name and number?

Name of the primary caregiver: _____

- ☐ I don't know the primary caregiver's name or number
- ☐ No, I refuse to provide caregiver's number

Number of primary caregiver: (__ __ __) __ __ __ - __ __ __ __

- ☐ I don't know the primary caregiver's name or number
- ☐ No, I refuse to provide caregiver's number

→ **End Two-Day Post-Discharge Follow-Up**

D. (Patient name) was discharged from the hospital approximately two days ago, and I would like to follow up with you to see how he/she has been doing.

To whom am I speaking with?
Name: _____

D (a). What is your relationship with (patient name)?

- ☐ Spouse
- ☐ Sibling
- ☐ Son/Daughter
- ☐ Neighbor/Friend
- ☐ Parent/Legal Guardian
- ☐ Other → **Go to Question E (c)**

D (b). Specify for "other" _____

D (c). Does the (patient name) have communication challenges that prevent him/her from answering questions?

- ☐ No
- ☐ Yes, significant aphasia
- ☐ Yes, cognitive deficits
- ☐ Both, significant aphasia & cognitive deficits
- ☐ No response

→ **Go to Question 1**

The Post – Acute Care Coordinator will now ask the following open-ended questions of the patient:

You were discharged from the hospital approximately two days ago, and I would like to follow up with you to see how you have been doing

1. I would like to discuss your medications and any changes that have been made. (Obtain medication list. Complete medication reconciliation, and list any discrepancies). Was medication reconciliation completed?
   - ☐ Yes → **Go to Question 1a**
   - ☐ No → **Go to Question 1c**

   1a. Were there any discrepancies during medication reconciliation?
   - ☐ Yes
   - ☐ No → **Go to Question 2**

   1b. _____

   1c. Why was medication reconciliation not completed?
   _____

2. Do you have any concerns about your medications?
   - ☐ Yes
   - ☐ No → **Go to Question 3**

   2a. What are these concerns?
   - ☐ _____
   - ☐ No Response

3. Are you on Coumadin (Warfarin)?
   - ☐ Yes
   - ☐ No → **Go to Question 4**

   3a. Have you had a test to see how long it takes for your blood to clot? This is known as an INR test.
   - ☐ Yes
   - ☐ No → **Go to Question 4**

   3b. What is your INR (Typical normal range 2-3)?
   - ☐ _____
   - ☐ I don't know
   - ☐ No response

   3c. When did you have your INR test?

		/			/				
Month			Day			Year			

☐ I don't know
☐ No response

4. Have you had any **new** stroke symptoms since being discharged from the hospital?
☐ Yes ☐ No → **Go to Question 5**

4a. What are these new symptoms?

	Yes	No	No Response
Numbness or weakness of the face, arm, or leg, especially on one side of the body	☐	☐	☐
Confusion / trouble understanding	☐	☐	☐
Difficulty speaking	☐	☐	☐
Trouble seeing in one or both eyes	☐	☐	☐
Trouble walking	☐	☐	☐
Dizziness, loss of balance or coordination	☐	☐	☐
Severe headache	☐	☐	☐
No response	☐		

5. After being discharged from the hospital, some stroke survivors may need a primary caregiver to provide assistance with activities such as taking your medicines, bathing, dressing, performing housework, and/or going places around town. Is there a primary caregiver who is currently assisting you with these tasks?
☐ Yes ☐ No → **Go to Question 6**

5a. What activities is your primary caregiver assisting with?

	Yes	No	No Response
Medication management	☐	☐	☐
Assisting with ADLs (bathing, dressing, feeding, etc.)	☐	☐	☐
Assisting with IADLs (cooking, housework, shopping, etc.)	☐	☐	☐
Transportation	☐	☐	☐
None	☐		
No response	☐		

5b. What is the name of the primary caregiver? _____
☐ No response

5c. What is the primary caregiver's relationship to you?
☐ Spouse
☐ Sibling
☐ Son/Daughter
☐ Neighbor/Friend
☐ Parent/Legal Guardian
☐ Other → **Go to Question 7d**
☐ No response

5d. Specify "other": _____

6. Do you have a follow-up appointment scheduled with your primary care provider?
☐ Yes
☐ No → **Go to Question 7**
☐ I don't know → **Go to Question 7**

6a. What is the date and time of your follow-up visit at your primary care provider?

		/			/				
Month			Day			Year			

☐ I don't know
☐ No response

6b. What is the first and last name of your primary care provider?
☐ _____
☐ I don't know
☐ No response

7. Do you have a follow-up appointment scheduled with our comprehensive stroke clinic? (Post-Acute Care Coordinator will need to have appointment date readily available).
☐ Yes, I do have an appointment → **Go to Question 8**
☐ No, I don't have an appointment (Post-Acute Care Coordinator will confirm an appointment was not established) → **Go to Question 9**

☐ I don't know if I have an appointment (Post-Acute Care Coordinator will confirm appointment or establish an appointment) → **Go to Question 11**

8. What is the date and time of your follow-up visit at our Comprehensive Stroke Clinic?
☐ Patient confirmed date and time correctly → **Go to Question 11**
☐ Patient didn't confirm date/time correctly or patient didn't know date/time → **Go to Q 10**

9. I will now establish an appointment for you to our Comprehensive Stroke Clinic. Your appointment is on (XX/XX/XXXX) at (XX:XX AM/PM). Did appointment get established?
☐ Yes → **Go to Question 11** ☐ No

9a. Why did appointment not get established?
☐ Patient prefers to follow-up with his/her own PCP or another doctor
☐ Patient reported that he/she is too sick or disabled to attend
☐ Patient cannot afford to attend the 7-14 day visit
☐ Patient does not have transportation
☐ Patient reported that he/she lives out of the area & doesn't want to travel
☐ No available appointment within 14 days
☐ Other: _____

10. Your appointment at our Comprehensive Stroke Clinic is on (XX/XX/XXXX) at (XX:XX AM/PM) Did confirmation take place?
☐ Yes ☐ No

11. Have you had any falls since your discharge?
☐ Yes ☐ No → **Go to Question 11a**

11a. Did you sustain any injuries and have to go to the emergency room or see a doctor?
☐ Yes ☐ No ☐ No response

12. Were you prescribed home health services after hospital discharge?
☐ Yes ☐ No → **Go to Question 13** ☐ I don't know → **Go to Question 13**

12a. What home health agency will provide you with home health care?
- ☐ _____
- ☐ I don't know
- ☐ No response

12b. What service(s) has been scheduled?

	Yes	No	N/A
Home health PT	☐	☐	☐
Home Health OT	☐	☐	☐
Home Health SLP	☐	☐	☐
Home Health Nursing	☐	☐	☐
No response	☐		

12c. Do you plan to receive and continue the home health service(s) that have been scheduled?
☐ Yes ☐ No ☐ No response

12d. [If a service(s) has not been scheduled], why hasn't the service(s) been scheduled?
- ☐ I chose not to participate in home health services
- ☐ The home health agency has not contacted me to schedule appointments
- ☐ Other

→ **Go to Question 14**

13. Were you prescribed any outpatient therapy after hospital discharge?
☐ Yes ☐ No → **Go to Question 14**

13a. What service(s) has been scheduled?

	Yes	No	N/A
Outpatient OT	☐	☐	☐
Outpatient PT	☐	☐	☐
Outpatient SLP	☐	☐	☐
No response	☐		

13b. Do you plan to attend and continue the therapy service(s) or appointment(s) that have been scheduled?
☐ Yes ☐ No ☐ No response

13c. [If a service(s) has not been scheduled], why hasn't the service(s) been scheduled?
- ☐ I chose not to participate in outpatient services
- ☐ There were not any available appointments in the outpatient rehabilitation center
- ☐ Other

You had a stroke, and it's important to remember the signs and symptoms of a stroke and when to go to the emergency department. An easy way to remember this is think of the word, FAST.
Face. Look for an uneven smile.
Arm. Check if one arm is weak or numb.
Speech. Listen for slurred speech.
Time. Call 911 immediately.

14. As a reminder, attending your appointment at the Comprehensive Stroke Clinic is important for your recovery, health, and independence. Do you have any issues with transportation that may prevent you from attending your appointment?
☐ Yes → **Go to Section F** ☐ No → **Go to Section G**

(F) There are resources within your area that can assist you with transportation to our comprehensive stroke clinic if you need assistance getting to your appointment. (Post-Acute Care Coordinator will relay resources to patient or caregiver) Thank you for taking the time to answer these follow-up questions. We have scheduled you to come to our Comprehensive Stroke Clinic on (XX/XX/XXX) at (XX:XX AM/PM).

(G) Thank you for taking the time to answer these follow-up questions. We have scheduled you to come to our Comprehensive Stroke Clinic on (XX/XX/XXX) at (XX:XX AM/PM).

15. Are there any challenges or discrepancies to medication reconciliation, or any concerns (new or worsening symptoms, patient sustaining an injurious fall, etc) that need to be immediately triaged to the Advanced Practice Provider?
    ☐ Yes ☐ No

    15a. What are these challenges or concerns?
    _____

END OF 2-DAY POST-DISCHARGE FOLLOW-UP

Appendix 17 - Post-stroke Functional Assessment

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Post-Stroke Functional Assessment for Personalized Care©

For Each Patient, the *"Right Care, Right Place, Right Time"*

ID Number: | | | | | | Form Code: | P | S | F | A | | Date: 2JUN2016 Version 1.0

ADMINISTRATIVE INFORMATION (0a-0b are auto-populated)

0a. Completion Date: | | | / | | | / | | | | | Month / Day / Year

0b. Staff ID: | | | | | |

We are going to ask you a series of questions about your health and well-being, and your ability to take care of yourself and move around since your stroke. Some questions will also ask you about your preferences for care. The goal is to share this information with your doctors, nurses, and therapists so that they can develop a care plan made especially for you. Please answer the following questions on the state of your health or function and the activities you would prefer to do to help you recover and stay healthy.

1. Since you were hospitalized for your stroke, have you had enough to buy your medicines and take them as your doctor prescribed?
   ☐ Yes ☐ No ☐ No response

2. Do you know any of the risk factors that may lead to a stroke? ☐ Yes ☐ No → **Go to Question 3**

   2a. What are these risk factors? (check all that apply)
   - ☐ High Blood Pressure
   - ☐ Smoking
   - ☐ Diabetes or High Blood Sugar
   - ☐ Irregular Heart Beat (Atrial Fibrillation)
   - ☐ Heart Disease
   - ☐ High Cholesterol
   - ☐ Physical Inactivity
   - ☐ Sickle Cell Anemia
   - ☐ Family History of Stroke
   - ☐ Prior Stroke
   - ☐ Response not on this list

   2b. Did the patient know <u>any</u> of the risk factors for stroke? ☐ Yes ☐ No

3. Compared to others your age, how would you rate your health since your stroke using a scale of 1 to 5, with 1 being "poor" and 5 being "excellent?"

   (1) Poor (2) Fair (3) Good (4) Very Good (5) Excellent ☐ No response

4. Can you go up and down 10 stair steps without help? ☐ Yes ☐ No ☐ No response

5. How difficult is it to use your hand most affected by your stroke?

   (1) Cannot use at all (2) Very difficult (3) Somewhat difficult (4) A little difficult (5) Not difficult at all
   ☐ No response

6. Have you fallen in the last 3 months? ☐ Yes ☐ No → **Go to Question 8**

   6a. In the last 3 months, did you get injured and need to go to the doctor or emergency room due to a fall?
   ☐ Yes ☐ No ☐ No response

   6b. Have you fallen more than once in the last 3 months? ☐ Yes ☐ No ☐ No response

7. Have you fallen since your stroke? ☐ Yes ☐ No → **Go to Question 8**

   7a. How many times have you fallen since your stroke? _____ ☐ don't know ☐ No response

8. Please continue this sequence: 1, A, 2, B, 3, C, _, _, _, _, _, _.

   Choose "yes" if the patient completed the entire sequence correctly.
   ☐ Yes ☐ No ☐ No response

9. How many different medications do you take per day? _____ ☐ don't know ☐ No response

10. Is there someone to help you move about, bathe, dress, etc. for 30 days if you ever need assistance?
    ☐ Yes ☐ No → **Go to Question 11**

    10a. What relationship is he/she to you?
    ☐ Spouse
    ☐ Sibling
    ☐ Son/Daughter
    ☐ Neighbor/Friend
    ☐ Parent/Legal Guardian
    ☐ Other (Specify) → **Specify other in 10b**
    ☐ No response

    10b. Specify other: _____

11. Since your stroke, have you often been bothered by feeling down, depressed, or hopeless?
☐ Yes ☐ No ☐ No response

12. Since your stroke, have you often been bothered by little interest or pleasure in doing things?
☐ Yes ☐ No ☐ No response

If the following criteria are met:	Only the following questions will be asked:
Question 1: Yes **Question 2: Yes or No** **Question 2b: Yes or No** **Question 3: (3) Good or (4) Very Good or (5) Excellent** **Question 4: Yes** **Question 5: (4) A little difficult or (5) Not difficult at all** **Question 6: No** **Question 8: Yes** **Question 9: 4 or less** **Question 10: Yes** **Question 11: No** **Question 12: No**	**Question 14** **Question 26-27** **Question 34-38** **Question 42-43** **Question 47**
If the above criteria are met, BUT	**Only the following questions will be asked:**
Question 11: Yes **OR** **Question 12: Yes**	**Question 14** **Question 26-27** **Question 34-38** **Question 40-41** **Question 42-43** **Question 47**

13. Over the next 3 months, do you think your health is going to:
☐ Improve
☐ Stay the same
☐ Get worse
☐ No response

14. What are your primary reasons for staying as healthy as you can?
(Open-ended question)

For example,

	Yes	No	No Response
Work – return to work	☐	☐	☐
Social – visit with friends, go out, and/or travel	☐	☐	☐
Family – visit with family, play with my grandchildren	☐	☐	☐
Independence – be independent, take care of myself	☐	☐	☐
Better quality of life	☐	☐	☐
Other → **Specify other in 14b**	☐	☐	☐
No response	☐		

14b. Specify other_____

These next few questions ask about your ability to take care of yourself and move around.

15. Can you walk for at least 15 minutes without getting short of breath or needing to stop and rest?
☐ Yes ☐ No ☐ No response

16. Can you walk without feeling unsteady?
☐ Yes ☐ No ☐ No response

17. Can you get up out of a chair **without** using your hands?
☐ Yes ☐ No ☐ No response

18. Can you use the phone to call your family or doctor if needed?
☐ Yes ☐ No ☐ No response

19. Can you prepare your own meals or do your own housework without any assistance?
☐ Yes ☐ No ☐ No response

20. Can you bathe/take a shower and dress yourself without any assistance?
☐ Yes ☐ No ☐ No response

21. Are you having trouble controlling your bladder or bowels?
☐ Yes ☐ No ☐ No response

Because ability to remember is so important for managing your health, I am going to ask a few questions about this area of your life. There really is no right or wrong answer. These are helpful questions to assist your doctors and nurses to help you have the assistance you need to manage your health.

22. Can you tell me the day of the week, month, and year? (Choose "Yes" if the patient was able to correctly identify day of the week, month, and year.)
☐ Yes ☐ No ☐ No response

I am going to read a list of words to you that you will have to remember. Please listen carefully. When I am through, repeat as many words as you can remember. It doesn't matter in what order you say them.

Trial 1: School, blue, apple.

I am going to read the list for a second time. Repeat as many words as you can.

Trial 2: School, blue, apple.

I will ask you to recall these words again later on in this assessment.

23. Tell me why you are taking two of your medicines. (Choose "Yes" if patient was able to recall two medicines and reasons for taking them).
☐ Yes ☐ No ☐ No response

24. Does anyone help you manage your medications? (Puts your medicine in a pill box, hands your medicines to you, etc).
☐ Yes ☐ No ☐ No response

25. In the last month, **were you unable** to buy your medicines because of not having enough money?
☐ Yes ☐ No ☐ No response

26. Do you stop taking your medicine if you feel better or worse?
☐ Yes ☐ No ☐ No response

27. Do you ever forget to take your medicine?
☐ Often
☐ Sometimes
☐ Rarely
☐ Never
☐ No response

28. Please recall the three words I asked you to remember. It doesn't matter in what order you list them. (Choose "Yes" if patient was able to recall all 3 words : school, blue, apple).
☐ Yes ☐ No ☐ No response

29. Since your stroke, do you eat at least two meals a day?
☐ Yes ☐ No ☐ No response

30. Since your stroke, have you had new problems swallowing or chewing your food?
☐ Yes ☐ No ☐ No response

31. Since your stroke, have you had increased stiffness in your hand, arm, or leg that interferes with your activities of daily living?
☐ Yes ☐ No ☐ No response

32. Since your stroke, have you been able to drive yourself to and from places?
☐ Yes ☐ No ☐ No response

33. If unable to drive, is there someone who can take you to the doctor or pharmacy?
☐ Yes ☐ No ☐ No response

34. Do you have one doctor that knows you and all of your medical conditions?
☐ Yes ☐ No → **Go to Question 39**

35. What is the doctor's first and last Name? _____ ☐ don't know ☐ No response

36. Have you seen him/her in the past 3 months?
☐ Yes ☐ No → **Go to Question 38**

37. Have you seen him/her since your stroke?
☐ Yes ☐ No ☐ No response

38. In the past 3 months, did you miss any scheduled appointments with this doctor?
☐ Yes ☐ No ☐ No response

39. Do you have a network of family and friends who visit you as often as you like?
☐ No, I am often lonely
☐ Yes, I can count on my family and friends to lean on when I feel down
☐ No response

40. Stress means a situation in which a person feels tense, restless, nervous, or anxious, or is unable to sleep at night because his or her mind is troubled all the time. Do you feel this kind of stress these days?

☐ Yes ☐ No ☐ No response

41. Since your stroke has your relationship with your family become more difficult or stressed?
☐ Yes ☐ No ☐ No response

42. In the last 3 months, with the exception of your stroke, how many times were you seen in the emergency department?

_____ ☐ don't know ☐ No response

43. How many times in the last 3 months have you been hospitalized overnight, with the exception of your hospitalization due to your stroke?

_____ ☐ don't know ☐ No response

44. What home health services are you currently receiving?
(Open-ended question)

	Yes	No	No Response
None → **Go to Question 45**	☐		
Nursing	☐	☐	☐
Physical Therapy	☐	☐	☐
Occupational Therapy	☐	☐	☐
Speech & Language Therapy	☐	☐	☐
Personal Care Assistant	☐	☐	☐
No response → **Go to Question 45**	☐		

45. What type of outpatient therapy are you currently receiving?
(Open-ended question)

	Yes	No	No Response
None	☐		
Outpatient Physical Therapy	☐	☐	☐
Outpatient Occupational Therapy	☐	☐	☐
Speech & Language Therapy	☐	☐	☐
No response	☐		

46. What Durable Medical Equipment (DME) are you currently using?
(Open-ended question)

	Yes	No	No Response
None	☐		
Walker	☐	☐	☐
Cane	☐	☐	☐
Wheelchair	☐	☐	☐
Bath Safety Equipment (Toilet rails/frames, shower bench/seat)	☐	☐	☐
Bedside Commode	☐	☐	☐
No response	☐		

47. What is the best way to reach you to discuss your health and how you are doing?

☐ Telephone call → **If checked, answer 47a**
☐ Text message → **If checked, answer 47a**
☐ Email → **If checked, answer 47b**
☐ I will visit My Health portal on the internet
☐ No response

a. What is the best number to reach you? _____ ☐ don't know ☐ No response

b. What is your email address? _____ ☐ don't know ☐ No response

Your doctor and nurses want to take good care of you and respect your values and views. Your doctor wants to make sure he/she understands your views on treatment so they can take good care of you. Because unexpected things can happen, you have the right to make decisions about your healthcare. This includes the right to accept or refuse medical or surgical treatment when you are seriously ill or lose the ability to participate in decision-making about your own treatment. Fortunately, you have the right to plan and direct the types of healthcare and life sustaining treatments you wish to receive in the future. You can do this by making an advance directive (living will). An advance directive gives you a voice in decisions about your medical care.

48. Do you have a living will? ☐ Yes → **Go to Question 49** ☐ No

48a. Would you be interested in information to assist you in creating a living will?
☐ Yes ☐ No ☐ No response

49. Did someone other than the patient answer the majority of these questions?
☐ Yes ☐ No

49a. What was their relationship to the patient?
☐ Spouse
☐ Sibling
☐ Son/Daughter
☐ Neighbor/Friend
☐ Parent/Legal Guardian
☐ Other (Specify) → **Specify other in 49b**
☐ No response

49b. Specify other: _____

Based on your answers, we have found the following [Summarize to patient results from the questionnaire].

What support/services do you have to help you? And what resources would you like to receive in order to help you?

Thank you for responding to our questions. I am going to discuss your questionnaire with the provider (nurse practitioner/physician assistant/physician) and use your responses to arrange any services that will be useful to ensure the best possible stroke recovery. Do you have any questions for me?

[The question and checklist below will only be completed at Wake Forest Baptist Medical Center – Vanguard Site]

To be completed by the interviewer. Which of the following factors do you think this patient will need help or assistance with to speed their stroke recovery?

- ☐ Activities of Daily Living (Bathing, dressing, walking)
- ☐ Exercise to improve strength, balance, and endurance
- ☐ Falls prevention
- ☐ Durable medical equipment or home modifications
- ☐ Transportation to follow-up appointments
- ☐ Manage medications (pill box, etc)
- ☐ Monitor/control of stroke risk factors (blood pressure, hypertension)
- ☐ Pharmacy referral
- ☐ Financial assistance to purchase medications
- ☐ Depression services, treatment, and support
- ☐ Patient doesn't have a primary care physician & needs help getting one
- ☐ Identify caregiver to assist & be available during instructions
- ☐ Refer to Outpatient Therapy (PT/OT)
- ☐ Refer to Speech and Language
- ☐ Refer to Home Health Services
- ☐ Refer to Skilled Nursing Home
- ☐ Refer to Community Services
- ☐ Assistance with Advance Directive
- ☐ Nutritional support
- ☐ None

Thank you!
Thanks for completing this questionnaire!
Go out and live the best day possible.
You deserve it.

END OF POST STROKE FUNCTIONAL ASSESSMENT

Appendix 18 - Caregiver Assessment

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Stroke Caregiver Assessment©

For Each Caregiver the *"Right Care at the Right Time"*

ID Number: ☐☐☐☐☐ Form Code: S C A ☐☐ Date: 27MAR2016 Version 1.0

ADMINISTRATIVE INFORMATION (0a-0c are auto-populated)

0a. Completion Date: ☐☐ / ☐☐ / ☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐☐☐

0c. Caregiver ID: ☐☐☐☐☐☐☐

A. ***[Patient name] has indicated that he/she has assistance with some, or all, routine activities of daily living and that he/she depend on the help of a caregiver. Are you [patient name]'s primary caregiver?***

☐ Yes → **Go to Section C** ☐ No → **Go to Section B**

B. Who is the patient's primary caregiver, and what is the best number I can reach him/her? (Obtain name and number so that Post-Acute Care Coordinator can call primary caregiver).

Name of the primary caregiver: _____-_____

Number of primary caregiver: (__ __ __) __ __ __ - __ __ __ __

C. ***Since you are the primary caregiver, I would like to discuss the services and tasks that [patient name] needs assistance with during his/her stroke recovery. Do you have time to answer a few questions? This will take about 5 minutes to complete.***

1. What is your name? _____ ☐ No response
2. What is your relationship?
   - ☐ Spouse
   - ☐ Sibling
   - ☐ Son/Daughter
   - ☐ Neighbor/Friend
   - ☐ Parent/Legal Guardian
   - ☐ Other
     - a. Specify for "other" _____
   - ☐ No Response
3. What is your age? _____ ☐ No response
4. What is your gender? ☐ Male ☐ Female ☐ No response

5. Do you provide assistance for **[patient name]** with any of the following activities?

6. Which of those activities do you need additional assistance with?

	5. Provide assistance? If Yes, go to Q6 →			**6. Caregiver needs help with task?**		
	Yes	**No**		**Yes**	**No**	**No response**
a. Bathing / showering	☐	☐		☐	☐	☐
b. Dressing	☐	☐		☐	☐	☐
c. Getting out of bed / chair	☐	☐		☐	☐	☐
d. Helping to / from bathroom	☐	☐		☐	☐	☐
e. Feeding	☐	☐		☐	☐	☐
f. Preparing Meals	☐	☐		☐	☐	☐
g. Shopping	☐	☐		☐	☐	☐
h. Laundry	☐	☐		☐	☐	☐
i. Handling finances	☐	☐		☐	☐	☐
j. Assistance with housework	☐	☐		☐	☐	☐
k. Transportation to medical appointments	☐	☐		☐	☐	☐
l. Transportation to grocery store, places around town, etc.	☐	☐		☐	☐	☐
None → **Go to Section B**	☐					
No Response → **Go to Section B**	☐					

7. Do you assist **[patient name]** with medications?

☐ Yes → **Go to Question 7a and b (skip 7c)** ☐ No → **Go to Question 7c**

7a. Can you name at least two medicines that **[patient name]** is taking and why he/she is taking these medications?

☐ Yes
☐ No
☐ No Response

7b. Do you need assistance with managing the patient's medications?

☐ Yes ☐ No ☐ No response

7c. Does someone else assist with managing the patient's medications?

☐ Yes ☐ No ☐ No Response

Appendix 19 - Post-stroke Advanced Practice Assessment

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Post Stroke Advanced Practice Assessment
For Each Patient the *"Right Care, Right Place, Right Time"*

ID Number: ☐☐☐☐☐ Form Code: P S A P A Date: 31MAR2016 Version 1.0

ADMINISTRATIVE INFORMATION (0a-0b are auto-populated)

0a. Completion Date: ☐☐ / ☐☐ / ☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐☐☐

1. Since the stroke, on average, how many minutes/ per day has the patient engaged in continuous physical activity?
   - ☐ Walking/ moving about for <10 min/day
   - ☐ Walking/moving about for 10-20 minutes/day
   - ☐ Walking/moving about for > 20 minutes/day
   - ☐ No response

2. Did you educate patient on importance of physical activity?
   - ☐ Yes ☐ No

3. How often does the patient smoke cigarettes?
   - ☐ Not at all → **Go to Question 4**
   - ☐ Some days
   - ☐ Every day
   - ☐ No response

   3a. Has the patient received counseling to end addiction to cigarettes?
   - ☐ Yes ☐ No ☐ No Response

4. Does the patient exceed the recommended alcohol per day? (1-2 drinks/day for men, 1 drink for women) (Wine=5oz., beer=12 oz.)
   - ☐ Yes ☐ No ☐ No Response

5. Does the patient engage in recreational drug use? (marijuana, cocaine, heroin, street drugs/ non-prescription opioids)
   - ☐ Yes ☐ No ☐ No Response

6. Has patient received counseling to end addiction to recreational drug or alcohol?
   - ☐ Yes ☐ No ☐ No Response

Post-Stroke AP Assessment Page 1 of 2

7. Blood Pressure

Systolic _____ mm HG
Diastolic _____ mm HG

8. HgbA1c _____ ☐ Not Available

9. INR _____ ☐ Not Available

10. LDL _____ (mg/dL) ☐ Not Available

11. Are there any severe communication deficits such as severe dysarthria, expressive or receptive aphasia that require speech therapy?
☐ Yes ☐ No

12. If indicated, MOCA score _____
☐ Not Indicated
☐ Patient refused

13. If indicated, PHQ-9 _____
☐ Not Indicated
☐ Patient refused

14. Modified Rankin score
☐ 0 No symptoms at all
☐ 1 No significant disability despite symptoms; able to carry out all usual duties and activities
☐ 2 Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
☐ 3 Moderate disability; requiring some help, but able to walk without assistance
☐ 4 Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
☐ 5 Severe disability; bedridden, incontinent and requiring constant nursing care and attention

15. If the patient needs a caregiver, does the patient have a willing and able caregiver? (provider opinion)
☐ Yes ☐ No ☐ Patient does not need a caregiver

END OF POST STROKE AP ASSESSMENT

Appendix 20 - Individualized Patient Care Plan (eCare Plan)

COMPASS: Finding My Way to Recovery, Independence, and Health

My Goals for My Recovery, Independence, and Health are:

COMPASS COMPREHENSIVE POST-ACUTE STROKE SERVICES	What are my concerns?	Why is this important to me?	How do I find my way forward?
NUMBERS N **Numbers: Know My Numbers. Know my Risks.**	My Blood Pressure is VALUE	High blood pressure damages the arteries that bring blood to the brain. This can cause another stroke. A blood pressure less than 120/80 is considered normal.	Healthy numbers lead to a healthy life. Keeping track of my numbers will decrease my chances of having another stroke.
	My hemoglobin A1c level is VALUE	Keeping track of my blood sugar levels can reduce my risk of another stroke. My ideal A1c level is 6-7.	
	My LDL(bad) cholesterol level is VALUE	A high LDL (bad) cholesterol level puts me at risk for another stroke. My bad cholesterol level should be less than 70.	
	My INR is VALUE. This means my blood is (thinner or thicker) than desired.	If I am on warfarin (Coumadin), frequent monitoring is important. The right level is between 2.0 – 3.0, unless my health care provider states it should be higher.	

	I do not know all of the risk factors for stroke.	There are risk factors I didn't realize could cause another stroke. It's important that I am aware of these risk factors, and my own specific risk factors, so I can make correct lifestyle choices to prevent or manage them.	There are many factors that can put me at a higher risk of having another stroke. These risk factors are: • High blood pressure • Smoking • Diabetes or high blood sugar • Irregular heartbeat or atrial fibrillation • Heart disease • High cholesterol • Physical Inactivity My specific risk factors are:

Engage:
Be engaged to manage my recovery, independence, and health

Engage to Manage my Stress and Mood		
I have been experiencing stress that keeps my mind troubled.	Stress can increase my blood pressure. Stress can lead to another stroke.	I can reduce my stress by: • Being physically active and having a daily exercise routine • Getting individual or group counseling • Attending a stroke support group.
Since my stroke, my relationship with my family has become more difficult or stressed.	Strained relationships with my family can cause me to be more stressed. More stress can slow down my recovery.	I can get help for my family and me to make our relationships better by: • Going to a stroke or brain injury support group • Using the services of Care Net
I feel hopeless and sad, and have lost interest in doing my favorite things.	Sadness that does not go away may be due to depression. Depression can slow down my stroke recovery.	I can feel better and less sad by: • Being physically active and having a daily exercise routine • Getting individual or group counseling • Attending a stroke support group. • Getting support from my church or other community groups • Taking medicine for my mood
Engage to Promote Physical Activity & Safe Mobility		
It is difficult to use my hand affected by my stroke	Therapy, exercise, and physical activity will improve the use of my hand and arm.	I can improve the use of my hand and arm by: • Working with a physical and/or occupational therapist in my home or an outpatient clinic. • Exercising regularly on my own or in an exercise class. • Being physically active in my daily life and trying to use my arm and hand as much as possible.
My muscles feel stiff and I am having trouble moving, walking, or using my hand and arm.	Medicines, therapy, exercise, and physical activity can decrease the stiffness (also called spasticity) in my muscles. This will help me be more independent and safe in my daily activities.	I can decrease the stiffness in my muscles by: • Working with a physical and/or occupational therapist in my home or an outpatient clinic. • Doing stretching and strengthening exercises. • Taking medicines to relax my muscles. • Seeing a specialist in spasticity treatment.
I have fallen or I am at risk for falling	I am more likely to fall since I had a stroke. Improving my balance and strength will help decrease my chances of falling and improve my overall independence.	I can decrease my chances of falling by: • Working with a physical therapist in my home or an outpatient clinic. • Attending a falls prevention class • Using appropriate walking aids for support • Having a home safety assessment.

	I am only physically active less than 10 minutes per day (or 10-20 minutes per day).	Movement matters for my stroke recovery. I can decrease my risk for another stroke, increase my endurance, and feel better if I am physically active.	I can be more active by • Working with a physical and/or occupational therapist in my home or an outpatient clinic. • Exercising regularly on my own or in an exercise class. • Walking every day for at least 20 minutes a day. I can break this up into smaller chunks 10 minutes at a time. • Movement around the house can keep me physically active as well (e.g doing laundry, gardening, putting up groceries).
	I have limitations in walking, being able to go up/down steps, or getting out of a chair.	Regaining safe mobility will prevent me from falling. If I have strength and balance, I will be safer and more independent. This will improve my stroke recovery.	I can work on my strength and balance • With a home based program that encourages me to challenge my strength and balance during my usual daily activities. A physical therapist can help design the most appropriate exercises and activities for me to do. • I can join a community exercise program or exercise is medicine program affiliated with my hospital
	Engage for my Recovery to Independence		
	I am not independent in some of my routine activities like dressing or bathing myself, or being able to control my bladder/bowels.	Being as independent as possible will increase my confidence in my recovery. This will make it easier for my loved ones to care for me.	I can become more independent in my routine activities by: • Working with a physical and/or occupational therapist in my home or an outpatient clinic. • Working with a home health aide on bathing and dressing • Getting adaptive equipment (e.g., tub chair) that can help with my activities
	I cannot prepare my own meals, do housework, drive myself, or use the phone	Eating healthy meals and taking care of my home is important for my recovery and overall health.	I can get healthy meals from: • Meals on Wheels • Congregate meals I can get help with housework and meal preparation from: • Senior Services aide services • CAP worker referrals (as appropriate), • Community resources for respite care • Home health aide services I can improve my ability to prepare meals and do housework by: • Working with an Occupational therapist in my home or an outpatient clinic. I can identify family members or community agencies that will help me with transportation.
	Engage to Manage my Communication Recovery		
	I am having trouble speaking and communicating clearly.	Therapy services can help me with my swallowing and speaking and with my "thinking" tasks so I can be more independent.	I can improve my speaking, swallowing, and thinking by: • Working with a speech therapist in my home or an outpatient clinic • Working with an occupational therapist in my home or an outpatient clinic Attending a support group for stroke survivors who have trouble speaking or understanding language (sometimes called aphasia).

	Engage with my Health Care Team		
	I need a regular doctor (primary care provider) who knows my medical history and conditions	A primary doctor will help me monitor my cholesterol, blood pressure, blood sugar and blood thinning.	I can find a regular doctor by: • Using the information given to me in the stroke clinic • Using the information on free clinics if I do not have insurance.
	I haven't seen my regular doctor (primary care provider) in 3 months or since I had my stroke, or I have missed scheduled appointments.	Seeing my doctor regularly will allow for better management of my blood pressure, blood sugar, cholesterol, and other stroke risk factors.	I can • Keep a calendar reminder for my appointments • Ask for help with transportation to my doctor • If you are not happy with your doctor there may be other doctors you connect with better
	I am not receiving home health or outpatient therapy services, but I may benefit from this.	Skilled therapists can help me improve my strength, balance and ability to safely care for myself and be more independent.	I can ask my doctor or health care provider to make the referrals for home health or outpatient therapy services. .

 **Support: Be Aware of my Community Support**	Since my stroke, I do not eat at least two meals a day.	Eating enough healthy food is important for me to recover and can help reduce my chances of having another stroke.	I can get healthy meals from Meals on Wheels or at a congregate meal site. If I cannot afford food, a social worker can help.
	I am having trouble with transportation.	Being able to get to my medical appointments and social events is important for my recovery, health and happiness.	I can get help with transportation by: • Being referred to Transportation services • Getting support from Faith Health for my medical and non-medical appointments.
	My caregiver needs additional assistance with helping me with my transportation needs.	Being able to get to my medical appointments and social events is important for my recovery, health and happiness.	I can get help with transportation by: • Being referred to Transportation services • Getting support from Faith Health for my medical and non-medical appointments.
	My network of family and friends do not (or cannot) visit me as often as I would like.	Being around others who understand what I am going through can help me stay positive about my recovery.	I can get support from others who care about me at stroke support groups and/or day programs as well as from members of my faith community.
	I do not have someone to help me bathe/dress if I ever get to the point where I need assistance	It is important that I have a someone to assist me to live at home.	I can get support and assistance from a personal care assistant
	My caregiver needs additional assistance with helping me bathe, go to the toilet, dress, etc. My caregiver also needs assistance with preparing my meals and handling my finances, etc.	My caregiver and I need help with what I have to do every day to take care of myself and get better.	My caregiver and I can get help with taking care of me by letting my health care provider know what we need and asking them to refer us to resources like: • Area Agency for Aging Caregiver specialist • Home Health Occupational Therapy or Physical therapy • Outpatient Occupational Therapy or Physical therapy • PACE Personal Care Assistant • Meals on Wheels • Caregiver section of COMPASS website (American Heart Association resources and CareLiving Guide)
	Since I had my stroke, my caregiver has been stressed.	If my caregiver is under a lot of stress it causes me stress, which is not good for my health and recovery.	My caregiver and I can get help with dealing with our stress by telling our health care provider about it and asking them to refer us to resources for stress management like: • Area Agency for Aging Powerful Tools for Caregivers • Area Agency for Aging Caregiver Specialist • American Stroke Association - Stroke Warm 1-888-4-STROKE (1-888-478-7653) • Caregiver support groups • Faith-based organizations

			• Refer to caregiver section of COMPASS website (American Heart Association resources and CareLiving Guide) • CareNet Respite Care • Stroke support groups and/or day programs
	My caregiver would like additional assistance with helping me take my medicines.	It is important for me to take my medicines as my health care provider directs me to so that I can recover from my stroke and not have another stroke.	My health care provider can get my caregiver and me help with my medicines by referring me to: • Home Health Nursing for medication management • Pharmacy referral for medication management assistance to help us understand my medicines and fill my pill box.
	My caregiver needs information about stroke and secondary prevention.	It is important for my caregiver to know the signs and symptoms of another stroke so that they can get me help fast if they see something that concerns them.	My health care provider can give my caregiver information about stroke signs and symptoms. We can also get information in: • the Caregiver Section of the COMPASS Study website • AHA/ASA website's CareLiving Guide • http://www.heart.org/HEARTORG/Caregiver/Resources/OtherResources/Other-Resources-for-Caregivers_UCM_301861_Article.jsp#

 **Willingness:** **I am willing to Manage My Medication and Lifestyle Choices**	I am taking a lot of medicines I am not sure I know my medicines.	Taking multiple medicines after a stroke may be normal. Many of these medicines help to decrease your chance of having another stroke. You should review your medicines with your provider to make sure that all your medicines are still necessary to keep you healthy.	I can share my concerns about my medicines and can get help with how to take them by reviewing them with: • My doctor • My Home Health Nurse • My local Pharmacist I may need someone everyday to help manage my medicines, fill my pillbox, or remind me so I can take them right.
	Sometimes, I forget to take my medicines and/or I quit taking my medicines when I begin to feel better or worse	Most medicines prescribed after stroke must be taken for a long time to prevent another stroke. Stopping them or missing doses may increase my risk of another stroke.	
	I do not have anyone to help me manage my medicines, and I may be getting confused about when to take them.	Medicines help to decrease the chance of having another stroke. They are also useful to keeping you healthy. Taking my medicines as directed will give me the best chance for preventing stroke. Skipping doses or stopping my medicines may increase my risk of another stroke.	
	I have not been able to purchase some of my medicines for financial reasons.	Most medicines following stroke need to be filled and started when I get home from the hospital. There may be other medicines for prevention that cost less.	My health care provider or my local pharmacist can help me find cheaper medicines. Other resources include: • Medication Management Assistance • Financial Resources

	My concerns with lifestyle management: -Current use of cigarettes -Current use of alcohol -Current use of recreational drugs	Cigarette smoking, drinking too much alcohol (more than 2/day for men and more than 1/day for women), and the use of recreational drugs are habits that can increase my risk of another stroke.	I can get help with my habits through: • North Carolina Quit Line -1-800-QUIT-NOW (1-800-784-8669). • Behavioral Counseling • Treatment/Addiction Support Groups
	Should I get treatment for addiction?	Getting counseling and treatment for my addiction will promote a happy and healthier lifestyle. My overall well-being will be improved.	

My recovery and my health require that:

- Numbers: I manage my blood pressure
- Engage: I am physically active
- Support: I ask for help when I need it
- Willingness: I take my medicines correctly

Living Will	Are you interested in making a living will?	Living wills (also called advance directives) can help make sure I get the kind of care I would want if I became too sick to make my own treatment choices.	Begin a Conversation With Your Family and Doctor: • Beginning the conversation with your family and health care providers. http://www.begintheconversation.org/ • Ask your primary care doctor to discuss your preferences for a living will . • Contact agencies in your community to fully understand advanced directives and select your options (community agencies include the Community Care of North Carolina, palliative and hospice programs)

For additional information, and to investigate local resources, visit the COMPASS study website at:
https://www.nccompass-study.org

Appendix 21 - Consent and HIPAA Authorization for Clinical Data

Wake Forest School of Medicine

COMPASS STUDY
Informed Consent and HIPAA Authorization

Your hospital is participating in a statewide study called the Comprehensive Post-Acute Stroke Services (COMPASS) Study. The purpose of the COMPASS Study is to determine the best ways to care for stroke survivors after they go home.

The PI for the COMPASS Study is Dr. Pamela Duncan at Wake Forest Baptist Medical Center (WFBMC). This study is funded by the Patient-Centered Outcome Research Institute (PCORI).

We would like to ask you for your consent and HIPAA authorization to keep a record of your personal health information and responses to the questions we asked you during the COMPASS telephone calls and this visit. This includes information from your recent hospitalization, visits to your doctor, and medications. We would like keep your responses to learn more about how we can improve the delivery of care to patients who have had a stroke. This information will be kept completely confidential and it will be kept in a secure place.

Your consent is completely voluntary. If you choose not to provide consent, you will still receive the same quality treatment and follow up. This medical facility may not condition (withhold or refuse) treating you on whether you sign this Authorization.

You may change your mind and withdraw your consent later. However, if you withdraw your consent, the organization may still use information that was previously collected about you. WFBMC and some study team members may financially benefit from the creation of an electronic tool that is being used in this study. The health information listed above may be used by and/or disclosed to the study investigators at this site and others, study management centers, the study sponsor, and other groups, including federal agencies, which have a responsibility to assist in the oversight and management of the research study. This Authorization does not have an expiration date.

If you have any questions or if you would like to withdraw your consent, you can call us toll-free at 1-844-501-7668 or if it easier, you can email us at: thecompassstudy@gmail.com.

Do you have any questions?

By signing below, you give permission to disclose your identifiable health information for the COMPASS research study. Would you like to give us permission to keep your data for research purposes?

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):

Person Obtaining Consent Signature:_____ Date:_____ Time:_____ am pm

Wake Forest School of Medicine

The following page should be included if you are recruiting subjects with diminished mental capacity:

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature: _____ Date:_____ Time:_____ am pm

Appendix 22 - 30 and 60 Day Call Forms (60 Day Call Form is Identical)

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

30-Day PAC Call Form

ID Number: ☐☐☐☐☐ Form Code: D Y 3 0 ☐ Date: 06JUN2016 Version 1.0

ADMINISTRATIVE INFORMATION (0a-0c are auto-populated)

0a. Completion Date: ☐☐ / ☐☐ / ☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐☐☐

Instructions for the PAC: Please summarize the outcome of your conversation with the patient during the 30-day follow-up call by answering the questions below.

1. Does patient know what his/her target BP should be? ☐ Yes ☐ No

2. Is patient monitoring their BP? ☐ Yes ☐ No
   a. If Yes, how many times per week on average? ____

3. Did the patient know their last blood pressure? ☐ Yes ☐ No

4. Has the patient received any home health rehabilitation services since discharge? ☐ Yes ☐ No
   a. **If Yes**, indicate which types (check all that apply)
      - ☐ Physical therapy
      - ☐ Occupational therapy
      - ☐ Speech therapy
   b. **If No**, what are the reason(s) for no home health rehab services? (check all that apply)
      - ☐ Patient did not need therapy
      - ☐ No transportation
      - ☐ Financial / insurance
      - ☐ Patient did not think necessary / refused
      - ☐ No reason given
      - ☐ Other _____

5. Has the patient received any outpatient rehabilitation services since discharge? ☐ Yes ☐ No
   a. **If Yes**, indicate which types (check all that apply)
      - ☐ Physical therapy
      - ☐ Occupational therapy
      - ☐ Speech therapy

b. **If No**, what are the reason(s) for no outpatient rehab services? (check all that apply)

- ☐ Patient did not need therapy
- ☐ No transportation
- ☐ Financial / insurance
- ☐ Patient did not think necessary / refused
- ☐ No reason given
- ☐ Other _____

6. Did the patient receive the support they needed from community services during this intervention?

- ☐ No, none of the support needed
- ☐ Some of the support needed
- ☐ Most of the support needed
- ☐ All the support needed

To be answered by PAC for administrative purposes:

7. Did you complete the 30-day telephone call including the telephone script?

☐ Yes ☐ No → **Go to Question 7a**

7a. If no, why not

- ☐ Patient refused
- ☐ Unable to reach after 3 calls
- ☐ Partially complete / did not finish call
- ☐ Other _____

8. Did you speak with the patient or a proxy? ☐ Patient ☐ Proxy

END OF 30-DAY PAC CALL DATA FORM

COMPASS 90 Day Patient Survey

LABEL	VALUE	TEXT	INSTRUCTIONS
INTRO	0=R DOES NOT HAVE Q'NAIRE FOR REFERENCE 1=R DOES HAVE Q'NAIRE FOR REFERENCE 8=DON'T KNOW	I'm going to be asking you a series of questions about [IF NO PROXY: your] [IF PROXY=1 OR 2: FILL R NAME]'s health and activities since NO PROXY: you were PROXY: he/she was hospitalized for stroke or TIA. Most of the questions are on the questionnaire we mailed [NO PROXY: to you] about a week ago. Do you have that in front of you or would you like to go get it? IN: GIVE THE R TIME TO GO GET IT, BUT IF THEY DON'T HAVE OR CAN'T FIND PAPER Q'NAIRE: That's OK, we can complete the call without it. IF NEEDED: TIA stands for transient ischemic attack and is sometimes referred to as a mini-stroke or warning stroke.	
SIS_INTRO	EMPTY	I'd like to start by asking you about the physical problems NO PROXY: you PROXY: he/she may have because of your/his/her stroke (or TIA). I want to know NO PROXY: [from **YOUR POINT OF VIEW]** how stroke has affected your/his/her physical	

		function in the past two weeks. I'm going to read a list of tasks and for each one, I'd like you to tell me whether it is not difficult at all, a little difficult, somewhat difficult, very difficult or if the task can't be done at all. IF NEEDED: I'm required to ask all the questions, but please just answer to the best of your ability.	
SIS1	1=Not difficult at all 2=A little difficult 3=Somewhat difficult 4=Very difficult 5=Or you could not do this activity at all? 8=DON'T KNOW 9=REFUSE	In the past two weeks how difficult was it PROXY: for him/her to dress the top part of your/his/her body? Would you say . . .	
SIS2	1 =Not difficult at all 2=A little difficult 3=Somewhat difficult 4=Very difficult 5=Or you could not do this activity at all? 8=DON'T KNOW 9=REFUSE	In the past two weeks, how difficult was it [for him/her]to bathe yourself/himself/herself? Would you say… INTERVIEWER NOTE: Bathing oneself does not include getting into the tub.	
SIS3	1 =Not difficult at all 2=A little difficult 3=Somewhat difficult 4=Very difficult 5=Or you could not do this activity at all? 8=DON'T KNOW 9=REFUSE	In the past two weeks, how difficult has it been [for him/her] to get to the toilet on time? (Would you say…) INTERVIEWER NOTE: For this question we are interested in how quickly	

		you/he/she can get to the bathroom.	
SIS4	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	In the past two weeks how difficult has it been [for him/her] to control your/his/her bladder, that is, not have an accident? (Would you say . . .) IN: OKAY TO DROP "DIFFICULT" WHEN READING RESPONSE OPTIONS IN NOTE: LOSING A LITTLE URINE/DRIBBLING IS CONSIDERED AN ACCIDENT. IF PERSON HAS INTERMITTENT CATHETER AND IS HAVING NO LEAKING PROBLEMS CODE THEM AS PER REPORT. IF PERSON HAS AN IN-DWELLING FOLEY CATHETER, CODE AS *CANNOT DO AT ALL*.	
SIS5	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	In the past two weeks how difficult has it been [for him/her] to control your/his/her bowels, that is, not have an accident? (Would you say…) IN NOTE: CONSTIPATION IS NOT COUNTED HERE. THE PERSON HAS TO HAVE AN ACCIDENT.	
SIS6	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT)	(In the past two weeks, how difficult has it been [for him/her] to) Stand without losing balance?	

	5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	(Would you say. . .)	
SIS7	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	(In the past two weeks, how difficult has it been [for him/her] to) Go shopping? (Would you say…) IN NOTE: THIS CAN BE SHOPPING ALONE OR WITH SOMEONE.	
SIS8	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	(In the past two weeks, how difficult has it been [for him/her] to) Do heavy household chores, for example, vacuum, laundry or yard work? (Would you say…)	
SIS9	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	(In the past two weeks, how difficult has it been[for him/her] to) Stay sitting without losing your/his/her balance? (Would you say…)	
SIS10	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	(In the past two weeks, how difficult has it been [for him/her] to) Walk without losing your/his/her balance? (Would you say…) IN NOTE: THE DISTANCE IS NOT IMPORTANT	
SIS11	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL?	(In the past two weeks, how difficult has it been [for him/her] to) Move from a bed to a chair? (Would you say…)	

	8=DON'T KNOW 9=REFUSE		
SIS12	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	(In the past two weeks, how difficult has it been [for him/her] to) Walk fast? (Would you say…)	
SIS13	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	(In the past two weeks, how difficult has it been[for him/her] to) Climb one flight of stairs? (Would you say…)	
SIS14	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	(In the past two weeks, how difficult has it been[for him/her] to) Walk one block? (Would you say…) IN NOTE: THIS COULD INVOLVE WALKING WITH SUPPORT, SUCH AS WITH A CANE OR A WALKER.	
SIS15	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT) 4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	(In the past two weeks, how difficult has it been[for him/her] to) Get in and out of a car? (Would you say…) IN NOTE: IF THE RESPONDENT WANTS TO KNOW WHAT KIND OF CAR SAY YOUR CAR OR THE CAR YOU RIDE IN THE MOST.	
SIS16	1=NOT (DIFFICULT) AT ALL 2=A LITTLE (DIFFICULT) 3=SOMEWHAT (DIFFICULT)	(How about) Carry heavy objects, for example, a bag of groceries, with	

	4=VERY (DIFFICULT) 5=OR YOU COULD NOT DO THIS ACTIVITY AT ALL? 8=DON'T KNOW 9=REFUSE	your/his/her affected hand? (Would you say…) IF NEEDED: By 'affected' we mean the side of your body that was affected by your/his/her stroke. IN NOTE: THIS MEANS ANY PART OF THEIR BODY AFFECTED EVEN IF NOT THEIR HAND. E.G. FACE, LEG, ETC.	
HEALTH_INTRO		The next two questions are about how you perceive or view your general health.	PROGRAMMING: SKIP IF PROXY=1 OR 2
RateHlt	1=poor 2=fair 3=good 4=very good 5=excellent 8=DON'T KNOW 9=REFUSE	Compared to others your age, how would you rate your health since your stroke or TIA? Would you say…	PROGRAMMING: SKIP IF PROXY=1 OR 2
PredHlt	1=Stay the same 2=Improve 3=Get worse 8=DON'T KNOW 9=REFUSE	Over the next 3 months, do you think your health is going to:	PROGRAMMING: SKIP IF PROXY=1 OR 2
MRS_INTRO		This next set of questions is asking about the level of assistance you/he/she may or may not need with certain tasks and your/his/her ability to do things since your/his/her stroke or TIA." [IF INTRO=1, FILL]Depending on your responses I may skip some of the questions on the survey you have in front of you.	

		IF NEEDED: TIA stands for transient ischemic attack and is sometimes referred to as a “mini-stroke” or “warning stroke.”	
MRS1	0=NO (GO TO MRS4) 1=YES (GO TO MRS2) 8=DON’T KNOW (GO TO PA _INTRO) 9=REFUSE (GO TO PA_INTRO)	Could you/he/she live alone without any help from another person? This means being able to bathe, use the toilet, shop, prepare or get meals and manage finances. IN: AVOID DK OR REFUSE. ENCOURAGE THE R TO ANSWER YES OR NO.	
MRS2	0=NO (GO TO PA_INTRO) 1=YES (GO TO MRS3) 8=DON’T KNOW (GO TO PA_INTRO) 9=REFUSE (GO TO PA_INTRO)	Can you/he/she do everything that you/he/she were/was doing right before your/his/her stroke, even if slower and not as much?	
MRS3	0=NO (GO TO PA_INTRO) 1=YES (GO TO PA_INTRO) 8=DON’T KNOW (GO TO PA_INTRO) 9=REFUSE (GO TO PA_INTRO)	Are/Is you/he/she completely back to the way you/he/she were/was right before your/his/her stroke?	
MRS4	0=NO (GO TO MRS5) 1=YES (GO TO PA_INTRO) 8=DON’T KNOW (GO TO PA_INTRO) 9=REFUSE (GO TOPA_INTRO)	Can you/he/she walk from one room to another without help from another person? IN NOTE: WALKING FROM ONE ROOM TO ANOTHER WITHOUT THE HELP OF ANOTHER PERSON – INCLUDES WALKING WITH A CANE OR WALKER AS LONG AS THE PERSON DOES IT INDEPENDENTLY.	

MRS5	0=NO (GO TO PA_INTRO) 1=YES (GO TO PA_INTRO) 8=DON'T KNOW (GO TO PA_INTRO) 9=REFUSE (GO TO PA_INTRO)	Can you/he/she sit up in bed without any help?	
PA_INTRO		The next few questions are about the amount of time you/he/she have/has spent walking in the last 7 days.	
PAday_YN	0=NO (GO TO MOOD INTRO) 1=YES (GO TO PADAY) 8=DON'T KNOW (GO TO MOOD INTRO) 9=REFUSE (GO TO MOOD INTRO)	In the past 7 days did you/he/she walk continuously for at least 10 minutes on any day?	
PAday	ENTER A NUMBER FROM 0-7 IF >0, THEN GO TO PAMIN IF 0 GO TO MOOD_INTRO 8=DON'T KNOW (GO TO MOOD_INTRO) 9=REFUSE (GO TO MOOD INTRO)	During the last 7 days **on how many days** did you/he/she walk continuously, for at least 10 minutes, for recreation, exercise, or to get to or from places? IN: IF R RESPONDS 'DON'T KNOW', PROBE WHETHER DON'T KNOW # OF DAYS (IF THIS, ENCOURAGE BEST GUESS) OR DON'T KNOW IF 10 MINUTES CONTINUOUSLY (IF THIS, GO BACK TO PADAY_YN AND CHOOSE DON'T KNOW) IF NEEDED: Think only about the walking that you/he/she do/does for at least 10 minutes at a time.	
PAmin		On days when you/he/she walked for at least 10 minutes, how much total	

	Enter a numeric value between 10 and 840 (GO TO MOOD INTRO) 8=DON'T KNOW (GO TO PAWALK) 9=REFUSE (GO TO PAWALK)	time per day, did you/he/she spend walking? IN: We're looking for an average time per day that you/he/she walked.	
PAwalk	Enter a number of minutes 8=DON'T KNOW 9=REFUSE	What is the total amount of time you/he/she spent walking over the last 7 days?	
MOOD_INTRO		The next two questions are about your mood. I now want you to think about the past **two weeks,** how often have you been bothered by any of the following problems? IN: STRESS 2 WEEKS SINCE RESPONDENT JUST FOCUSED ON PAST WEEK.	PROGRAMMING: SKIP IF PROXY=1 OR 2
Mood1	1=Not at all 2=Several days 3=More than half of the days 4=Nearly every day 8=DON'T KNOW 9=REFUSE	Little interest or pleasure in doing things? Would you say you've been bothered . . .	PROGRAMMING: SKIP IF PROXY=1 OR 2
Mood2	1=Not at all 2=Several days 3=More than half of the days 4=Nearly every day 8=DON'T KNOW 9=REFUSE	How about feeling down, depressed, or hopeless? Would you say you've been bothered . . .	PROGRAMMING: SKIP IF PROXY=1 OR 2
	EMPTY	The next set of questions are not on the paper survey. This is a memory assessment. I am going to read a list of words that you will have to remember now and later on. **Please listen**	PROGRAMMING: SKIP IF PROXY=1 OR 2

		carefully but do not write them down. When I am through, tell me as many words as you can remember. It doesn't matter in what order you say them. Are you ready to hear the words?	
MOCA1_1 MOCA1_2 MOCA1_3 MOCA1_4 MOCA1_5	1=FACE 2=VELVET 3=CHURCH 4=DAISY 5=RED	IN: WHEN R IS READY, READ THE FOLLOWING OUT LOUD AT A RATE OF 1 WORD PER SECOND: Face, Velvet, Church, Daisy, Red Now, please tell me which words you remember. IN: IF R SAYS SIMILAR SOUNDING WORD, COUNT AS CORRECT AND SAY: Thank you. I will count that as the correct answer, but to clarify, the word was [REPEAT WORD], spelled [SPELL WORD]. WHEN THE SUBJECT INDICATES THAT (S)HE HAS FINISHED (HAS RECALLED ALL WORDS), OR CAN RECALL NO MORE WORDS, MOVE ON.	PROGRAMMING: SKIP IF PROXY=1 OR 2
	EMPTY	Thank you. I'm going to read the same list a second time. Try to remember and tell me as many words as you can, including words you said the first time.	PROGRAMMING: SKIP IF PROXY=1 OR 2 (do second trial even if 1st trial successful)

MOCA12_1 MOCA12_2 MOCA12_3 MOCA12_4 MOCA12_5	1=FACE 2=VELVET 3=CHURCH 4=DAISY 5=RED 1=FACE 2=VELVET 3=CHURCH 4=DAISY 5=RED 1=FACE 2=VELVET 3=CHURCH 4=DAISY 5=RED 1=FACE 2=VELVET 3=CHURCH 4=DAISY 5=RED 1=FACE 2=VELVET 3=CHURCH 4=DAISY 5=RED	Are you ready to hear the words? IN: WHEN R IS READY, READ THE FOLLOWING: Face, Velvet, Church, Daisy, Red IF NEEDED: Now please tell me which words you remember. IN: IF R SAYS SIMILAR SOUNDING WORD, COUNT AS CORRECT AND SAY: Thank you. I will count that as the correct answer, but to clarify, the word was [REPEAT WORD], spelled [SPELL WORD]. CHECK EACH ONE THAT THE R SAYS CORRECTLY THE 2ND TIME. WHEN THE SUBJECT INDICATES THAT (S)HE HAS FINISHED (HAS RECALLED ALL WORDS), OR CAN RECALL NO MORE WORDS, MOVE ON.	PROGRAMMING: SKIP IF PROXY=1 OR 2
MOCA_THANKS	EMPTY	Thank you. I will ask you to recall these words again at the end of the test. IN: DO NOT REPEAT THE WORDS OR TELL THE R WHICH ONES S/HE FORGOT	PROGRAMMING: SKIP IF PROXY=1 OR 2
MOCA2_01 MOCA2_02 MOCA2_03 MOCA2_04	ANIMAL1=1 ANIMAL2=2 ANIMAL3=3	I'd like you to name as many animals as you can in	PROGRAMMING: SKIP IF PROXY=1 OR 2

MOCA2_05 MOCA2_06 MOCA2_07 MOCA2_08 MOCA2_09 MOCA2_10 MOCA2_11 MOCA2_12 MOCA2_13 MOCA2_14 MOCA2_15 MOCA2_16 MOCA2_17 MOCA2_18	ANIMAL4=4 ANIMAL5=5 ANIMAL6=6 ANIMAL7=7 ANIMAL8=8 ANIMAL9=9 ANIMAL10=10 ANIMAL11=11 ANIMAL12=12 ANIMAL13=13 ANIMAL14=14 ANIMAL15=15 ANIMAL16=16 ANIMAL17=17 ANIMAL18=18 Value is missing (.) when no animal was named	one minute. You can start now. IF NEEDED: Animal can include mammals, reptiles, fish, birds, insects, etc. Anything that moves on its own and eats. IN: DO NOT COUNT THE EXACT SAME ANIMAL TWICE; E.G. HORSE AND HORSE **DO** COUNT VARIATIONS; E.G. BIRD AND EAGLE IN: CHECK THE BOX FOR EACH ANIMAL NAMED. STOP RESPONDENT AT ONE MINUTE OR WHEN 18 ANIMALS HAVE BEEN NAMED, WHICHEVER COMES FIRST.	
MOCA3_1 MOCA3_2 MOCA3_3 MOCA3_4	1=MONTH 2=DATE 3=YEAR 4=DAY OF THE WEEK 1=MONTH 2=DATE 3=YEAR 4=DAY OF THE WEEK 1=MONTH 2=DATE 3=YEAR 4=DAY OF THE WEEK 1=MONTH 2=DATE 3=YEAR 4=DAY OF THE WEEK	Thank you. Can you tell me today's date? IF RESPONDENT GIVES AN INCOMPLETE ANSWER, PROMPT ACCORDINGLY: Can you tell me the year, month, exact date, and day of the week? IN: MARK EACH CORRECT RESPONSE, **THE DATE AND DAY OF THE WEEK CAN BE OFF BY A DAY AND STILL BE COUNTED.** E.G. TODAY'S DATE IS 5/10, SO 5/9, 5/10, OR 5/11 ARE CORRECT	PROGRAMMING: SKIP IF PROXY=1 OR 2
MOCA3e	ENTER STREET [50 CHAR]	Can you tell me the name of the street you live on?	PROGRAMMING: SKIP IF PROXY=1 OR 2

		STREET ADDRESS ON RECORD IS: [FILL]	PROGRAMMING: THESE ARE PRELOADED
MOCA3f	ENTER CITY	Now, can you tell me the city you live in? CITY ON RECORD IS: [FILL]	PROGRAMMING: SKIP IF PROXY=1 OR 2 PROGRAMMING: THESE ARE PRELOADED
MOCA13_1 MOCA13_2 MOCA13_3 MOCA13_4 MOCA13_5	1=FACE 2=VELVET 3=CHURCH 4=DAISY 5=RED 1=FACE 2=VELVET 3=CHURCH 4=DAISY 5=RED 1=FACE 2=VELVET 3=CHURCH 4=DAISY 5=RED 1=FACE 2=VELVET 3=CHURCH 4=DAISY 5=RED 1=FACE 2=VELVET 3=CHURCH 4=DAISY 5=RED	I read some words to you earlier, which I asked you to remember. Can you tell me those words? CHECK EACH ONE THAT THE R SAYS CORRECTLY. IN: IF R SAYS SIMILAR SOUNDING WORD, COUNT AS CORRECT AND SAY: Thank you. I will count that as the correct answer, but to clarify, the word was [REPEAT WORD], spelled [SPELL WORD].	PROGRAMMING: SKIP IF PROXY=1 OR 2
MOCA_HELP		Thank you. Let me help you remember the ones you forgot.	PROGRAMMING: SKIP IF PROXY=1 OR 2 PROGRAMMING: SKIP TO MED INTRO IF ALL FIVE (MOCA1a3-MOCA1e4) WERE CHECKED
MOCA4a_MISS	1=FACE	IF MOCA1a3 MISSING:	PROGRAMMING: SKIP IF PROXY=1 OR 2

	8=DON'T KNOW (GO TO MOCA4a_MISS2) 9=REFUSE (GO TO MOCA4a_MISS2)	Do you remember the word that is a part of the body?	
MOCA4a_MISS2	1=FACE 2=OTHER RESPONSE 8=DON'T KNOW 9=REFUSE	Do you think the word was eyes, shoulder or face?	PROGRAMMING: SKIP IF PROXY=1 OR 2 PROGRAMMING: OTHER RESPONSE, DON'T KNOW AND REFUSE GO TO EITHER NEXT MISSED WORD OR MED INTRO IF NO MORE MISSED WORDS
MOCA4b_MISS	1=VELVET 8=DON'T KNOW (GO TO MOCA4b_MISS2) 9=REFUSE (GO TO MOCA4b_MISS2)	IF MOCA1b3 MISSING: Do you remember the word that is a type of fabric?	PROGRAMMING: SKIP IF PROXY=1 OR 2
MOCA4b_MISS2	1=VELVET 2=OTHER RESPONSE 8=DON'T KNOW 9=REFUSE	Do you think the word was satin, velvet or cotton?	PROGRAMMING: SKIP IF PROXY=1 OR 2 PROGRAMMING: OTHER RESPONSE, DON'T KNOW AND REFUSE GO TO EITHER NEXT MISSED WORD OR MED INTRO IF NO MORE MISSED WORDS
MOCA4c_MISS	1=CHURCH 8=DON'T KNOW (GO TO MOCA4c_MISS2) 9=REFUSE (GO TO MOCA4c_MISS2)	IF MOCA1c3 MISSING: Do you remember the word that is a place people go to worship?	PROGRAMMING: SKIP IF PROXY=1 OR 2
MOCA4c_MISS2	1=CHURCH 2=OTHER RESPONSE 8=DON'T KNOW 9=REFUSE	Do you think the word was library, church or store?	PROGRAMMING: SKIP IF PROXY=1 OR 2 PROGRAMMING: OTHER RESPONSE, DON'T KNOW AND REFUSE GO TO EITHER

			NEXT MISSED WORD OR MED INTRO IF NO MORE MISSED WORDS
MOCA4d_MISS	1=DAISY 8=DON'T KNOW (GO TO MOCA4d_MISS2) 9=REFUSE (GO TO MOCA4d_MISS2)	IF MOCA1d4 MISSING: Do you remember the word that is a type of flower?	PROGRAMMING: SKIP IF PROXY=1 OR 2
MOCA4d_MISS2	1=DAISY 2=OTHER RESPONSE 8=DON'T KNOW 9=REFUSE	Do you think the word was rose, iris or daisy?	PROGRAMMING: SKIP IF PROXY=1 OR 2 PROGRAMMING: OTHER RESPONSE, DON'T KNOW AND REFUSE GO TO EITHER NEXT MISSED WORD OR MED INTRO IF NO MORE MISSED WORDS
MOCA4e_MISS	1=RED 8=DON'T KNOW (GO TO MOCA4e_MISS2) 9=REFUSE (GO TO MOCA4e_MISS2)	IF MOCA1e4 MISSING: Do you remember the word that is a color?	PROGRAMMING: SKIP IF PROXY=1 OR 2
MOCA4e_MISS2	1=RED 2=OTHER RESPONSE 8=DON'T KNOW 9=REFUSE	Do you think the word was red, blue or green?	PROGRAMMING: SKIP IF PROXY=1 OR 2 PROGRAMMING: OTHER RESPONSE, DON'T KNOW AND REFUSE GO TO MED INTRO
MED_INTRO		Thank you. The next 4 questions are about medications you take. Think about how you have taken your medications during the past four weeks when answering these questions.	PROGRAMMING: SKIP IF PROXY=1 OR 2
MMAS1	0=NO (GO TO MMAS2 1=YES (GO TO MMAS2	Do you ever forget to take your medicine?	PROGRAMMING: SKIP IF PROXY=1 OR 2

	8=DON'T KNOW (GO TO MMAS2 9=REFUSE (GO TO MMAS2		
MMAS2	0=NO (GO TO MMAS3 1=YES (GO TO MMAS3 8=DON'T KNOW (GO TO MMAS3 9=REFUSE (GO TO MMAS3	Are you careless at times about taking your medicine?	PROGRAMMING: SKIP IF PROXY=1 OR 2
MMAS3	0=NO (GO TO MMAS4 1=YES (GO TO MMAS4 8=DON'T KNOW (GO TO MMAS4 9=REFUSE (GO TO MMAS4	Sometimes if you feel worse when you take the medicine, do you stop taking it?	PROGRAMMING: SKIP IF PROXY=1 OR 2
MMAS4	0=NO (GO TO BPHome Intro) 1=YES (GO TO BPHome Intro) 8=DON'T KNOW (GO TO BPHome Intro) 9=REFUSE (GO TO BPHome Intro)	When you feel better, do you sometimes stop taking your medicine?	PROGRAMMING: SKIP IF PROXY=1 OR 2
BPHome_Intro		Now I'd like to ask some questions about checking your/his/her blood pressure and your/his/her usual or regular health care provider.	
BPHome	0=NO (GO TO BPVAL) 1=YES (GO TO BPFREQ) 8=DON'T KNOW(GO TO PCP) 9=REFUSE(GO TO PCP)	Do/Does you/he/she check your/his/her blood pressure **<u>at home</u>**? IN: BP COULD BE CHECKED BY A FAMILY MEMBER, FRIEND. ANY CHECKING OF BP SINCE INITIAL HOSPITALIZATION WOULD QUALIFY AS A YES.	
BPFREQ	1=daily (GO TO BPVALsys) 2=weekly or (GO TO BPVALsys) 3=monthly? (GO TO BPVALsys)	How frequently do/does you/he/she check your/his/her blood pressure? Would you say…	

	8=DON'T KNOW (GO TO BPVALsys) 9=REFUSE (GO TO BPVALsys)		
BPVALsys	Enter number between 50 and 250. (GO TO BPVALdia) 8=DON'T KNOW(GO TO PCP) 9=REFUSE(GO TO PCP)	What was the value of your/his/her last blood pressure? Please provide the systolic (top number) and diastolic (bottom number). IN: ENTER **TOP NUMBER** HERE AND BOTTOM NUMBER ON FOLLOWING SCREEN. IF NEEDED: We are interested in your most recent BP no matter who took the measurement.	
BPVALdia	Enter number between 35 and 135. (GO TO BPWHO)	What was the value of your/his/her last blood pressure? Please provide the systolic (top number) and diastolic (bottom number). IN: ENTER **BOTTOM NUMBER** HERE	
BPWHO	1=you/the patient himself/the patient herself 2= a healthcare professional 3= a family member, or 4= someone else? (GO TO BPWHO_OTHER)	Was this blood pressure measurement taken by . . .	
BPWHO_OTHER	OPEN TEXT (50 CHARACTERS)	Who took the blood pressure?	
PCP	0=NO (GO TO PTVIS) 1=YES (GO TO PCPVIS) 8=DON'T KNOW (GO TO PTVIS) 9=REFUSE (GO TO PTVIS)	Is there a particular doctor's office, health center, or other place that you/he/she usually go/goes if you/he/she are/is sick and	

		need/needs advice about your/his/her health? IN: THIS COULD INCLUDE ANY TYPE OF DOCTOR IF THE RESPONDENT USES THEM REGULARLY. IT DOES NOT INCLUDE A HOSPITAL EMERGENCY DEPARTMENT.	
PCPvis	0=NO (GO TO PTVIS) 1=YES(GO TO PTVIS) 8=DON'T KNOW(GO TO PTVIS) 9=REFUSE(GO TO PTVIS)	Have/Has you/he/she visited a doctor or nurse from that office, health center or other place since you/he/she were/was discharged from the hospital after your/his/her stroke?	
PTvis	0=NO (GO TO OTvis) 1=YES (GO TO PTvisL) 8=DON'T KNOW (GO TO OTvis) 9=REFUSED (GO TO OTvis)	Since you/he/she were/was discharged home on [PRELOAD DISCHARGE OR NEW_DISCHARGE, IF FILLED] after your/his/her stroke or TIA, have/has you/he/she received any services from a physical therapist? IF NEEDED: Physical therapists help patients with their mobility, (for example, walking, moving from sitting to standing, going up stairs, getting in and out of bed) and physical activity.	
PTvisL	1=your/his/her home (GO TO OTvis) 2=an outpatient clinic, or (GO TO OTvis) 3=both? (GO TO OTvis) 8=DON'T KNOW (GO TO OTvis) 9=REFUSED (GO TO OTvis)	Did you/he/she receive the services in …	

OTvis	0=NO (GO TO STvis) 1=YES (GO TO OTvisL) 8=DON'T KNOW (GO TO STvis) 9=REFUSED (GO TO STvis)	Since you/he/she were/was discharged home on <autofill date> after your/his/her stroke or TIA, have/has you/he/she received any services from an occupational therapist? IF NEEDED: Occupational therapists help patients with their activities of daily living (for example, dressing, bathing, cooking, eating).	
OTvisL	1=your/his/her home (GO TO STvis) 2=an outpatient clinic, or (GO TO STvis) 3=both? (GO TO STvis) 8=DON'T KNOW (GO TO STvis) 9=REFUSED (GO TO STvis)	Did you/he/she receive the services in …	
STvis	0=NO (GO TO FALL_INTRO) 1=YES (GO TO STvisL) 8=DON'T KNOW (GO TO FALL_INTRO) 9=REFUSED (GO TO FALL_INTRO)	Since you/he/she were/was discharged home on <autofill date> after your/his/her stroke or TIA, have/has you/he/she received any services from a speech therapist? IF NEEDED: Speech therapists help patients with their communication and swallowing.	
STvisL	1=your/his/her home 2=an outpatient clinic, or 3=both? 8=DON'T KNOW (GO TO FALL_INTRO) 9=REFUSED (GO TO FALL_INTRO)	Did you/he/she receive the services in …	

FALL_INTRO		The next few questions are about any falls or hospitalizations you've/he's/she's had since your/his/her stroke/TIA.	
Fall1	0=NO (GO TO ReAdmit) 1=YES (GO TO Fall2) 8=DON'T KNOW (GO TO ReAdmit) 9=REFUSE (GO TO ReAdmit)	Since you/he/she were/was discharged from the hospital on [PRELOAD DISCHARGE DATE] after your/his/her stroke or TIA, have/has you/he/she fallen?	
Fall2	0=NO (GO TO Fall3) 1=YES (GO TO Fall3) 8=DON'T KNOW (GO TO Fall3) 9=REFUSE (GO TO Fall3)	Did you/he/she get injured and need to go to the doctor or emergency room due to a fall?	
Fall3	0=NO (GO TO ReAdmit) 1=YES (GO TO FALL4) 8=DON'T KNOW (GO TO READMIT) 9=REFUSE (GO TO READMIT)	Have/Has you/he/she fallen more than once since your/his/her stroke?	
FALL4	Enter a number between 2 and 99. (GO TO ReAdmit) 8=DON'T KNOW (GO TO ReAdmit) 9=REFUSE (GO TO ReAdmit)	How many times have/has you/he/she fallen? IF NEEDED: A best guess is fine.	
ReAdmit	0=NO (GO TO PROMIS_INTRO) 1=YES (GO TO READMITN) 8=DON'T KNOW (GO TO PROMIS_INTRO) 9=REFUSE (GO TO PROMIS_INTRO)	Since you/he/she were/was discharged from the hospital on <date>, have/has you/he/she been hospitalized overnight for any reason?	
ReAdmitN	Enter a number between 1 and 99. (GO TO PROMIS_INTRO)	How many times have/has you/he/she been in the	

	8=DON'T KNOW (GO TO PROMIS_INTRO) 9=REFUSE (GO TO PROMIS_INTRO)	hospital overnight for any reason? IN NOTE: WE ARE INTERESTED IN NUMBER OF ADMISSIONS, NOT NIGHTS	
PROMIS_INTRO		The next few questions are about feelings of tiredness or fatigue	PROGRAMMING: SKIP IF PROXY=1 OR 2
PROMIS1	1=Not at all 2=A little bit 3=Somewhat 4=Quite a bit 5=Very much 8=DON'T KNOW 9=REFUSE	During the past 7 days, how often have you felt tired or fatigued? Would you say . . .	PROGRAMMING: SKIP IF PROXY=1 OR 2
PROMIS2	1=Not at all 2=A little bit 3=Somewhat 4=Quite a bit 5=Very much 8=DON'T KNOW 9=REFUSE	During the past 7 days, how often have you had trouble starting things because you were tired? Would you say . . .	PROGRAMMING: SKIP IF PROXY=1 OR 2
PROMIS3	1=NOT AT ALL 2=A LITTLE BIT 3=SOMEWHAT 4=QUITE A BIT 5=VERY MUCH 8=DON'T KNOW 9=REFUSE	(In the past 7 days,) how run-down did you feel on average? (Would you say. . .)	PROGRAMMING: SKIP IF PROXY=1 OR 2
PROMIS4	1=NOT AT ALL 2=A LITTLE BIT 3=SOMEWHAT 4=QUITE A BIT 5=VERY MUCH 8=DON'T KNOW 9=REFUSE	(In the past 7 days,) how fatigued were you on average? (Would you say. . .)	PROGRAMMING: SKIP IF PROXY=1 OR 2
SATIS_INTRO		The next several questions are about the care you've/he's/she's received from your/his/her physicians, nurses and other health care providers since you/he/she had your/his/her stroke or TIA.	

Satis1	1=Never 2=Sometimes 3=Usually 4=Always 8=DON'T KNOW 9=REFUSE	Thinking about the care you/he/she have/has received for your/his/her stroke or TIA recovery since you/he/she were/was discharged from the hospital on [PRELOAD DISCHARGE DATE], how often did your/his/her physicians, nurses and other health care providers… Explain things in a way that was easy [for him/her] to understand? Would you say. . . INTERVIEWER NOTE: PATIENTS SHOULD THINK ABOUT THE CARE THEY'VE RECEIVED FROM ALL OF THEIR PHYSICIANS (E.G., SPECIALIST AND PRIMARY CARE PROVIDERS)	
Satis2	1=Never 2=Sometimes 3=Usually 4=Always 8=DON'T KNOW 9=REFUSE	(Thinking about the health care providers you/he/she have/has seen since you/he/she were/was discharged from the hospital) How often did these providers listen carefully to you/him/her? Would you say. . .	
Satis3	1=NEVER 2=SOMETIMES 3=USUALLY 4=ALWAYS 8=DON'T KNOW 9=REFUSE	(Thinking about the health care providers you/he/she have/has seen since you/he/she were/was discharged from the hospital) How often did they seem to know the important	

		information about your/his/her medical history? (Would you say. . .)	
Satis4	1=NEVER 2=SOMETIMES 3=USUALLY 4=ALWAYS 8=DON'T KNOW 9=REFUSE	(Thinking about the health care providers you/he/she have/has seen since you/he/she were/was discharged from the hospital, How often did they) Show respect for what you/he/she had to say? (Would you say . . .)	
Satis5	1=NEVER 2=SOMETIMES 3=USUALLY 4=ALWAYS 8=DON'T KNOW 9=REFUSE	(Thinking about the health care providers you/he/she have/has seen since you/he/she were/was discharged from the hospital, How often did they) Spend enough time with you/him/her? (Would you say . . .)	
Satis6	1=NEVER 2=SOMETIMES 3=USUALLY 4=ALWAYS 8=DON'T KNOW 9=REFUSE	(Thinking about the health care providers you/he/she have/has seen since you/he/she were/was discharged from the hospital, How often did they)Talk about all the prescription medicines you/he/she were/was taking? (Would you say . . .)	
COMRES_INTRO		Now I'd like to ask you about any community services you/he/she have/has used since your/his/her stroke or TIA	
ComRes1	0=NO 1=YES 8=DON'T KNOW 9=REFUSE	Thinking back since discharge from the hospital after your/his/her stroke, have/has you/he/she used any adult day care programs or other adult	

		services for social support or recreation for stroke survivors? NOTE: These are programs that provide care and companionship for older adults who need assistance or supervision during the day. These programs offer some relief to family members and caregivers.	
ComRes2	0=NO 1=YES 8=DON'T KNOW 9=REFUSE	Since discharge from the hospital after your/his/her stroke, have/has you/he/she used community services or classes to help with your ability to speak, read, or write? IN NOTE: An example would be an aphasia support group.	
ComRes3	0=NO 1=YES 8=DON'T KNOW 9=REFUSE	Since discharge from the hospital after your/his/her stroke, have/has you/he/she used counseling services or therapy for stress or depression IN NOTE: (An example is CareNet counseling)?	
ComRes4	0=NO 1=YES 8=DON'T KNOW 9=REFUSE	(Since discharge from the hospital after your/his/her stroke) How about any programs that promote healthy living like classes on diet or managing diabetes? IN NOTE: Other examples include classes on managing chronic pain, problems with	

		breathing, high blood pressure.	
ComRes5	0=NO 1=YES 8=DON'T KNOW 9=REFUSE	(Since discharge from the hospital after your/his/her stroke) How about exercise classes that are open to the general public, like ones offered at a church or fitness center?	
ComRes6	0=NO 1=YES 2=DOES NOT SMOKE 8=DON'T KNOW 9=REFUSE	(Since discharge from the hospital after your/his/her stroke, how about) programs to help you quit smoking?	
ComRes7	0=NO 1=YES 8=DON'T KNOW 9=REFUSE	(Since discharge from the hospital after your/his/her stroke, how about) a falls prevention program that teaches you how to improve your balance and strength so you don't fall?	
ComRes8	0=NO 1=YES 8=DON'T KNOW 9=REFUSE	(Since discharge from the hospital after your/his/her stroke, how about) programs that provide meals – either delivered to your house or a central location like a church or community center?	
ComRes9	0=NO 1=YES 8=DON'T KNOW 9=REFUSE	(Since discharge from the hospital after your/his/her stroke, how about) a support group for stroke survivors? IN NOTE: these are groups that provide social support, information, and resources for stroke survivors	
ComRes10	0=NO 1=YES	(Since discharge from the hospital after your/his/her stroke, how about)	

	8=DON'T KNOW 9=REFUSE	medication assistance or management services to help pay for the medications or to help understand and manage the medications? IN NOTE: management services are usually offered by pharmacists.	
ComRes11	0=NO 1=YES 8=DON'T KNOW 9=REFUSE	(Since discharge from the hospital after your/his/her stroke, how about) transportation services to get you to your healthcare appointments or community activities? IN NOTE: THIS DOES NOT INCLUDE REGULAR PUBLIC TRANSPORTATION	
ComRes12	0=NO 1=YES 8=DON'T KNOW 9=REFUSE	(Since discharge from the hospital after your/his/her stroke, how about) support services for your family or caregivers? IN NOTE: these are groups or services that provide social support, information, and resources for caregivers/family members of storke survivors?	
ComRes13	0=NO (GO TO EDUC) 1=YES (GO TO COMRES14) 8=DON'T KNOW (GO TO EDUC) 9=REFUSE (GO TO EDUC)	Are there any other services you've/he's/she's used that I haven't mentioned?	
ComRes14	SPECIFY OTHER OPEN TEXT [250 CHAR]	What are those?	

Educ	1=8TH GRADE OR LESS 2=SOME HIGH SCHOOL, BUT DID NOT GRADUATE 3=HIGH SCHOOL GRADUATE OR GED 4=SOME COLLEGE OR 2-YEAR DEGREE 5=4-YEAR COLLEGE GRADUATE 6=MORE THAN 4-YEAR COLLEGE DEGREE 8=DON'T KNOW 9=REFUSE	What is the highest grade or level of school that you/he/she have/has completed?	
PROMIS_INTRO	EMPTY	These last few questions are about your health and how you have been feeling.	
Global01	1=Excellent 2=Very good 3=Good 4=Fair, or 5=Poor	In general, would you say your health is...	
Global02	1=Excellent 2=Very good 3=Good 4=Fair, or 5=Poor	In general, would you say your quality of life is...	
Global03	1=EXCELLENT 2=VERY GOOD 3=GOOD 4=FAIR, OR 5=POOR	In general, how would you rate your physical health? (Would you say...)	
Global04	1=EXCELLENT 2=VERY GOOD 3=GOOD 4=FAIR, OR 5=POOR	In general, how would you rate your mental health, including your mood and your ability to think? (Would you say...)	
Global05	1=EXCELLENT 2=VERY GOOD 3=GOOD 4=FAIR, OR 5=POOR	In general, how would you rate your satisfaction with your social activities and relationships? (Would you say...)	

Global09	1=EXCELLENT 2=VERY GOOD 3=GOOD 4=FAIR, OR 5=POOR	In general, please rate how well you carry out your usual social activities and roles. This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc. (Would you say...)	
Global06	1=Completely 2=Mostly 3=Moderately 4=A little, or 5=Not at all	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair? Would you say...	
Global10	1=Never 2=Rarely 3=Sometimes 4=Often, or 5=Always	In the past 7 days, how often have you been bothered by emotional problems such as feeling anxious, depressed or irritable? Would you say ...	
Global08	1=None 2=Mild 3=Moderate 4=Severe, or 5=Very severe	In the past 7 days, how would you rate your fatigue on average? Would you say...	
Global07	ENTER NUMBER (RANGE 0-10)	Picture a scale from 0 to 10, with zero being no pain and ten being the worst imaginable pain. In the past 7 days, how would you rate your pain on average?	
THANK_YOU		Thank you. That's the end of the survey. Goodbye.	

Appendix 24 - 90d Patient Survey (Full Survey Mailed with the 80 day letter)

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

This is a copy of the questions you will be asked during the phone call. You do not have to fill this out, but can if you would like to prepare for the call. It will be helpful to have this copy with you during the call.

A. **PHYSICAL CHALLENGES SINCE YOUR HOSPITAL VISIT**: These questions are about the physical problems you may have experienced recently because of your stroke or TIA. ("TIA" stands for *transient ischemic attack* and is sometimes referred to as a *mini-stroke*, *warning stroke*, *brain episode*, or *brain bleed*.) We want to know ***from your point of view*** how your stroke or TIA has affected your physical function in the past 2 weeks?

In the past 2 weeks, how difficult was it to...	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Could not do at all
Dress the top part of your body?	☐	☐	☐	☐	☐
Bathe yourself?	☐	☐	☐	☐	☐
Get to the toilet on time?	☐	☐	☐	☐	☐
Control your bladder (not have an accident)?	☐	☐	☐	☐	☐
Control your bowels (not have an accident)?	☐	☐	☐	☐	☐
Stand without losing balance?	☐	☐	☐	☐	☐
Go shopping?	☐	☐	☐	☐	☐
Do heavy household chores (e.g. vacuum, laundry or yard work)?	☐	☐	☐	☐	☐
Stay sitting without losing your balance?	☐	☐	☐	☐	☐
Walk without losing your balance?	☐	☐	☐	☐	☐
Move from a bed to a chair?	☐	☐	☐	☐	☐
Walk fast?	☐	☐	☐	☐	☐
Climb one flight of stairs?	☐	☐	☐	☐	☐
Walk one block?	☐	☐	☐	☐	☐
Get in and out of a car?	☐	☐	☐	☐	☐
Carry heavy objects (e.g. bag of groceries) with your affected hand?	☐	☐	☐	☐	☐

1

B. **GENERAL HEALTH QUESTIONS**: These questions are about how you perceive or view your general health.

1. **Compared to others your age, how would you rate your health since your stroke or TIA using a scale between 1 and 5 with 1 being "poor" and 5 being "excellent?"**

Poor	Fair	Good	Very Good	Excellent
1	2	3	4	5

2. **Over the next 3 months, do you think your health is going to:**
   - ☐ Improve
   - ☐ Stay the same
   - ☐ Get worse

C. **LEVEL OF ASSISTANCE QUESTIONS**: This next set of questions is asking about the level of assistance you may or may not need with certain tasks and your ability to do things since your stroke (or TIA).

1. **Could you live alone without any help from another person? This means being able to bathe, use the toilet, prepare or get meals, and manage finances.**
   - ☐ Yes
   - ☐ No

2. **Can you do everything that you were doing right before your stroke (or TIA), even if slower and not as much?**
   - ☐ Yes
   - ☐ No

3. **Are you completely back to the way you were right before your stroke (or TIA)?**
   - ☐ Yes
   - ☐ No

4. **Can you walk from one room to another without help from another person?**
   - ☐ Yes
   - ☐ No

5. **Can you sit up in bed without any help?**
   - ☐ Yes
   - ☐ No

D. **PHYSICAL ACTIVITY QUESTIONS**: The next few questions are about the amount of time you have spent walking in the last 7 days.

During the last seven days:

1. **Did you walk continuously for at least 10 minutes on any day?**
   ☐ Yes
   ☐ No

2. **On how many days did you walk continuously, for at least 10 minutes, for recreation, exercise, or to get to or from places?**

   Enter a number from 0 - 7: _____

3. **On days that you walked for at least 10 minutes, how much total time per day did you spend walking?**

   Enter a number _____ minutes

4. **What is the total amount of time you spent walking over the last seven days?**

   Enter a number _____ minutes

E. **MOOD QUESTIONS**: The next 2 questions are about your mood over the past 2 weeks.
Over the past two weeks, how often have you been bothered by any of the following problems:

1. **Little interest or pleasure in doing things:**
   ☐ Not at all
   ☐ Several days
   ☐ More than half of the days
   ☐ Nearly every day

2. **Feeling down, depressed, or hopeless:**
   ☐ Not at all
   ☐ Several days
   ☐ More than half the days
   ☐ Nearly every day

The interviewer will now ask you some questions to assess your memory.

These are not printed on the survey because they need to be asked over the phone.

After these 4 questions, the survey will continue on the next page in Section F: Medication Questions

F. **MEDICATION QUESTIONS**: The next 4 questions are about medications you take. Think about how you have taken your medications during the past 4 weeks when answering these questions.

1. **Do you ever forget to take your medicine?**
   - ☐ Yes
   - ☐ No

2. **Are you careless at times about taking your medicine?**
   - ☐ Yes
   - ☐ No

3. **Sometimes if you feel worse when you take the medicine, do you stop taking it?**
   - ☐ Yes
   - ☐ No

4. **When you feel better, do you sometimes stop taking your medicine?**
   - ☐ Yes
   - ☐ No

G. **SELF-MANAGEMENT & USE OF CARE QUESTIONS**: These next questions are about checking your blood pressure and your usual health care provider.

1. **Do you check your blood pressure at home?** ☐ Yes ☐ No

   1a. If yes, how frequently do you check your blood pressure?
   - ☐ Daily
   - ☐ Weekly
   - ☐ Monthly

   1b. What was the value of your last blood pressure? Please provide the systolic (top number) and diastolic (bottom number).

   _____ (systolic) / _____ (diastolic)

   1c. Who took this blood pressure measurement?
   - ☐ You
   - ☐ A healthcare professional
   - ☐ A family member
   - ☐ Someone else: _____ (please specify)

2. **Is there a particular doctor's office, health center, or other place that you usually go if you are sick and need advice about your health?**
   - ☐ Yes ☐ No

   2a. If yes, have you visited a doctor or nurse from that office, health center, or other place since you were discharged from the hospital after your stroke (or TIA)?
   - ☐ Yes ☐ No

3.a. Since you were discharged home after your stroke (or TIA), have you received any services from:		3.b. If yes, did you receive services in:		
		Your home?	Outpatient clinic?	Both?
i. A physical therapist?	☐ Yes ☐ No	☐	☐	☐
ii. An occupational therapist?	☐ Yes ☐ No	☐	☐	☐
iii. A speech therapist?	☐ Yes ☐ No	☐	☐	☐

H. **FALLS AND HOSPITALIZATION QUESTIONS**: The next few questions are about any falls or hospitalizations you've had since your stroke (or TIA).

1. **Since you were discharged from the hospital after your stroke (or TIA), have you fallen?**
   ☐ Yes ☐ No

   1a. If yes, did you get injured and need to go to the doctor or emergency room due to a fall?
   ☐ Yes ☐ No

   1b. If yes, have you fallen more than once since your stroke (or TIA)?
   ☐ Yes ☐ No

   1c. If yes, how many times have you fallen?

   Enter a number _____

2. **Since you were discharged from the hospital, have you been hospitalized overnight for any reason?**

   ☐ Yes ☐ No

   2a. If yes, how many times have you been in the hospital overnight for any reason?

   _____

I. **FATIGUE QUESTIONS**: The next few questions are about feelings of tiredness or fatigue.

During the past 7 days how often have you:	Not At all	A little bit	Somewhat	Quite a bit	Very much
1. Felt tired or fatigued?	☐	☐	☐	☐	☐
2. Had trouble starting things because you were tired?	☐	☐	☐	☐	☐
In the past 7 days:	**Not At all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
3. How run-down did you feel on average?	☐	☐	☐	☐	☐
4. How fatigued were you on average?	☐	☐	☐	☐	☐

J. **SATISFACTION WITH CARE QUESTIONS**: The next several questions are about the care you've received from your physicians, nurses and other health care providers since you had your stroke (or TIA).

Thinking about the care you have received for your stroke (or TIA) recovery since you were discharged from the hospital, how often did your physicians, nurses, and other healthcare providers:

	Never	Sometimes	Usually	Always
1. Explain things in a way that was easy to understand?	☐	☐	☐	☐
2. Listen carefully to you?	☐	☐	☐	☐
3. Seem to know the important information about your medical history	☐	☐	☐	☐
4. Show respect for what you had to say?	☐	☐	☐	☐
5. Spend enough time with you?	☐	☐	☐	☐
6. Talk about all the prescription medicines you were taking?	☐	☐	☐	☐

K. **COMMUNITY RESOURCES QUESTIONS**: These next questions are about any community services you have used since your stroke (or TIA).

Thinking back since you were discharged from the hospital after your stroke (or TIA), have you used any of the following services to assist you with your care?

	Yes	No
1. Adult day care programs or other services for social support or recreation for stroke (or TIA) survivors	☐	☐
2. Community services or classes to help with your ability to speak, read, or write (e.g. Aphasia Support Group)	☐	☐
3. Counseling services or therapy for stress or depression (e.g. CareNet counseling)	☐	☐
4. Any programs that promote healthy living, like classes on diet or managing diabetes, chronic pain, problems with breathing, or high blood pressure	☐	☐
5. Exercise classes that are open to the general public, like ones offered at a church or fitness center (e.g. Silver Sneakers, Silver & Fit, Hospital wellness programs)	☐	☐
6. Programs to help you quit smoking	☐	☐
7. Falls prevention program that teaches you how to improve your balance and strength so you don't fall	☐	☐
8. Programs that provide meals (delivered to your house or a central location like a church or community center)	☐	☐
9. A support group for stroke (or TIA) survivors	☐	☐
10. Medication assistance or management services to help pay for the medications or to help understand and manage the medications	☐	☐
11. Transportation services to get you to your healthcare appointments or community activities	☐	☐

12. Support services for your family/caregivers	☐	☐
13. Other services? If yes, describe: _____	☐	☐

L. EDUCATION QUESTION:

1. **What is the highest grade or level of school that you have completed?**
   - ☐ 8th grade or less
   - ☐ Some high school, but did not graduate
   - ☐ High school graduate or GED
   - ☐ Some college or 2-year degree
   - ☐ 4-year college graduate
   - ☐ More than 4-year college degree

M. PRIMARY CAREGIVER: Please verify who is the family member, friend, or neighbor who may have helped you with activities such as shopping and transportation since your recent stroke (or TIA).

THIS IS THE END OF THE SURVEY - THANK YOU!

The website for this study can be accessed at: **https://www.nccompass-study.org/**

If you have any questions about the study, please contact our project manager at 1-844-501-7668.

If you have any questions about your rights as a research study participant, you may contact, anonymously if you wish, the Institutional Review Board. Their job is to protect your rights and welfare as a research participant. They have reviewed and approved this study. You can reach them at 919-966-3113 or by email to IRB_subjects@unc.edu.

Appendix 25 – 90d Patient Non-Responder Survey and Letter (Mailed if unable to reach over phone)

Dear <NAME>, <DATE>

Greetings from the COMPASS Study team! We are working with your care team at <HOSPITAL NAME> to find the best ways to improve healthcare for people who had a transient ischemic attack (TIA), mini-stroke, stroke, or related episode. A few weeks ago we tried calling you and are sorry that we haven't been able to reach you!

We'd like to know how you've been doing since your hospital visit 3 months ago. Your participation is completely voluntary and confidential. Your response is very valuable and will help improve healthcare for others in North Carolina.

How you can participate:

[-] Answer the questions on the next page and mail the completed survey back to us in the postage-paid envelope. Please return it within 5 days.

OR

[-] Contact us, toll-free, at 1-844-501-7668 if you would prefer to answer the questions by phone.

This is your last chance to let us know how you are doing. We need your help and thank you for your valuable contribution!

Find out more about the COMPASS Study:

[-] To learn more about the COMPASS Study please visit our website: www.nccompass-study.org

[-] If you would like to speak with a team member about the study, call us at: 1-844-501-7668

Thanks for filling out the included survey and returning it to us!

Best regards,

The COMPASS Study Team

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

We are sorry to have missed you on the phone. We value your response and hope you will complete this brief questionnaire. Please return it within 5 days in the envelope provided.

A. **PHYSICIAL CHALLENGES SINCE YOUR HOSPITAL VISIT:** These questions are about the physical problems you may have experienced recently because of your stroke or TIA. ("TIA" stands for *transient ischemic attack* and is sometimes referred to as a *mini-stroke, warning stroke, brain episode*, or *brain bleed*.) We want to know ***from your point of view*** how has your stroke or TIA affected your physical function in the past 2 weeks?

In the past 2 weeks, how difficult was it to...	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Could not do at all
Dress the top part of your body?	☐	☐	☐	☐	☐
Bathe yourself?	☐	☐	☐	☐	☐
Get to the toilet on time?	☐	☐	☐	☐	☐
Control your bladder (not have an accident)?	☐	☐	☐	☐	☐
Control your bowels (not have an accident)?	☐	☐	☐	☐	☐
Stand without losing balance?	☐	☐	☐	☐	☐
Go shopping?	☐	☐	☐	☐	☐
Do heavy household chores (e.g. vacuum, laundry or yard work)?	☐	☐	☐	☐	☐
Stay sitting without losing your balance?	☐	☐	☐	☐	☐
Walk without losing your balance?	☐	☐	☐	☐	☐
Move from a bed to a chair?	☐	☐	☐	☐	☐
Walk fast?	☐	☐	☐	☐	☐
Climb one flight of stairs?	☐	☐	☐	☐	☐
Walk one block?	☐	☐	☐	☐	☐
Get in and out of a car?	☐	☐	☐	☐	☐
Carry heavy objects (e.g. bag of groceries) with your affected hand?	☐	☐	☐	☐	☐

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B. **GENERAL HEALTH QUESTIONS**: These questions are about how you perceive or view your general health.

1. **Compared to others your age, how would you rate your health since your stroke or TIA using a scale between 1 and 5 with 1 being "poor" and 5 being "excellent?"**

Poor	Fair	Good	Very Good	Excellent
1	2	3	4	5

2. **Over the next 3 months, do you think your health is going to:**
   - ☐ Improve
   - ☐ Stay the same
   - ☐ Get worse

3. **What was the value of your last blood pressure? Please provide the systolic (top number) and diastolic (bottom number).**

_____ (systolic) / _____ (diastolic)

THIS IS THE END OF THE SURVEY – THANK YOU!

The website for this study can be accessed at: **https://www.nccompass-study.org/**

If you have any questions about the study, please contact our project manager at 1-844-501-7668.

If you have any questions about your rights as a research study participant, you may contact, anonymously if you wish, the Institutional Review Board. Their job is to protect your rights and welfare as a research participant. They have reviewed and approved this study. You can reach them at 919-966-3113 or by email to IRB_subjects@unc.edu.

Appendix 26 - Caregiver Letter (First Attempt)

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Dear <NAME_CG>, <DATE>

Greetings from the COMPASS Study team! We are writing to invite you to participate in our survey. With your help, we hope to understand more about the best way to care for stroke survivors and their families after they go home from the hospital - **to help them find the way forward to recovery**.

We know how important family, friends, and neighbors are during the recovery process. We also understand that it can be difficult to care for loved ones who have had a stroke. Through the COMPASS Study, we hope to learn more about the needs of those who provide care and assistance to stroke survivors.

<PATIENT NAME> has identified you as the person who has been helping <HIM/HER> recover following <HIS/HER> stroke. <HE/SHE> was discharged on <DSCHRGDATE> from <HOSPITAL NAME>, which is participating in the COMPASS study. We invite you to take part in the COMPASS Study by completing a survey about caring for <HIM/HER>. This survey should only take about 15 minutes and is completely voluntary and confidential.

Your input is important and will help us improve support systems for family members and friends who provide care to stroke survivors. Please complete the enclosed survey and send it back in the postage-free envelope we have provided by <Due Date>

Find out more about the COMPASS Study

- To learn more about the COMPASS Study and to find other useful information about care after stroke, please visit our website: **www.nccompass-study.org**
- If you would like to speak with a team member about the study, call us at: 1-844-501-7668

We thank you very much for your time and contribution to the COMPASS Study!

Best regards,
The COMPASS Study Team

<CG_ID>

UNC GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH
Wake Forest Baptist Medical Center

Appendix 27 - Caregiver Survey

CAREGIVER QUESTIONNAIRE

Please complete this questionnaire to the best of your abilities and return it in the enclosed postage-free envelope. If you have questions about the survey, you can contact a COMPASS Study Team Member at 1-844-501-7668.

1. **During the past 3 months, did you help the stroke/TIA survivor with activities like preparing meals, shopping, getting and/or taking medications, scheduling and/or getting to doctor's appointments.**

   O Yes, I helped with these activities → **PROCEED TO QUESTION 2**

   O No, I did not help with these activities

   IF NO, did someone else help? O Yes O No, the stroke survivor did not need help with these activities

   You may stop the survey, please mail this survey back. Thank you for your time!

2. **How are you related to the stroke survivor?** *I am his/her…*

   O Spouse O Neighbor or friend O Brother or sister O Parent or legal guardian O Daughter or son

   O Other, please specify ☐

3. **Since your loved one or friend was discharged from the hospital following his/her stroke, what is the <u>total</u> length of time you provided care for him/her? (check only one)**

   O I have been providing care ever since he/she came home
   O I provided care for 1-2 weeks
   O I provided care for 3-4 weeks
   O I provided care for 5-6 weeks
   O I provided care for 7-8 weeks
   O I provided care for 9-10 weeks
   O I provided care for 11-12 weeks

4. **At the time you were providing the <u>most</u> care, how many hours per week did you spend providing care?**

   O Less than 10 hours per week O 10-19 hours per week O 20-29 hours per week O 30 or more hours per week

5. At any time over the past 3 months, have you provided assistance with the following activities?			Do you need help providing this assistance?		Did you also help with this before the stroke?	
	YES	NO	YES	NO	YES	NO
Bathing/showering	O	O	O	O	O	O
Dressing	O	O	O	O	O	O
Getting out of bed/chair	O	O	O	O	O	O
Helping to/from bathroom	O	O	O	O	O	O
Feeding	O	O	O	O	O	O
Preparing Meals	O	O	O	O	O	O
Shopping	O	O	O	O	O	O
Laundry	O	O	O	O	O	O
Handling Finances	O	O	O	O	O	O
Assistance with housework	O	O	O	O	O	O
Assisting with yardwork /house or car maintenance	O	O	O	O	O	O
Scheduling appointments (doctors, rehab, home health, etc.)	O	O	O	O	O	O
Transportation to pharmacy and medical appointments	O	O	O	O	O	O
Transportation to grocery store, places around town, etc.	O	O	O	O	O	O
Using Medication	O	O	O	O	O	O

☐☐☐☐☐☐

6. Is there anything else that you helped with that is not listed above? O Yes O No

If yes, please describe:

7. Does anyone else provide care for this stroke survivor? O Yes O No

If YES, please indicate who these people are and how they are related to the stroke survivor. ***(Check all that apply)***

O Spouse
O Brother or sister
O Daughter or son
O Neighbor or friend
O Parent or legal guardian
O Other, please specify

8. Below is a list of things that other caregivers have found to be difficult. For each item, please fill in ONE bubble that indicates how often you have found this difficult. We have included some examples that are common caregiver experiences to help you think about each item. Your situation may be slightly different, but the item could still apply.

	Yes, on a regular basis	Yes, sometimes	No
My sleep is disturbed (For example: the person I care for is in and out of bed or wanders around at night)	O	O	O
Caregiving is inconvenient (For example: helping takes so much time or it's a long drive over to help.)	O	O	O
Caregiving is a physical strain (For example: lifting in or out of a chair; effort or concentration is required.)	O	O	O
Caregiving is confining (For example: helping restricts free time or I cannot go visiting.)	O	O	O
There have been family adjustments (For example: helping has disrupted my routine; there is no privacy.)	O	O	O
There have been changes in personal plans (For example: I had to turn down a job; I could not go on vacation.)	O	O	O
There have been other demands on my time (For example: other family members need me.)	O	O	O
There have been emotional adjustments (For example: severe arguments about caregiving.)	O	O	O
Some behavior is upsetting (For example: incontinence; the person cared for has trouble remembering things; or the person I care for accuses people of taking things.)	O	O	O
It is upsetting to find the person I care for has changed so much from his/her former self (For example: he/she is a different person than he/she used to be)	O	O	O
There have been work adjustments (For example: I have to take time off for caregiving duties.)	O	O	O
Caregiving is a financial strain (For example: I have concerns about how I will be able to pay bills.)	O	O	O
I feel completely overwhelmed (For example: I worry about the person I care for.)	O	O	O

9. Please indicate if the caregiver services are available in your area and whether you have used them.

Service	Is this service available in your area?		Have you used this service?	
	Yes	No/Don't Know	Yes	No
Respite: Programs or services that provide short-term care of a few hours or weeks to provide relief to the regular caregiver (family member or friend).	O	O	O	O
Skills Building: Programs or services that help family caregivers gain skills needed to safely provide care for their loved one.	O	O	O	O
Adult Day Care: Programs or services that provide care to disabled adults to help caregivers that may need to work or are not available to provide care during the day.	O	O	O	O
Caregiver Support Group: Groups that provide social support, information, and resources for caregivers.	O	O	O	O
Information and Referral Services: Information about available services and resources to help families/friends in their caregiver roles.	O	O	O	O
Assistance: Assistance gaining access to services from public and private agencies that can help in the care of their loved one.	O	O	O	O

10. What is your age? ☐ **years**

11. What is your gender? O Male O Female

12. What is your race?

O African American O Asian

O White O Other, please specify ☐

O Hispanic O American Indian / Alaskan Native

13. Compared to others your age, how would you rate your health?

O Poor O Fair O Good O Very Good O Excellent

14. Are you aware of the information about caregiver resources that is on the COMPASS website? O Yes O No

Your Name: (optional) ☐

Today's Date ☐☐ ☐☐ ☐☐

MM **DD** **YY**

Thank you very much for completing this survey!

The COMPASS Study Team

☐☐☐☐☐☐

Appendix 28 - Proxy SIS-16

Removed – COMPASS is no longer asking caregiver's questions about the patient. The Proxy SIS-16 has been removed.
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Appendix 29 - Caregiver Letter (Second Attempt)

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Dear <NAME_CG>, <DATE>

Greetings from the COMPASS Study team! We are writing to invite you to participate in our survey. With your help, we hope to understand more about the best way to care for stroke survivors and their families after they go home from the hospital - **to help them find the way forward to recovery**.

We know how important family, friends, and neighbors are during the recovery process. We also understand that it can be difficult to care for loved ones who have had a stroke. Through the COMPASS Study, we hope to learn more about the needs of those who provide care and assistance to stroke survivors.

<PATIENT NAME> has identified you as the person who has been helping <HIM/HER> recover following <HIS/HER> stroke. <HE/SHE> was discharged on <DSCHRGDATE> from <HOSPITAL NAME>, which is participating in the COMPASS study. We invite you to take part in the COMPASS Study by completing a survey about caring for <HIM/HER>. This survey should only take about 15 minutes and is completely voluntary and confidential.

Your input is important and will help us improve support systems for family members and friends who provide care to stroke survivors. Please complete the enclosed survey and send it back in the postage-free envelope we have provided by <Due Date>

Find out more about the COMPASS Study

- To learn more about the COMPASS Study and to find other useful information about care after stroke, please visit our website: **www.nccompass-study.org**
- If you would like to speak with a team member about the study, call us at: 1-844-501-7668

We thank you very much for your time and contribution to the COMPASS Study!

Best regards,
The COMPASS Study Team

<CG_ID>

UNC GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH
Wake Forest Baptist Medical Center

Appendix 30 - Caregiver Thank You Note

Removed – COMPASS will no longer be sending a 10 dollar gift card to caregivers.

Appendix 31 - IRB Approval Letter for PCORI Stakeholder Interviews

WAKE FOREST UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Sabina Gesell, Ph.D.
PHS-Social Sciences

From: Protocol Analyst, Institutional Review Board

Date: 8/4/2015

Subject: Human Protocol: IRB00028495
Stakeholder interviews to shape PCORI Pragmatic Clinical Trial application
Amendment 2 for IRB Study #IRB00028495

Study Documents:
Protocol Version: PCORI Focus Group_Protocol.docx, Protocol_Stakeholder Interviews_v2.doc; Other Documents: PCORI Focus Group_Consent Form_compensated_CLEAN.docx, PCORI Focus Group_Consent Form_not compensated_CLEAN.docx, PCORI Interviewing Script.docx, PCORI Interviewing_Consent Form_v3_CLEAN.docx

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

1. A new protocol for focus groups has been added that will ask more specific questions about the recent developments of the COMPASS Intervention.
2. Two new consent forms that align with the new focus group protocol have been added. One consent form will be for participants that will not be compensated for their time in the study. The other consent form will be for participants that will be compensated for their time in the study.

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.

Jeannie Sekits

Medical Center Boulevard, Winston-Salem, NC 27157-1023 (336) 716-4542 / fax (336) 716-4480

Appendix 32 - DSMB Template Sections

List of Report Sections

1. Executive Summary
2. Protocol Synopsis
    a. Project Organizational Chart
    b. Study Purpose
    c. Projected Timetable And Schedule
    d. List Of Participating Hospitals
3. Narrative & Trial Summary
    a. Study Status
4. Recruitment And Randomization
5. Training
6. Implementation Of The Compass Study And Assessment Of Fidelity
7. Vanguard Hospital
8. Safety And Privacy Of Participants
9. Outcomes
10. Publications
11. Contract Modifications
    a. Recommendations From The DSMB
    b. Summary Of Protocol Changes
12. Recruitment And Participant Status: Figures & Tables
    a. Hospital Recruitment And Randomization
    b. Participant Enrollment And Outcome Ascertainment
13. Data Quality Tables
    a. Study Activity Completion
    b. Quality Analysis Of Implementation
    c. Summary Of Data Form Completion
14. Appendices
    a. Bimonthly Survey For Implementation Site Webinars With Post-Acute Coordinators (Pac) And Advanced Practice Providers (App)
    b. Monthly Performance Report Templates
    c. Bimonthly Survey For Implementation Site Webinars With Home Health And Outpatient Rehabilitation Teams
    d. List Of Publications And Presentations For Compass

Appendix 33 – CTSI Supplemental Proposal (Implementation of COMPASS)

Implementation of an evidence-based chronic disease care model: Identifying individual, organizational, and community facilitators (Gesell / Lutz)

RESEARCH PLAN

Specific Aims:

Aim 1. Evaluate the Reach, Adoption, Implementation, and Maintenance (RE-AIM) of the COMPASS intervention, an evidence-based chronic disease care management model.

Aim 2. Identify individual, organizational, and community factors that facilitate or are challenges to implementation of COMPASS.

Aim 3. Identify strategies to build, maximize, and sustain community resource networks working together with the local hospital-based post-acute care coordination teams to support local implementation of COMPASS.

Design & Methods

Study Design: We will capture quantitative data via (1) bi-weekly questionnaires to the hospital-based post-acute care (PAC) teams and Home Health Outpatient Therapy (HHOP) Teams to capture perceived barriers to uptake, and (2) real-time data on enrollment and performance measures at each site. We also will capture qualitative data via (1) transcription and coding of bi-weekly phone calls with PAC teams, and HOPP team and (2) semi-structured interviews with the Director of Implementation for the COMPASS study and members of the Implementation Committee. These calls will be facilitated by the Director of Implementation for the COMPASS study (S. Coleman) and will allow post-acute care coordinators to problem-solve together. These 4 data sources, collected from 20 health systems over one year, will identify which patient, staffing, and community-level factors drive intervention uptake, challenges to uptake, and how health systems can improve performance on pre-defined performance measures.

Sample: In the COMPASS study, 41 hospitals have been randomized (stratified by stroke volume and primary stroke center status) to receive COMPASS or usual care (control group). The proposed pilot will include the 20 hospitals randomized to receive COMPASS. Roll-out of these 20 intervention sites has occurred in 3 waves (n=5, n=5, n=10), starting in August 2016. Within each wave, hospitals trained together and started implementation at the same time; they also participate in bi-monthly problem-solving calls together. We are adapting strategies after each wave to meet health systems' unique environments and optimize approaches accordingly.

Measurement Framework: The RE-AIM Framework, developed by Glasgow et al (1999), will guide the process evaluation of the implementation of COMPASS. RE-AIM guides the assessment of the **R**each, **E**ffectiveness, **A**doption, **I**mplementation, and **M**aintenance of public health interventions (e.g., policy or programmatic). **Table 1** defines the RE-AIM components for COMPASS. **Table 2 (Appendix)** shows how the RE-AIM framework will guide the proposed process evaluation. Re-Aim has been used to evaluate the implementation of other large trials (e.g., ATTEND https://clinicaltrials.gov/ct2/show/NCT02123875).

Table 1. RE-AIM Components Defined for COMPASS

Reach of intended population	**Effectiveness**	**Adoption** by target staff, settings, or institutions	**Implementation** consistency, and adaptations made during delivery	**Maintenance** of intervention effects in individuals and settings over time

The absolute number, proportion, and representativeness of patients who are enrolled in COMPASS at hospital discharge	The impact of COMPASS on important outcomes, including potential negative effects, quality of life, and economic outcomes	The absolute number, proportion, and representativeness of hospitals and clinicians who are willing to initiate COMPASS	The intervention agents' fidelity to the various elements of an intervention's protocol, including consistency of delivery as intended and the time and cost of the intervention	The extent to which COMPASS becomes institutionalized or part of the routine organizational practices and policies

Data Collection: In this mixed methods design, we will collect quantitative data via (1) bi-weekly questionnaires to the hospital-based post-acute care (PAC) teams and HHOP teams to capture perceived barriers to uptake (see **Appendix** for survey), and (2) how well the clinic is actually implementing the new care model (i.e., real-time data on enrollment and performance measures). We also will capture qualitative data via (1) transcription and coding of bi-weekly phone calls with PAC teams and HHOP Calls (2) semi structured interviews with the Director of Implementation for the COMPASS study and members of the Implementation Committee (see **Table 3**). The bi-weekly calls are facilitated by the Director of Implementation for the COMPASS study (Coleman) and allow PAC teams across the state to problem-solve together. These 4 data sources, collected from 20 health systems over one year, will allow us to triangulate which patient, staffing, and community-level factors drive intervention uptake, which pose challenges to uptake, and which drive health systems' ability to improve performance.

Table 3. Data Sources

Quantitative Data Source	Qualitative Data Source
Bi-weekly questionnaires to the hospital-based post-acute care (PAC) and HHOP teams to capture perceived barriers to uptake	Transcription of bi-weekly phone calls with PAC and HHOP teams to problem solve barriers to uptake
Real-time data on patient enrollment	Semi-structure interviews with the Director of Implementation for the COMPASS study (Coleman, RN)
Real-time data on 6 performance measures	Semi-structured interviews with members of the COMPASS Implementation Committee

Quantitative Data Analysis: Descriptive statistics (e.g., frequencies) will be used to aggregate questionnaire responses.

Qualitative Data Collection and Analysis: PAC team phone calls and interviews with the Director of Implementation and members of the Implementation Committee will be audio recorded and transcribed verbatim by Accukey Transcription (vendor #25466). Transcripts will be de-identified and verified by study investigators. Transcripts will be imported into NVivo for data management and analysis. The transcripts will be coded independently by members of the research team including the PI and Co-PI, and a graduate student research assistant (RA) trained in qualitative research methods. Initially, phone calls and interviews will be coded using open coding procedures as described by Charmaz (2006) and Ryan and Bernard (2003). The research team will meet to discuss the codes identified in the data. Codes will be sorted and categorized into themes that represent the factors that affect implementation (e.g. challenges, facilitators, and strategies). A coding schema will be developed collaboratively by the PI, Co-PI (Gesell / Lutz), and student RA. This schema will be used to code subsequent team meeting transcripts. The coders will meet regularly (monthly) to discuss the ongoing coding and resolve discrepancies. Major themes will be reported with supporting quotations. Credibility of analysis will be enhanced by (1) independent coding; (2) examination of negative cases and situations of considerable agreement or disagreement; (3) qualitative assessment of agreement between coders over time; and (4) discussing the major themes with the PACs in the 3 Waves to get input and feedback (member checking). Our analysis will also include cross-comparisons of subgroups (urban/rural sites, large/small volume sites) to determine differences within a heterogeneous population of health systems.

Table 4. Mapping the RE-AIM framework (Glasgow et al 1999) to the proposed process evaluation

	Reach	Effectiveness*	Adoption	Implementation	Maintenance
Characteristics of enrolled patients (age, language, sex, race, Hispanic, insurance, diagnosis, aphasia, ambulatory status at discharge, NIH stroke score)	X				
PM1. Receipt of follow-up telephone call within 2 business days of hospital discharge				X	
PM2. Receipt of follow-up visit within 7 to 14 days of hospital discharge				X	
PM3. Receipt of e-Care plan during follow-up clinic visit				X	
PM4. Receipt of all home health and outpatient rehabilitation services (including physical therapy, occupational therapy, and speech and language therapy) prescribed at hospital discharge, 2-day follow-up call, or 7-14-day follow-up clinic visit by 30-days after hospital discharge				X	
PM5. Receipt of all home health rehabilitation services (including physical therapy, occupational therapy, and speech and language therapy) prescribed at hospital discharge, 2-day follow-up call, or 7-14-day follow-up clinic visit by 30-days after hospital discharge				X	
PM 6. Receipt of all outpatient rehabilitation services (including physical therapy, occupational therapy, and speech and language therapy) prescribed at hospital discharge, 2-day follow-up call, or 7-14-day follow-up clinic visit by 30-days after hospital discharge				X	
Characteristics of enrolled health systems (size, location, Comprehensive Stroke Center certification)			X		
Characteristics of PAC teams (number of FTE, license, etc)			X		
Characteristics of Community Resource Networks			X		
Characteristics of clinical staff participating in bi-weekly problem solving calls			X		
Challenges with enrollment, 2 day call, 14 day visit, e care plan, receipt of therapy, community resource network, administrative tasks				X	
Requests for additional training				X	
Time it takes to integrate COMPASS components into system (ramp up)					X
What are sites doing to maintain COMPASS? What are they changing? Are they returning to their original model of care?					X
90-day outcomes and claims data are part of the COMPASS trial, not this pilot		*X			
PM = Performance Measure					

Appendix 34 – 2Day Disposition Form

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

2-Day Call Disposition Form

ID Number: [ ][ ][ ][ ][ ] Form Code: [C][D][S][P][ ] Date: 07JUN2016 Version 1.0

ADMINISTRATIVE INFORMATION (0a-0c are auto-populated)

0a. Completion Date: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (Month / Day / Year) 0b. Staff ID: [ ][ ][ ][ ][ ]

1. Did you complete a follow-up call with the patient or caregiver after the patient was discharged from the hospital?
   - ☐ Yes → **Go to Q1a**
   - ☐ No → **Go to Q1b**

1a. What was the date this call was conducted?

[ ][ ] / [ ][ ] / [ ][ ][ ][ ] (Month / Day / Year)

2b. Reason for no follow-up call:

- ☐ Did not attempt call
- ☐ Could not reach patient/caregiver after 2 attempts
- ☐ Patient/caregiver refused
- ☐ Patient/caregiver could not complete (e.g. confused, unable to communicate, too sick, etc.)
- ☐ Patient/caregiver did not have workable number
- ☐ Patient hospitalized
- ☐ Patient transferred to a skilled nursing facility
- ☐ Patient deceased
- ☐ Other (specify) _____

END OF 2-DAY CALL DISPOSITION FORM

Appendix 35 – Clinic Disposition Form

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Clinic Visit Disposition Form

ID Number: | | | | | | Form Code: | V | D | S | P | | Date: 10Feb2017 Version 2.0

ADMINISTRATIVE INFORMATION (0a-0c are auto-populated)

0a. Completion Date: | | / | | / | | | | | Month / Day / Year

0b. Staff ID: | | | | | |

1. Was the follow-up clinic visit conducted?
   - ☐ Yes → **Go to Q1a**
   - ☐ No → **Go to Q1b, then END OF FORM**

1a. Date of clinic visit: | | / | | / | | | | |

1b. If no visit was completed, select reason:
   - ☐ Visit **NOT** scheduled: Patient prefers to follow-up with his/her own PCP or another doctor
   - ☐ Visit **NOT** scheduled: Patient reported that he/she is too sick or disabled to attend
   - ☐ Visit **NOT** scheduled: Patient cannot afford to attend the scheduled visit
   - ☐ Visit **NOT** scheduled: Patient does not have transportation
   - ☐ Visit **NOT** scheduled: Patient reported that he/she lives out of the area and doesn't want to travel
   - ☐ Visit was scheduled, but patient did not attend
     - Transportation Issues
     - No insurance coverage for visit
     - Conflicting medical appointment
     - Patient/caregiver preferred not to drive a long distance for the follow-up visit
     - Patient cancelled
     - No show / reason unknown
     - Other:_____
   - ☐ Patient transferred to nursing home
   - ☐ Patient hospitalized
   - ☐ Patient deceased
   - ☐ Other _____

2. Was the Stroke Caregiver Assessment triggered by the Post-Stroke Functional Assessment?
   - ☐ Yes → **Go to Q2a**
   - ☐ No

2a. Was it performed?

- ☐ Yes
- ☐ No → **Go to Q2b**

2b. Why not?

- ☐ Primary caregiver not present
- ☐ Primary caregiver refused

3. Was the eCare Plan generated?

- ☐ Yes, electronically on the iPad → **Go to Q3a**
- ☐ No → **Go to Q3b**

3a. Was the eCare Plan printed and shared with the patient?

- ☐ Yes
- ☐ No

3b. Reason for no eCare Plan:

- ☐ Acute change of patient's status requiring emergent care
- ☐ Technical error / server problem
- ☐ Clinic workflow wouldn't allow generation of eCare Plan
- ☐ Other _____

4. Is the patient in need of any rehabilitation services that they are not currently receiving?

- ☐ Yes → **Go to Q4a**
- ☐ No

4a. What referrals were made after the clinic visit (check all that apply)?

- ☐ Home health PT
- ☐ Home health OT
- ☐ Home health SLP
- ☐ Outpatient PT
- ☐ Outpatient OT
- ☐ Outpatient SLP

5. Were referrals made to any pharmacy-based services?

- ☐ Yes → **Go to Q5a**
- ☐ No

5a. Which services (check all that apply)?

- ☐ Community Care of North Carolina (CCNC) pharmacy network
- ☐ Local pharmacy outside of the CCNC pharmacy network
- ☐ Free clinic with on-site pharmacist
- ☐ Hospital-based pharmacist follow-up

6. Were referrals made to community resources such as Area Agency on Aging, support groups, etc. (check all that apply?)

☐ Yes → **Go to Q6a**

☐ No

6a. Which community services (check all that apply)?

- ☐ Adult Services/Social Support Services
- ☐ Stroke Support Group
- ☐ Counseling Services for stress, depression (e.g. CareNet)
- ☐ Chronic Disease Management Programs
- ☐ Community Exercise Programs
- ☐ Falls Prevention Programs
- ☐ Nutrition Assistance Programs
- ☐ Aphasia Support Group
- ☐ Smoking Cessation Program
- ☐ Transportation Services
- ☐ Caregiver Support Services
- ☐ Other Services: _____

END OF CLINIC VISIT DISPOSITION FORM

Appendix 36 – Phase 2 Patient Brochure for Sustaining COMPASS Hospitals

Your recent hospital visit means that you are eligible for the COMPASS Study.

Your hospital is participating in a statewide study called the Comprehensive Post-Acute Stroke Services (COMPASS) Study. This study includes people who have had a stroke or transient ischemic attack (TIA), sometimes referred to as a mini-stroke. The purpose of the COMPASS Study is to determine the best ways to care for patients after they go home – to help survivors find their way forward to recovery.

Our hospital is providing the COMPASS model of post-acute care, which includes:

- A follow-up phone call 2 days after discharge
- A visit with a nurse practitioner, physician assistant, or doctor 7-14 days after discharge
- A plan of care that will be shared with your other health care providers
- Additional follow-up phone calls 30 and 60 days after discharge

We are committed to finding the best way to improve health and recovery after experiencing this health episode. In addition to the COMPASS care, you will continue to receive high-quality care at our hospital and at your usual follow-up visits with your primary care doctors.

After you have left the hospital, the COMPASS team would like to learn about your overall experience. They will:

- Call you in 3 months to ask questions about your recovery and satisfaction with your care.
- Mail you 3 reminder letters before you are called. The last letter will include a small gift to thank you for your time, so be sure to open it.

Whether or not you choose to participate in the survey, our hospital is committed to providing you with high-quality care for you during your recovery. All information provide will be kept strictly confidential and secure.

If you have any questions about the COMPASS Study, or prefer not to participate, feel free to ask the stroke coordinator, or you may call the COMPASS Study team using the toll-free number below.

COMPASS Study toll-free number: 1-844-501-7668
COMPASS Study website: www.nccompass-study.org

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Appendix 37 – Phase 2 Patient Brochure for Intervention Sites (formerly Usual Care)

Your recent hospital visit means that you are eligible for the COMPASS Study.

Your hospital is participating in a statewide study called the Comprehensive Post-Acute Stroke Services (COMPASS) Study. This study includes people who have had a stroke or transient ischemic attack (TIA), sometimes referred to as a mini-stroke. The purpose of the COMPASS Study is to determine the best ways to care for patients after they go home – to help survivors find their way forward to recovery.

Our hospital is providing the COMPASS model of post-acute care, which includes:

- A follow-up phone call 2 days after discharge
- A visit with a nurse practitioner, physician assistant, or doctor 7-14 days after discharge
- A plan of care that will be shared with your other health care providers
- Additional follow-up phone calls 30 and 60 days after discharge

We are committed to finding the best way to improve health and recovery after experiencing this health episode. In addition to the COMPASS care, you will continue to receive high-quality care at our hospital and at your usual follow-up visits with your primary care doctors.

After you have left the hospital, the COMPASS team would like to learn about your overall experience. They will:

- Call you in 3 months to ask questions about your recovery and satisfaction with your care.
- Mail you 3 reminder letters before you are called. The last letter will include a small gift to thank you for your time, so be sure to open it.

Whether or not you choose to participate in the survey, our hospital is committed to providing you with high-quality care for you during your recovery. All information provide will be kept strictly confidential and secure.

If you have any questions about the COMPASS Study, or prefer not to participate, feel free to ask the stroke coordinator, or you may call the COMPASS Study team using the toll-free number below.

COMPASS Study toll-free number: 1-844-501-7668
COMPASS Study website: www.nccompass-study.org

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Appendix 38 – Phase 2Enrollent Form

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Participant Enrollment Form

ID Number: ☐☐☐☐☐ Form Code: E N R ☐ Date: 2NOV2017 Version 2.0 (Phase 2)

ADMINISTRATIVE INFORMATION (auto-populated)

0a. Completion Date: ☐☐ / ☐☐ / ☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐☐☐

0c. NCSCC ID: ☐☐☐☐☐☐☐☐☐☐ 0d. Hospital ID: ☐☐☐ 0f. Form Status: ☐

A. PATIENT CONTACT INFORMATION

1. Patient full name _____ (First) _____ (Middle) _____ (Last)

2. Telephone number(s)

a. Primary number: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

Best time to call: ☐ Weekday daytime ☐ Weekday evening ☐ Weekend ☐ Anytime

b. Alternate 1: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

Best time to call: ☐ Weekday daytime ☐ Weekday evening ☐ Weekend ☐ Anytime

c. Alternate 2: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

Best time to call: ☐ Weekday daytime ☐ Weekday evening ☐ Weekend ☐ Anytime

4. Home address

_____ Address line 1

_____ Address line 2

_____ City State Zip County

B. CAREGIVER INFORMATION

Does the patient have a caregiver (i.e., a family member or friend who will help them with their recovery, for example, in preparing meals, shopping, getting or taking medications, scheduling or transporting to doctor appointments).

☐ Yes ☐ No ☐ Don't know

C. ADDITIONAL CONTACT INFORMATION

☐ Patient unable or unwilling to provide an additional contact / not documented → **Go to Question 16**

12. Full name

First _____ Middle _____ Last _____

13. Telephone numbers

a. Primary number: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

b. Alternate 1: (☐☐☐) ☐☐☐ - ☐☐☐☐

Type: ☐ Home ☐ Mobile ☐ Work ☐ Other _____

c. Alternate Mailing Address

_____
Address Line 1

_____
Address Line 2

_____
City State Zip

15. Relationship to patient?

☐ Spouse (husband or wife)
☐ Sibling
☐ Son or daughter
☐ Friend or neighbor
☐ Parent or legal guardian
☐ Other, specify: _____

D. DEMOGRAPHIC AND IN-HOSPITAL DATA

16. Patient gender: ☐ Male ☐ Female

17. Patient race (*check all that apply*):

- ☐ White
- ☐ Black / African American
- ☐ Asian
- ☐ American Indian / Alaska Native
- ☐ Native HI / Other Pacific Islander
- ☐ Unknown
- ☐ Other: _____

18. Hispanic ethnicity: ☐ Yes ☐ No

19. Insurance *(check all that apply)*:

- ☐ Medicare (traditional fee-for-service)
- ☐ Medicare Advantage
- ☐ Medicare Supplemental Insurance / Medigap
- ☐ Medicaid
- ☐ Private insurance
- ☐ VA / Champus / other
- ☐ Uninsured / self-pay

20. Does the patient have documented past medical history of the following *(check all that apply)*:

- ☐ Stroke
- ☐ Transient ischemic attack
- ☐ Atrial Fibrillation or Flutter
- ☐ Myocardial infarction or CAD
- ☐ Congestive heart failure
- ☐ Carotid stenosis
- ☐ Peripheral arterial disease
- ☐ Hypertension
- ☐ Dyslipidemia
- ☐ Smoking
- ☐ Depression
- ☐ Drug/alcohol abuse
- ☐ Family history of stroke
- ☐ Migraines
- ☐ Chronic renal insufficiency
- ☐ Heart Valve
- ☐ Current pregnancy or within 6 weeks post-partum
- ☐ Hormone replacement therapy
- ☐ Sickle cell
- ☐ Sleep apnea
- ☐ Diabetes mellitus

21. Please enter the body mass index (BMI). _____ kg/m^2 ☐ Not documented

22. What was the patient's ambulatory status <u>prior to admission</u>?

- ☐ Able to ambulate independently (with or without a device)
- ☐ With assistance (from person)
- ☐ Unable to ambulate
- ☐ Not documented

23. Initial NIH Stroke Scale Score (00-42) _____ ☐ Not documented

25. Did the initial exam show aphasia? ☐ Yes ☐ No / not documented

26. Hospital admission date for this event: ☐☐ / ☐☐ / ☐☐☐☐

☐ No admission date; patient was not admitted as an inpatient (select reason below)

- ☐ Discharged directly from ED to home
- ☐ Discharged from observation status without inpatient admission
- ☐ Other reason

27. Was the patient referred for rehabilitation services after discharge? ☐ Yes → **Go to 27a** ☐ No → **Go to 27**

27a. If YES, check all that apply:

☐ Home health Physical Therapy
☐ Home health Occupational Therapy
☐ Home health Speech Therapy
☐ Outpatient Physical Therapy
☐ Outpatient Occupational Therapy
☐ Outpatient Speech Therapy

27b. If NO, indicate why not

☐ Patient not evaluated for need of rehab services
☐ Patient not in need of rehab services
☐ Patient / family refused
☐ Other reason

28. What was the patient's ambulatory status <u>at discharge</u>?

☐ Able to ambulate independently (with or without a device)
☐ With assistance (from person)
☐ Unable to ambulate
☐ Not documented

30. Hospital discharge date: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

31. Was a follow-up clinic visit with a nurse, nurse practitioner, or physician assistant (i.e. primary care, transitional care clinic, neurologist, or other doctor visit) scheduled prior to discharge?

☐ Yes → **Fill in type and date below**
☐ No

31a. If YES, check all visit types that apply and enter the date (if known)

☐ Primary care ☐☐/☐☐/☐☐☐☐
☐ COMPASS clinic visit ☐☐/☐☐/☐☐☐☐
☐ Other transitional care visit with nurse and APP ☐☐/☐☐/☐☐☐☐
☐ Other transitional care visit with primary care ☐☐/☐☐/☐☐☐☐
☐ Rehab ☐☐/☐☐/☐☐☐☐
☐ Neurologist ☐☐/☐☐/☐☐☐☐
☐ Cardiologist ☐☐/☐☐/☐☐☐☐
☐ Other _____ ☐☐/☐☐/☐☐☐☐

32. Name of patient's primary care provider: _____ ☐ Not known

34. Did the PAC notify the patient of the COMPASS study by distributing the brochure?

- ☐ Yes, distributed the brochure in person → **Fill in date below**
- ☐ Yes, mailed brochure to patient → **Fill in date below**
- ☐ No

If YES, enter date of notification or mailing: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

END OF PARTICIPANT ENROLLMENT FORM

Appendix 39 – Consent Matrix

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

MEMORANDUM

To:	**Wake Forest Health Sciences IRB**
From:	**Mysha Sissine, MSPH**
Date:	**May 12, 2016**
Subject:	**Outlines how data from COMPASS will be used for research purposes**

The COMPASS Study is enrolling all eligible patients from participating hospitals. All patients are informed about the study and they are enrolled. This is done prior to gaining explicit consent from the patient. This is permissible because of the low-risk nature of the study and meeting the criteria for HIPAA Waivers.

Recognizing that this process is novel and different from other traditional approaches to consent, the study team worked through a number of scenarios to better define who is included in research analysis and who is excluded. That is detailed in the consent matrix on the next page.

Like all other studies, COMPASS patients can opt out (or withdraw) from the study at any time. At four time points COMPASS letters are provided to each enrolled patient and each letter includes information on how they can opt-out from the study (a brochure, 30d letter, 60d letter, & 80d letter).

In determining what data were acceptable to use for analysis, our team considered both the regulatory requirements and additional protections to conservatively maintain the rights and welfare of study participants. In particular, we determined that we would not use any data past the eligibility screening form from patients who withdrew from the study regardless of the time point of withdrawl. This is more stringent from the regulation, which says that studies can use data up until the point that a patient withdraws. However, since COMPASS is not explicitly gaining consent prior to enrollment (instead we are relying on the patient to out-out) we will make the assumption that if someone was to opt-out (i.e. withdraw) that same patient would not have initially provided consent to be enrolled.

In addition, if a patient withdrawals from the study (again at any time point) that withdrawal will also remove that patient's clinical data from research analysis, even if that patient had provided signed clinical consent (at the 7-14 day visit). This was put in place because the study team made the conservative estimate that a study patient would not be able to adequately distinguish between the two consent processes and articulate their wish to withdraw from some but all parts of the study.

COMPASS
COMPREHENSIVE POST-ACUTE STROKE SERVICES

Data Usage for Research Purposes

Data Form	Covered by	Rules for Use	Exclusions from Analysis
ELG	Limited HIPAA waiver	All patients (includes patients who withdrew).	
ENR	Full HIPAA waiver	All patients, except any patients who withdrew from the study (at any time point).	Withdraw=1
NCSCC	Full HIPAA waiver	All patients, except any patients who withdrew from the study (at any time point).	Withdraw=1
2-d call	eCare consent	Include all patients who provided signed "clinic consent" and who have not withdrawn.	Research_consent ^=1 | withdraw =1
Clinic forms	eCare consent	Include all patients who provided signed "clinic consent" and who have not withdrawn.	Research_consent ^=1 | withdraw =1
eCare Plan	eCare consent	Include all patients who provided signed "clinic consent" and who have not withdrawn.	Research_consent ^=1 | withdraw =1
30-d Call	eCare consent	Include all patients who provided signed "clinic consent" and who have not withdrawn.	Research_consent ^=1 | withdraw =1
60-d Call	eCare consent	Include all patients who provided signed "clinic consent" and who have not withdrawn.	Research_consent ^=1 | withdraw =1
90-d Data	90-d verbal consent	All patients, except any patients who withdrew from the study (at any time point).	Withdraw=1
Claims data	Full HIPAA waiver	We have a HIPAA Waiver to collect claims data on all patients. *The data that we are using to link is from the COMPASS Dataset. Here is our linkage plan:* • ELG form: We will use patient data from all records even if they withdrew from the study. • ENR form: We will use patient data to link them as long as they have not withdrawn from the study (at any time point).	
2-d Dispo	Full HIPAA waiver	All patients, except any patients who withdrew from the study (at any time point).	Withdraw=1
Clinic Dispo	Full HIPAA waiver	All patients, except any patients who withdrew from the study (at any time point).	Withdraw=1