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RESEARCH ARTICLE

Follow-up of Patients With Stroke Based on Opt-out Choice

Potential Approach for Acute Care Quality Registries or Observational Studies

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Abstract

Background and Objectives

Restricting follow-up assessment of both interventional and observational studies to patients who provide informed consent introduces relevant selection bias—particularly by underrepresenting patients with neurologic communication deficits and impaired capacity to consent. Many patients who are initially unable to give consent may be willing to do so after recovery. Informing patients on study purposes and procedures with offering them the option of nonparticipation but not requesting explicit consent is called "opt-out" approach. We investigated whether an opt-out strategy yields meaningful follow-up rates in an acute stroke registry with an embedded controlled study.

Methods

The citywide Berlin–SPecific Acute Treatment in Ischemic or hAemorrhagic Stroke With Long Term Follow-up (B-SPATIAL) registry was designed to provide reliable information on process indicators and outcomes of specific acute stroke treatments to inform health care providers about quality of care and best practice strategies including the effects of a mobile stroke unit implementation. Because this information was regarded of high public interest, Berlin data protection authorities permitted data sampling without prior informed consent, using instead follow-up assessment on an "opt-out" basis. Patients were included if they had neurologic symptoms at ambulance or hospital arrival within 6 hours of onset and had a final diagnosis of stroke or TIA. Information on data collection and outcome assessment was sent by letter to patients 1 month before follow-up.

Results

From February 1, 2017, to January 31, 2020, a total of 10,597 patients were assessed. Thirty-one (0.3%) patients declined any data use, whereas 578 (5.5%) opted out of follow-up assessment. Of those not opting out (n = 9,988), functional outcome (modified Rankin Scale) was collected in 8,330 patients (83.4%) and vital status in 9,741 patients (97.5%). We received no complaints regarding data collection procedures.

Discussion

Opt-out–based follow-up collection offers a way to achieve high follow-up rates along with respecting patients' preferences.

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The Berlin–SPecific Acute Treatment in Ischemic or hAemorrhagic Stroke With Long Term Follow-up (B-SPATIAL) registry coinvestigators are listed in the appendix at the end of the article.

Glossary

B_PROUD = Berlin_PRehospital Or Usual Delivery of acute stroke care; **B-SPATiAL** = Berlin–SPecific Acute Treatment in Ischemic or hAemorrhagic Stroke With Long Term Follow-up; **EMS** = emergency medical services; **EVT** = endovascular treatment; ***ICD-10*** = *International Classification of Diseases, Tenth Revision*; **MSU** = mobile stroke unit; **PHANTOM-S** = Prehospital Acute Neurological Treatment and Optimization of Medical care in Stroke.

Participation in both interventional and observational outcome studies is almost exclusively restricted to patients who give informed consent. However, this restriction on study inclusion implies that relevant public health questions cannot be answered for several reasons: First, the informed consent procedure introduces a selection—and thus most likely a selection bias—by excluding patients either not willing to participate or simply not accessible for informed consent procedures.[1] Second, the time-consuming procedure poses an ethical dilemma in emergency care scenarios with time-critical treatments.[2] Finally, it excludes patients not being able to give informed consent because of impaired consciousness and communication deficits,[3,4] which is a frequent condition particularly in acute neurologic diseases such as stroke.[1,5,6] This contrasts the urgent need for new treatment options in life-threatening emergencies and the perception that many patients would accept participation in observational or low-risk intervention studies.[7,8]

Similar to other stroke studies with outcome assessment,[5,9] we failed to achieve an acceptable informed consent rate for follow-up of 3-month functional outcome in the Prehospital Acute Neurological Treatment and Optimization of Medical care in Stroke (PHANTOM-S) trial.[9,10] Although the primary outcome of alarm-to-thrombolysis time with almost complete documentation was found to be significantly shorter in patients cared for by the Berlin Mobile Stroke Unit (MSU), no reliable conclusions on effects on functional outcome could be drawn from modified Rankin Scale (mRS) information that was available in only 58% of patients in this study. This low follow-up rate was mainly caused by the fact that patients not cared for by the MSU but treated in different hospitals did not provide informed consent because of heterogeneous on-site informed consent procedures and hospital staff often inexperienced in clinical research with insufficient inclusion of eligible patients due to time constraints. Missing informed consent was mostly explained by shortage of time of hospital staff, patient-related inability to consent for neurologic communication deficits, and unavailability of legal representatives.

Hence, when we planned the subsequent trial assessing functional outcome as the primary outcome in 2015,[11] we had to overcome the barrier of low follow-up rates with traditional study inclusion algorithms. In the meantime, MSU services were integrated into the regular emergency medical services (EMS) in Berlin under the condition of a parallel scientific evaluation of clinical outcomes. At the same time, several urgent questions regarding organization and quality of stroke care arose also beyond the direct scope of the planned trial, particularly in light of the new endovascular treatment (EVT) trials.[12-14] This included the issue of treatment delays with possible outcome disadvantage in patients qualifying for EVT primarily delivered to a nearby non–EVT-capable local stroke unit and requiring a secondary transfer to an EVT-capable stroke center. The same applied to patients with intracerebral hemorrhage delivered to hospitals with or without neurosurgery and neurointensive care, despite less robust evidence.

In these 2 patient groups, a high proportion is not able to provide timely informed consent because of severe neurologic deficits, which introduces a major bias if only patients with informed consent are followed up. To address these different research questions and in agreement with the data protection authorities in Berlin, we developed the concept of a prospective acute stroke registry using prehospital and in-hospital (independent of the mode of transport to the hospital) routine care data and an opt-out–based follow-up assessment. In this article, we describe the design of the registry and report on performance indicators such as follow-up rates, representativeness, and frequency of opt-out decisions or complaints.

Methods

This is an observational study exploring the feasibility and follow-up rates of an opt-out approach used in a German citywide stroke registry.

Aims of the Registry

In Germany, quality assessment of acute stroke care is organized in regional stroke registries. These registries are restricted to the documentation of in-hospital process quality and outcomes. Hence, questions of intersectoral quality of care—particularly prehospital stroke management—cannot be addressed on the basis of these regularly established registries. Within the ongoing Berlin–SPecific Acute Treatment in Ischemic or hAemorrhagic Stroke With Long Term Follow-up (B-SPATIAL) registry (NCT03027453), we aimed to assess the quality of acute stroke care regarding several topics of acute stroke care in general and in the local Berlin setting. These included the influence of hospital-specific indication processes on treatment rates, the impact of the transport of specific stroke subtypes to highly specialized neurointerventional or neurosurgical facilities, the influence of EVT volumes on process and outcome quality, and the associations of MSU dispatch vs conventional prehospital care on functional outcome.

The following types of variables were documented: demographics, comorbidities, neurologic symptoms, time metrics,

hospital outcomes, vital and residential status, as well as functional outcome and quality of life at 3 months.

Regulatory Aspects of the Registry

The main barrier for achieving acceptable follow-up rates in the PHANTOM-S study was the need of explicit informed consent for 3-month follow-up assessment. The informed consent collection was compromised by the fact that patients were delivered to a high number of Stroke Unit Hospitals in Berlin, many of them without experience in study inclusion and not having resources for the time-consuming informed consent procedure. In B-SPATiAL, we therefore aimed at data assessment independent of conventional informed consent. In the German Data Protection Legislation[15] and in the Berlin State Data Protection Act,[16] use of personal data for research purposes is generally bound to informed consent of participants. Both legislations allow the use of personalized data without explicit consent if (1) it is necessary to comply with another legal requirement and/or (2) the public interest in such matters clearly exceeds the personal interest, and the aim of the investigation cannot be achieved with alternative approaches. In addition, safeguards to protect the individual right of informational self-determination and privacy have to be implemented. The Berlin Hospital Act (Landeskrankenhausgesetz Berlin[17]) allows hospital-based researchers the use of patient data acquired and stored as part of regular patient care for research purposes within their own facility.

As the above-listed main topics of the registry were important questions of intersectoral quality assurance and were deemed to be of high public interest—particularly for future organization of EMS in Berlin—we approached the Berlin State Data Protection Commissioner for further exploration of prerequisites for the respective data collection. The Data Protection Commissioner agreed in principle but emphasized that the registry could only be approved under narrow conditions as listed in Table 1.

In summary, the collection of data regarding the quality of care for quality assessment purposes was allowed on an opt-out basis in a decentralized, yet standardized way of assessments with ample room for patients to object the data collection on more than 1 occasion. The different pathways of data collection in the PHANTOM-S trial and the B-SPATiAL registry are depicted in eFigure 1, links.lww.com/WNL/C230.

Patients

Patients were included if they fulfilled the following criteria: Final (hospital-based) diagnosis of ischemic or hemorrhagic stroke with *ICD-10* codes of I63, I62, and I61 or with a TIA diagnosis (*ICD-10*: G45.0-G45.3 and G45.5-G45.9), time of symptom onset within 6 hours of hospital arrival, and persistent neurologic symptoms at EMS or hospital arrival. To monitor intravenous thrombolysis (IVT) treatment rates of stroke mimics, we additionally included patients with other diagnoses who had neurologic symptoms and received IV thrombolysis (OPS 8-020.8 according to the German DRG coding system).

Outcome Measures

Measures of process quality included rates of specific treatments (IVT, EVT in ischemic stroke, anticoagulation reversal, and surgical treatment in intracerebral hemorrhage) and secondary referral, time metrics from symptom onset or emergency call to first cranial imaging and treatment start of IVT and EVT, type of anesthesia in EVT (general anesthesia or conscious sedation), and short-term complications. Outcome was assessed by in-hospital mortality, 3-month mRS, 3-month residential situation, and 3-month quality of life as assessed with the European Quality of Life–5 dimensions questionnaire.

Documentation Concept

All Berlin hospitals with a Stroke Unit and the Berlin Fire Department employed individual project-specific trained study nurses who received standardized training and participated in frequent team meetings to keep differences in data collection to a minimum. They documented all predefined data mainly from hospital electronic records and sometimes from paper-based patient files. If patients were identified as a stroke suspect at the dispatcher level, information on prehospital care—with or without MSU—was forwarded from the central database of the Berlin Fire Brigade being responsible for the Berlin Dispatch Center and organization of

Table 1 Conditions for the Intersectoral Stroke Registry With Opt-out–Based Follow-up Assessment in Berlin

Confirmation of high public interest for the planned evaluations by the Berlin State Administration/Senate
Transfer of personalized data only along the care pathway of patients (from emergency medical care to the primary admission hospital and in case of referral to the secondary hospital)
Transfer of pseudonymized data to the central registry server preventing patient identification outside the facilities directly involved in the patient's care
Provision of comprehensive information to patients or their legal representatives on the purpose and content of the registry as well as on his/her privacy rights
Provision of an opt-out choice for follow-up assessment or total data collection Provision of a choice for patients regarding the form of follow-up (either telephone assessment or written questionnaire)
Restriction of data collection to information required for the evaluation of quality aims
Implementation of all legally required measures to ensure data security with regard to data transfer, data storage, and access authorization
Monitoring of acceptance by the evaluation of opt-out rates and complaints

emergency medical care to the receiving hospital. Stroke patients who were not identified as stroke suspects at the dispatcher level were identified at the hospital level by the respective study nurses through their final diagnosis.

Follow-up assessment was decentral as conducted by study nurses in the first treating participating hospital. The medical staff of the participating hospitals was asked to hand out the patient information regarding data collection to patients at the time of discharge. After screening of the vital status through online access to the registration office, patient information was sent again 2 months after the index event to the patient's home address. If no opt-out information or choice of alternative questionnaire-based follow-up was received after 3 months of index event, patients were phoned for a structured follow-up interview. Before starting the interview, study nurses checked whether the attending person was the respective patient or authorized to provide information. If a patient could not be reached for a follow-up interview or questionnaire, 4 months after the index event, information on vital status and residential situation was retrieved from registration offices.

The B-SPATiAL registry was also designed to inform the Berlin_PRehospital Or Usual Delivery of acute stroke care (B_PROUD) study evaluating the effects of MSU care on functional outcome. The use of the quality registry information for research purposes required additional ethics approval. In case a patient was included in the B_PROUD study,[11] he/she was asked whether part of the interview could be recorded for final functional outcome rating by mRS-certified raters blinded to MSU treatment status to maintain the blinded evaluation of the outcome.

Patient Information

Patients were informed about the purpose and basic structure of the registry and that follow-up assessment was planned 3 months after their index stroke/TIA admission. Particular emphasis was given to the description of the follow-up procedure with preferred telephone interview and planned recording in case of being included in the MSU outcome study (B_PROUD). Along with the patient information, they received data protection information describing patients' rights and giving information about the current laws of data use applying to the registry. In a response form, patients or their legal representatives could express choices of requesting total deletion of their individual registry data, opt out from 3-month follow-up assessment, or request of a written questionnaire instead of a telephone call. They could also communicate preferred times for follow-up calls. Feedback information was accepted regardless whether it was shared through the response form, email, or telephone. Finally, patients could decline the follow-up assessment at any time of the telephone-based interview. The original information sheet for patients, response form, and data protection information, as well as unofficial translations of the information sheet for patients and response form, are available in the eAppendix, links.lww.com/WNL/C231.

Technical Resources

All data were entered in a pseudoanonymized manner in a central databank through virtual private network protected remote access from dedicated workspaces in the participating hospitals. Pseudonyms were used with registry logs safely stored in each hospital. Reidentification was therefore eventually only possible within the local hospitals. We used REDCap databank software (Vanderbilt University, Nashville, TN) with access from all participating hospitals through dedicated computers protected by encryption and password algorithms. The registry databank was stored and hosted on a protected server of the Charité IT department.

Safeguards Regarding Adherence to Data Protection Requirements

As requested by the State Data Protection Commissioner, patient information ought to be redundantly delivered to the patients—at the time of discharge and again 2 months after the index event. To monitor the acceptance of the chosen approach, we evaluated decline and opt-out rates in monthly intervals. Potential complaints regarding the opt-out approach for outcome assessment had to be systematically recorded and resolved. Major complaints had to be reported to the institutional data protection officer.

Standard Protocol Approvals, Registrations, and Patient Consents

The design of the registry was completed according to the advice of the Berlin State Data Protection Commissioner and then submitted to the institutional data protection officer of the Charité–Universitätsmedizin Berlin as the lead research institution. Afterward, the methodology of the registry was sent to the data protection officers of the Berlin Fire Department and all participating hospitals. After approval of the documentation processes in the respective institutions, we received ethics approval for the B_PROUD study that is based on the B-SPATiAL registry by the institutional review board of the Charité–Universitätsmedizin Berlin (EA4/109/15). The Charité Institutional Review Board also approved the scientific evaluation of routine care data of the registry (EA1/208/21).

Statistics

The results are provided as descriptive analysis. SPSS Version 25.0 (IBM, Armonk, NY) was used for statistical analyses. Metric data are presented as mean ± SD for age or medians with interquartile range because of non-normal distribution for other continuous variables and were compared using the Mann-Whitney *U* test. Categorical data were compared using the χ^2 test or Fisher exact test as appropriate. All tests were performed at $\alpha = 0.05$ level of confidence and were 2-sided.

Data Availability

Deidentified data will be stored for 10 years at the research facility. After publication of the ongoing analyses of the B-SPATiAL registry and the B_PROUD study (projected over the next 2 years), anonymized data will be made available

on reasonable request of any qualified investigator for purposes of replicating procedures and results.

Results

After a pilot phase during which we had tested the data collection procedures in patients treated at the Charité University Hospital in June 2016, the registry was rolled out to other hospitals on February 1, 2017. The enrollment, patient information, opt out, and outcome assessment processes are depicted in Figure 1.

As of January 31, 2020, a total of 10,597 patients were recruited into the B-SPATiAL registry. Of these, 31 (0.3%) declined the use of their data for the registry, and their records were deleted completely from the database except for leaving the entry number. On May 25, 2018, the General Data Protection Regulation was issued according to the new EU General Data Protection Regulation and required additions to the patient information about the legal basis of the quality assurance project and more detailed information on patients' rights concerning the use of their data and additional contact information. Fourteen of 4,852 patients (0.3%) had declined any documentation in the registry before this change, and 17 of 5,745 patients (0.3%) declined their participation afterward.

After deletion of the 31 records because of the total decline of documentation use in the registry, 10,566 patients remained in the B-SPATiAL registry at the time of the database export. The mean age of patients included in the registry was 72.5 years (SD; 13.7), with 4,937 (46.7%) females, 5,627 (53.2%) males, and 2 (0.2%) neither females nor males. Patient information and the response form were sent to 9,527 patients 2 months after stroke event if patients were alive according to information from registration offices and if the patients' address was known.

For 29 patients, patient information was sent later than 2 months from stroke event because data entry was delayed, e.g., for delayed access to hospital records. In these cases, patients were informed by telephone, and the written information was then sent after the telephone interview. For 104 patients, patient information was not sent because of unknown address (6), e.g., because access to hospital records was delayed, and we could therefore not perform direct follow-up (through the interview or questionnaire). In these patients, we collected vital and residential status information from registration offices. Of the 9,556 patients to whom we sent the patient information, we received 1,965 active replies (20.3%) including the aforementioned 31 requests for total data deletion. The majority of the replies (n = 1,611) were sent through the provided response form, 297 informed the study team through the telephone, and 49 sent an email. Twenty-three of the replies informed us that the patient had deceased in the meantime, 907 requested a written questionnaire, and 626 preferred follow-up by telephone call. From all 1,965 replies, 401 did not want to participate in the follow-up procedure. This corresponds to 20.2% of replies and 4.1% of participants to whom the patient information was sent. Of those patients who had not opted out in response to the sent patient information (n = 9,095), 177 (1.9%) declined follow-up assessment during the telephone call or in a written form on the questionnaire, adding up to 578—corresponding to 5.3% of all 10,557 patients initially entered in the B-SPATiAL registry. Patients who opted out of the follow-up assessment were older and more likely to be female, living in institution, or living with assistance prestroke compared with those who did not opt out (Table 2).

Functional outcome (mRS) at 3 months was assessed in 8,330 patients, which corresponds to 83.3% of patients who did not object follow-up assessment and 78.9% of all patients potentially eligible for inclusion in the registry. Vital status plus residential situation at 3 months was available in 9,622 patients (96.0% of patients without follow-up decline and 91.0% of all included). Vital status information could be collected in 9,741 patients, corresponding to 97.5% of patients without decline and 92.3% of all included patients.

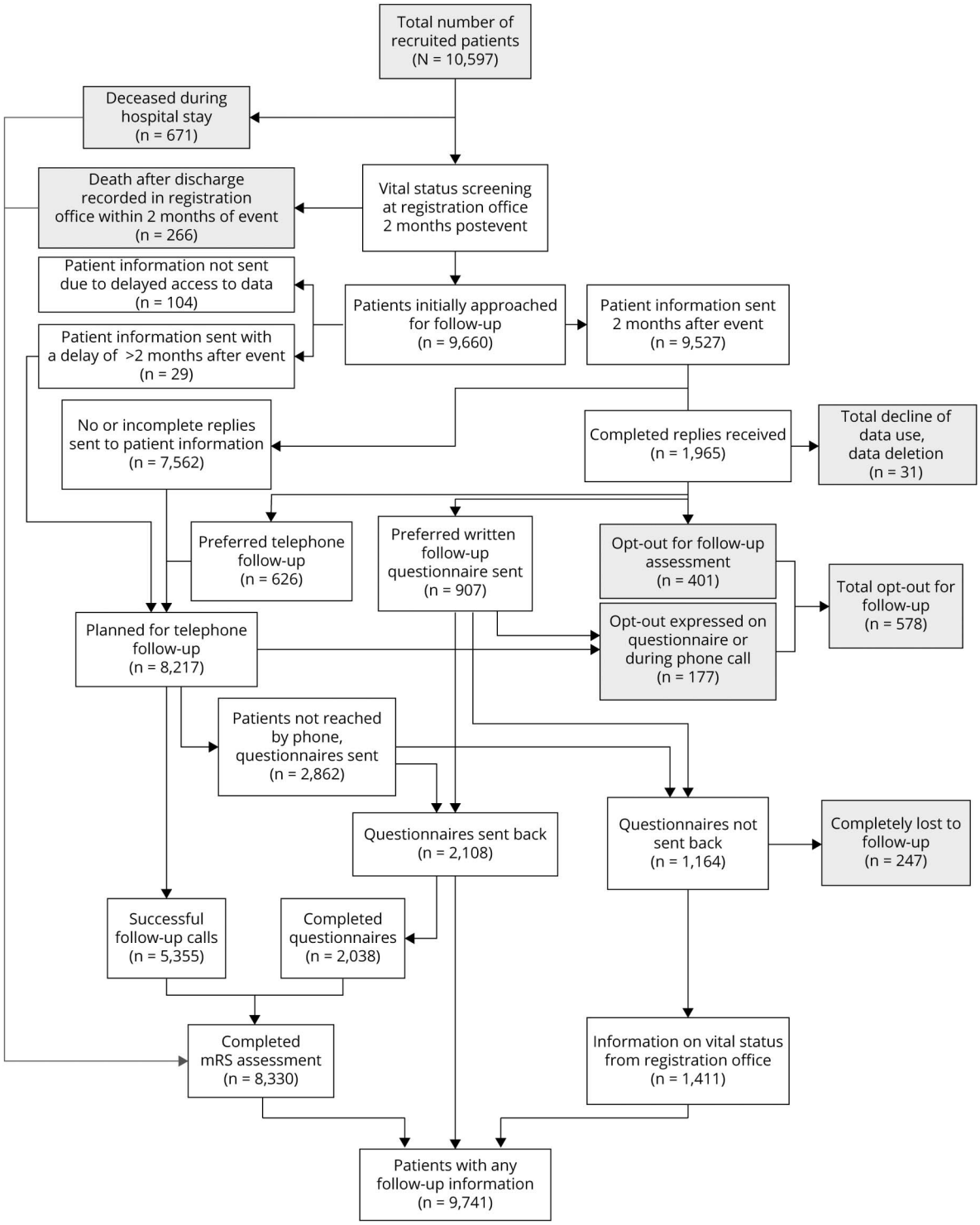
Complaints

From all 10,597 patients initially entered in the B-SPATiAL registry, 2 complaints were received in the study center or in participating hospitals. No complaints focused on the mode of study documentation and follow-up. One complaint was sent because of an erroneous call after the patient had sent an opt-out response, but this was not received in time. One additional complaint was caused by sending the patient information to a person with identical name and date of birth after address request at the registration office.

Discussion

In a citywide acute stroke registry, our opt-out approach for follow-up assessment allowed for a total follow-up collection in 92% of all patients and 98% of patients without decline of data collection or opt out against follow-up assessment. This is a remarkable improvement from the 59.8% we recorded using the opt-in procedure in a similar setting of the PHANTOM-S trial.[10] Only 0.3% of patients declined any use of data, and only 5% of patients opted against follow-up assessment. These results suggest that the overwhelming majority of patients who had had a stroke do not object to share information on their individual outcome if they are informed about the purpose and design of such a registry aiming to answer important questions regarding the current quality and future organization of acute stroke care. Although the follow-up rate of patients without opt-out choice was rather close to follow-up rates often seen in controlled stroke trials with written informed consent at study inclusion, the opt-out approach kept patient selection to a minimum and made the registry highly representative for the population of stroke patients admitted with acute neurologic symptoms within the

Figure 1 B-SPATiAL Recruitment February 1, 2017–January 31, 2020



mRS = modified Rankin Scale.

city of Berlin. Acceptance of the chosen approach is also supported by only receiving complaints not associated with the data collection procedures and the low number of patients declining any use of their data even after the change of the EU General Data Protection Regulation that strengthened individuals' rights on informational self-determination. Of note, the fact that of those eligible for inclusion approximately 20% got in touch with us for various reasons, yet only 0.3% opted out of the complete use of their data, is to us indicative that the information regarding the registry was indeed received and read by a high number of recipients. The observation that patients who opted out were older and more often needed

Table 2 Baseline Parameters in Patients[a] With and Without Opt-out Against Follow-up

All patients	Patients with opt-out choice (n = 578)	Patients without opt-out choice (n = 9,051)	*p* Value[b]
Demographics			
Age, y, mean (SD)	76.2 (12.5)	71.4 (13.7)	<0.01
Gender, female, n (%)	320 (55.4)	4,120 (45.5)	<0.01
Comorbidities			
Arterial hypertension, n (%)	488 (84.4)	7,105 (78.5)	<0.01
Atrial fibrillation, n (%)	168 (29.1)	2,410 (26.6)	0.20
Diabetes mellitus, n (%)	147 (25.4)	2,302 (25.4)	0.99
Functional status prestroke			
Living at home needing assistance, n (%)	160 (27.7)	1940 (21.4)	<0.01
Living in nursing institution, n (%)	88 (15.2)	855 (9.4)	<0.01
Clinical information			
NIHSS at hospital admission, median (interquartile range) (34 missing)	3 (1–8)	3 (1–8)	0.68
TIA, n (%)	137 (23.7)	1,864 (20.6)	0.15
Ischemic stroke, n (%)	414 (71.6)	6,645 (73.4)	
Hemorrhagic stroke, n (%)	27 (4.7)	542 (6.0)	

NIHSS = National Institutes of Health Stroke Scale.
[a] Excluding those who died within 2 months after event.
[b] Without correction for multiple testing.

assistance before their current stroke could be interpreted in the way that the decision against follow-up, at least in part, may be more driven by the wish to avoid additional workload than by a refusal against data collection per se. The higher proportions of patients living at home with assistance or living in nursing institution in those opting out could also be indicative that the opt-out option was chosen more frequently by legal representatives.

Opt-out approaches have been suggested or reported by several studies and registries.[18-21] The "exemption for informed consent" approach is in part an opt-out application and is used in the United States for emergency research intervention studies when investigational products have to be administered before informed consent can be obtained. In such cases, consent is obtained retrospectively from patients or legal representatives who can also "opt out." Although similar, this approach is not the same as the opt-out approach against follow-up assessment in quality registries because no intervention is being administrated in study context. The need for this approach in quality registries is underlined by the example from the Registry of the Canadian Stroke Network. Here, patient inclusion was initially through informed consent but suffered from low participation rates of 39% during the first phase and not higher than 51% after reinforcing the recruitment process.[5] Because major selection biases were observed, the registry changed to an opt-out approach of data use but stopped conducting follow-up interviews[22] still remaining the gold standard in functional outcome assessment after stroke.

To provide reliable information on intervention effects in unselected patient samples, registry-based randomized controlled trials have been suggested.[23] This type of studies is ideally based on large registries that have access to nationwide health care databases such as in several Scandinavian countries.[23,24] Although informed consent is still needed for active participation in such trials, the embedment in the registry allows for testing of the external validity of study findings.[23,25] Although some outcomes such as mortality or major vascular events can be extracted with acceptable reliability from routine health care documentation, patient-centered outcomes such as disability or quality of life will still need direct contact assessment. Our registry design with an opt-out approach for follow-up assessment offers an appropriate tool for collecting patient outcomes even without access to routine care databases. We therefore used the B-SPATiAL registry also for the B_PROUD trial investigating the effects of MSU care on functional outcome.[11,26,27]

However, there are several issues that should be considered before conducting such a type of registry: First, a convincing explanation is needed why alternative registry or study designs based on informed consent including deferred consent are impracticable. Second, the applicable legislation of health care

allows the retrospective use of clinical data for research purposes inside the treating institution/facility. Third, the respective data protection legislation allows the use of personalized data in case of high public interest, and this high public interest is confirmed by an independent public authority. Fourth, the specific aims of the data collection are accepted as high-priority research questions by approving authorities and peer groups of potential study participants. Fifth, study information is collected decentral in the respective treatment facilities in a way that prevents reidentification of participants outside these facilities. Sixth, all necessary safeguards of data protection and rigid fault management have to be in place. The usability and the low opt-out levels of the reported opt-out approach in Berlin may therefore not be generalizable to other settings.

The opt-out approach has limitations. As it is not suitable for studies with relevant intervention-related risk of harm, such studies will continue to require explicit informed consent before study participation. In our case, the 2 relatively new treatment strategies that motivated the Berlin stroke community to initiate the registry, i.e., MSU treatment and EVT, had both become (provisional) standard of care allowing the B-SPATiAL registry to be performed as observational research and the B_PROUD study conducted as an embedded low-risk intervention study.

A limitation of the current evaluation is that no data on the educational level were collected in the registry because this information was not routinely available in hospital records. With citywide inclusion of patients, we assume that the composition of patients was rather representative for the city of Berlin.

The opt-out process is itself not completely free from bias as shown in Table 2. Although stroke severity does not seem to be associated with increased opt-out rates, older age and preexisting dependency does. Including information on (short) duration of the announced telephone interview and the option of delegating the call to another person may be helpful to reduce fears of getting overwhelmed.

Running a decentralized registry such as B-SPATiAL with high levels of standardization is highly dependent on close collaboration with all involved health care providers. We could build on this level of trust and collaboration for the B-SPATiAL project because of earlier collaborations within the Berlin stroke community through long-lasting efforts of improving the quality of in-hospital stroke care within the Berlin Stroke Register[28] and the Stroke Emergency Mobile project in cooperation with the Berlin Fire Brigade.

In the current evaluation, we did not analyze the extent to which patients or their relatives understood the information conveyed. As we prepared the information leaflet together with the Data Protection Commissioner, comprehensibility for laypersons was considered. In addition, there was no time pressure, and patients or relatives could seek help within their own environment or by calling the registry center. Finally, the form of follow-up collection by the telephone interview or written questionnaire implies that interview partners or responding persons had sufficient capability to understand and provide information.

In summary, the opt-out approach for follow-up assessment was well applicable in the setting of acute stroke care in Berlin. It allows a widely unselected evaluation of specific patient cohorts and provides high follow-up rates. Our results suggest that most patients with critical health conditions would not object to participation in a registry with outcome assessment if they understand the purpose of answering important questions for future health care.

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Disclosure

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Irina Lorenz-meyer	Center for Stroke Research Berlin, Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Germany	Major role in the acquisition of data and analysis or interpretation of data
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Martin Ebinger, MD, PhD	Center for Stroke Research Berlin, Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Germany; Klinik für Neurologie, Medical Park Berlin Humboldtmühle, Germany	Drafting/revision of the manuscript for content, including medical writing for content; study concept or design; and analysis or interpretation of data
Erik Freitag	Center for Stroke Research Berlin, Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Germany	Major role in the acquisition of data and analysis or interpretation of data
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Follow-up of Patients With Stroke Based on Opt-out Choice: Potential Approach for Acute Care Quality Registries or Observational Studies

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