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Mapping patient encounters to identify recruitment timepoints after brain tumour surgery: a cohort and cross-sectional study

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ABSTRACT

Objective This study aims to develop a comprehensive process map for patients with brain tumours to identify opportunities for quality improvement and automated data collection. Through optimising workflows, the overall goal is to improve patient recruitment to clinical trials.

Design A two-stage mixed methods design, combining qualitative development of a process map with quantitative validation using electronic health records (EHR). Following this, a cross-sectional survey was conducted to assess how patients learn about clinical trials.

Setting A single neurosurgery centre in the United Kingdom.

Participants The process map was developed through stakeholder interviews with neuro-oncology multidisciplinary team members and patients (n=13). Clinical encounters were validated with EHR data from 50 patients. A cross-sectional survey presented the validated process map to 25 postoperative patients to identify the resources they used to learn about ongoing clinical trials.

Interventions Postoperative questionnaires were given to patients after brain tumour surgery, either on the ward or in follow-up clinic.

Primary and secondary outcome measures The primary outcome was the percentage of the study cohort that was present at encounters on the process map. Key timepoints were defined if >80% of patients were present. They represent high-yield opportunities to offer information on clinical trial recruitment. The secondary outcome was the resources used by patients to learn about ongoing clinical trials.

Results Quantitative validation of patient pathways identified 345 encounters involving 19 discrete events, including clinics, telephone follow-ups and treatments. The flow of encounters reflected the process map with 90.7% accuracy, with key timepoints identified at imaging and biopsy/surgical procedures. A cross-sectional survey conducted during outpatient neuro-oncology clinics identified that patients predominantly used self-directed internet searches (n=17, 68%) and verbal information from their neurosurgeon (n=16, 64%) to learn about clinical trials.

Conclusions This study demonstrates the effectiveness of process mapping in identifying key timepoints for automated data collection and opportunities for quality improvement for clinical trial recruitment. Integrating online and in-clinic education strategies could enhance patient awareness and participation in clinical trials.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ A limited number of eligible patients are invited to participate in clinical trials, primarily due to insufficient dissemination of information. Enhancing the accessibility of trial-related information has the potential to improve the diversity, cost-efficiency and overall success of patient recruitment efforts.

WHAT THIS STUDY ADDS

⇒ Process mapping provides a systematic approach to visualising patient recruitment pathways for clinical trials. Patients primarily rely on self-directed internet searches and verbal information from neurosurgeons to obtain trial-related knowledge.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Targeted recruitment strategies focusing on online platforms and in-clinic settings could significantly improve patient awareness and enrolment in clinical trials.

INTRODUCTION

Clinical trials should include a heterogeneous sample of patients to accurately reflect the broader population that they represent and increase the external validity of trial results. However, there is inequality in accessing clinical trials—only 20% of patients that are eligible to be enrolled are invited, but 91% of patients want to take part in research.[1] This disproportionately affects patients from low-income households and from ethnic minorities, who are under-represented in clinical trials.[2 3] Lack of information about clinical trials is a major cause of poor patient recruitment as it prevents patients from seeking trial enrolment themselves.[4] Therefore, improving the availability of clinical trial information

could lead to more diverse, cost-effective and successful patient recruitment.

To improve access to research information, process mapping can be used. This is a method of visualising the structure of care pathways to identify key areas for quality improvement.[5] It is a methodology that has been adapted from the engineering industry and has shown several benefits in a healthcare setting, including an improved understanding of local systems, informing the implementation of interventions, aligning the views of key stakeholders and facilitating collaboration with other centres.[6] Perhaps most exciting, process maps can be used to identify key timepoints for automated data collection in which a high percentage of a patient cohort participates.[7] These can be used to target quality improvement initiatives and have potential applications for data analysis purposes as it standardises the data that can be collected, stored, analysed and interpreted by artificial intelligence tools.[8] In the future, this may lead to personalised information communicated to patients regarding their diagnosis and available clinical trials relevant to them by means of an automated way.

In this case, we used patients undergoing brain tumour surgery as an exemplar. The complexity and heterogeneity of brain tumours result in diagnoses and management plans that can be challenging to understand by lay patients. Patients only recall 18% of the general information regarding elective brain tumour surgeries and one-third of patients are unable to recall any risks of medical oncology treatment.[9 10] Additionally, brain tumours are a highly active area of research and therefore, patients may be eligible for enrolment in multiple trials simultaneously. However, patient recruitment is a major obstacle for clinical trials to overcome, with 53% of randomised control trials failing to reach their recruitment target.[11] Empowering patients by streamlining the educational resources provided and recommending personalised information on clinical trials that are relevant to them may be a solution to these current challenges.

This study aimed to produce a comprehensive process map of the pathways available for patients with brain tumours to connect with up-to-date research and clinical trials relevant to their specific diagnosis. We propose that mapping these pathways will allow us to analyse how patients currently connect with clinical research and to identify key timepoints for quality improvement projects and automated data collection.

METHODS

Study design and setting

This study employed a two-stage mixed methods design, involving qualitative development of a process map followed by quantitative validation using EHR employed in previous research.[7] Additionally, a cross-sectional survey assessed the resources patients use to learn about ongoing clinical trials. The study was conducted between October and December 2022 at a single tertiary-academic centre in the UK.

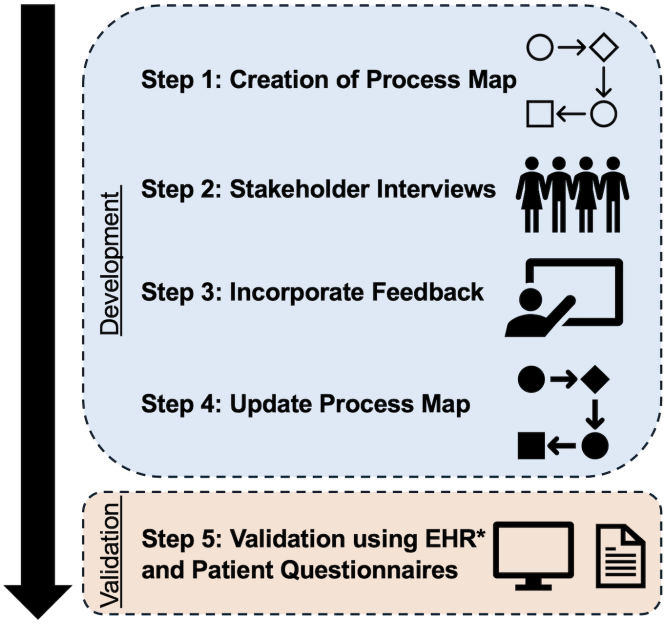

Figure 1 Study flow diagram. *Electronic Health Record.

Development of the process map

The process map was developed by adapting the methodology of Hanrahan *et al*, which systematically constructs a process map through stakeholder interviews and feedback review (figure 1).[7] The map focused on clinical encounters following brain tumour surgery.

In step 1, the first and senior author, who is a consultant neurosurgeon, drafted version 1 process map of the clinical pathway based on clinical experience (online supplemental figure 1). This allowed for key stakeholders in the clinical pathway to be identified. Key stakeholders were defined as healthcare professionals present at neuro-oncology multidisciplinary team (MDT) meetings.

During step 2, stakeholders were interviewed by the researchers, in an office space, using a semistructured format with a five-part questionnaire (online supplemental file 1) to gain objective information about the opinions and recommended changes that should be made. In addition, an illustration of the draft process map was reviewed on a tablet that could be illustrated on. The recommended changes to the process map were recorded in a spreadsheet. A 'snowball' sampling method was used, in which each interviewed stakeholder recommended additional stakeholders to interview. This process continued until no new stakeholders with unique perspectives on the clinical service could be identified.[12 13]

In step 3, stakeholder comments were compiled into a spreadsheet. Each comment was independently reviewed by the joint first authors, and the recommended changes were either accepted or rejected. Any disagreements were discussed in research meetings with the senior author. This resulted in version 2 of each process map (online supplemental figure 1).

Validation of the process map

The process map was validated using quantitative data from adult patients who had prospectively undergone brain biopsy or resection for a primary or secondary brain tumour. Patients who had redo craniotomy for recurrences were also included. Patients were identified through the EHR system Epic (Epic Systems Corporation, Wisconsin, USA) between January and June 2022, resulting in a cohort of 50 patients. Patients below 16 years of age and those with non-neoplastic pathology were excluded.

The study cohort was used to validate version 2 of the process map. Patient pathways were reviewed using the EHR, and clinical encounters post-histological diagnosis of a primary or secondary brain tumour were recorded. These data were compared with the version 2 process map, and the percentage of patients present at each clinical step was calculated. Key timepoints were defined as clinical steps where over 80% of patients were present and were categorised into three groups: 80%–89%, 90%–99% and 100%.

Investigation of exposure to clinical trial information

A cross-sectional survey was developed based on the validated process map and was conducted at a single centre between January and July 2023. The survey presented 25 postoperative patients with a paper copy of version 2 of the process map and asked which resources they utilised. Patients received questionnaires during follow-up clinics, 8–12 weeks after brain biopsy or brain tumour resection (online supplemental file 2).

Patient and public involvement

Patients were directly involved in the development of the process map, and they participated postoperatively through a questionnaire that gathered insights on the resources they used to learn about ongoing clinical trials. Their responses offered valuable perspectives on the effectiveness and relevance of the information provided, contributing to the broader study aim of improving clinical trial recruitment.

Data availability

Data used in this study and code used in analysis will be made available on reasonable request.

Study checklist

This study was written in accordance with the STrengthening the Reporting of OBservational studies in Epidemiology guidelines.[14]

RESULTS

Development of the process map

During stakeholder (n=13) interviews with key members of the neuro-oncology MDT and patients with brain tumours, the version 1 of the process map was reviewed and discussed. Stakeholders included two consultant neurosurgeons with a specialist interest in neuro-oncology, two consultant neuro-oncologists, four nurse specialists and five neuro-oncology patients. The cumulative professional experience of the stakeholders was >100 years. Three changes were made following input from the stakeholders. These changes included combining 'biopsy' and 'surgery' encounters as 'surgical procedures', adding a diagram key and simplifying the arrows using the process map. An illustration of version 2 process map for the brain tumour pathway after a histological diagnosis in a swimlane format is shown in figure 2.

The process map was quantitatively validated by reviewing the EHRs of 50 patients who prospectively presented to our neurosurgical centre between October and December 2022 and underwent either a brain biopsy or brain tumour resection procedure (table 1). One patient was excluded from analysis for having non-neoplastic pathology (Rathke's cleft cyst).

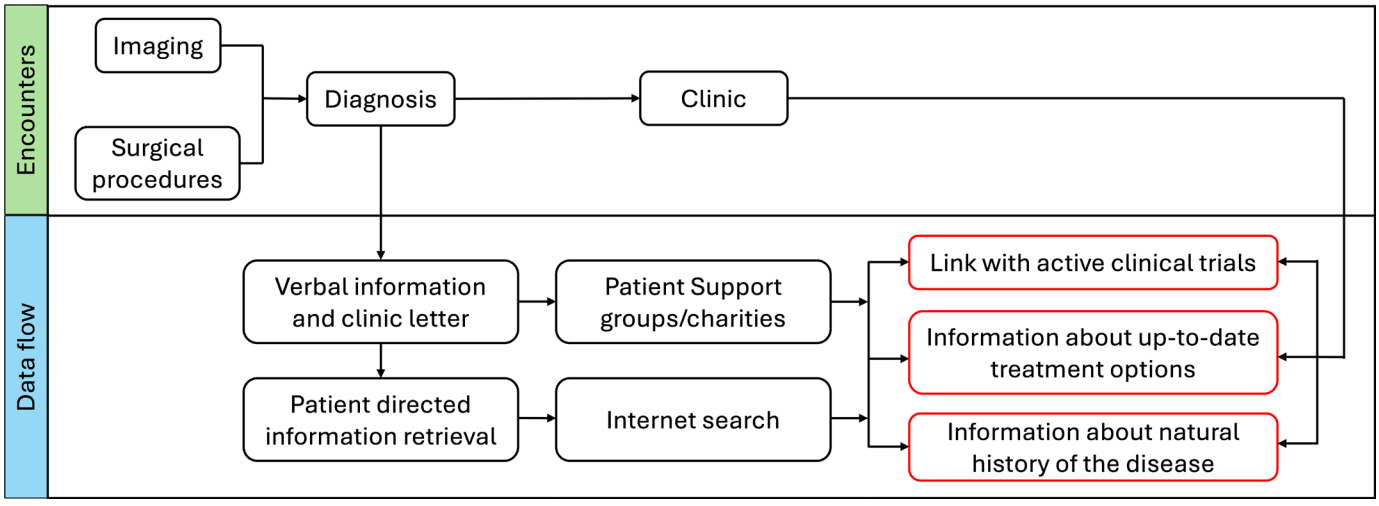

Figure 2 Process map illustrating the brain tumour patient pathway after histological diagnosis. Encounters mark face-to-face interactions between patients and healthcare professionals. Data flow includes information given to patients, information retrieved by patients themselves and information endpoints, which are the final outcomes of these information streams.

Table 1 Baseline demographics of validation cohort

Characteristic	N=49*
Sex	
Female	20 (42%)
Male	29 (58%)
Age at procedure (years)	53 (43, 65)
Operation	
Craniotomy and excision of neoplasm	20 (28%)
Endoscopic transsphenoidal removal of pituitary tumour	18 (28%)
Brain biopsy	11 (22%)
Histological diagnosis	
Pituitary adenoma	16 (2.0%)
Glioblastoma	12 (20%)
Astrocytoma	5 (2.0%)
Meningioma	4 (4.0%)
Metastases	4 (4.0%)
Chordoma	2 (4.0%)
Oligodendroglioma	2 (2.0%)
B-cell lymphoma	1 (2.0%)
Germ cell tumour	1 (2.0%)
Medulloblastoma	1 (2.0%)
Subependymoma	1 (2.0%)

*n (%); median (IQR).

Quantitative validation of 49 patient pathways identified 345 encounters, with 19 discrete events, in which patients were in contact with a medical professional, this included clinics, telephone follow-ups and treatments.

The flow of encounters for each patient reflected the patient pathway shown in process map version 2, on average 90.7%. There was no perfect agreement because some patients had clinics with alternative specialties, for example, neuro-ophthalmology, and some patients were readmitted to the hospital due to complications of their cancer or disease progression and required further treatment, for example, ventriculo-peritoneal shunt. Table 1 shows the basic demographics of the cohort.

We identified two key timepoints in the pathway—imaging and surgical procedure (biopsy or surgical resection). There was large heterogeneity in the patient's pathway following the histological diagnosis (table 2).

Use of educational resources

The educational resources that patients used to learn about relevant clinical trials after their brain tumour diagnosis were investigated via use of a cross-sectional survey during outpatient neuro-oncology clinics (table 3). The patient cohort comprised 25 patients, median age of 57 (IQR=44–76) and 52% (n=13) were women.

Table 2 Key timepoints in the process map

Key stages	Number of patients	Percentage of patients
Imaging	49	100
Surgical procedure*	49	100
Diagnostic meeting	20	40.8
Clinic (any)	38	77.6
Neurosurgery clinic	23	46.9
Oncology clinic	11	22.4
Nurse-led clinic	28	57.1
Total patients	49	

*Surgical procedure includes biopsy and surgical resection.

DISCUSSION

Principal findings

This study identified key timepoints for patient education following a brain tumour diagnosis and identified the educational methods patients use to understand their condition. By employing a robust methodology, including semistructured interviews with key stakeholders, a comprehensive process map of the patient pathway after brain tumour surgery was developed. These findings can inform automated data collection processes and drive quality improvement projects, ultimately enhancing the recruitment of brain tumour patients for clinical trials.

First, we demonstrated that process mapping is an effective method for illustrating the patient pathway to

Table 3 Educational resources used to learn about clinical trials

Educational resource	N=25
Written information	9 (36%)
Diagnosis meeting	1 (4%)
Neurosurgery letter	5 (20%)
Oncology letter	2 (8%)
Nurse letter	2 (8%)
Verbal information	16 (64%)
Diagnosis meeting	3 (12%)
Neurosurgeon	11 (44%)
Oncologist	6 (24%)
Nurse	1 (4%)
General Practitioner	8 (32%)
Friends and family	8 (32%)
Charity	1 (4%)
Other	1 (4%)
Printed hospital leaflets	1 (4%)
Printed Other	2 (8%)
E-learning NIHR	1 (4%)
E-learning self-directed	17 (68%)

identify key timepoints. We used an established methodology to generate an accurate patient pathway.[6 7 15] The validated process map identified that preoperative imaging and surgery were key timepoints where 100% of the patient cohort were present. These timepoints provide an opportunity for automated data extraction of a high proportion of patients with brain tumours. A current limitation of big data collected from EHR is the large amount of poor-quality data that is present.[16] By targeting specific timepoints where a high percentage of the target cohort are present and data collection follows a standardised format, automated data collection has been shown to have high precision and reduce time and financial costs of manual data collection.[17] For example, using the surgical intervention timepoint, data from the operation note could automatically be collected and used to inform eligibility screening for clinical trials. A recent study used a Retrieval-Augmented Generation-enabled GPT-4 system to screen patients for enrolment into a randomised control trial for heart failure. The model demonstrated a 92.3% sensitivity and 93.9% specificity for eligibility screening and outperformed research staff in identifying patients with symptomatic heart failure.[18] A similar pipeline could be implemented for the screening of patients for brain tumour clinical trials.[19] This could have a major impact on recruitment to clinical trials for advanced cancers whose largest barrier is access for potentially eligible patients.[20]

Second, following brain tumour surgery, there was considerable variation in the clinical encounters that patients had. The patient encounters followed the pathway outlined in the process map with an average accuracy of 90.7%. Additionally, a large proportion of patients attended a postoperative clinic (77.6%), most commonly with a neurosurgeon (46.9%). However, there were no postoperative key timepoints where more than 80% of the patient cohort had an encounter. This variability is attributed to the heterogeneity in clinical presentation among patients with brain tumours, both within the same diagnosis and across different diagnoses. Patients presenting early in the disease and suitable for maximum treatment were referred to neurosurgery and oncology clinics for further management. Conversely, patients presenting in extremis underwent biopsy procedures and were subsequently discharged to palliative care. Additionally, there are around 120 different types of brain tumours, with metastases from an extracranial site, glioma and meningioma being the most common.[21] Each diagnosis has separate disease characteristics and management options. This highlights the multiple challenges of enrolling patients with brain tumours in clinical trials. Many diagnoses are terminal, often identified at a late stage, and with patients who have impaired cognitive function, which reduces the likelihood of obtaining informed consent.[22] Process mapping has allowed us to identify the large variation in patient pathways among patients with brain tumours. This has implications for quality control in patient education and access to relevant information regarding trial opportunities. To combat this, we intend to review our patient pathways to standardise them where appropriate through quality improvement projects.

Third, we found that patients rely most on self-directed searching of the internet to educate themselves on ongoing trials. It is well established that patients are no longer passive recipients of healthcare information but actively consume information on their own accord using the internet.[23] It is critical that clinicians work in collaboration with patients in obtaining and analysing information by steering them to appropriate and trusted resources. Aside from being a rich source of information, the internet could also connect patients with brain tumours to clinical trials. A meta-analysis comparing online recruitment strategies to traditional in-clinic/offline approaches found that online recruitment is time and cost-effective, but that resulted in a lower conversion rate to recruitment.[24] This highlights the need to have a multifaceted approach to modern clinical trial recruitment using both online and offline methods. We found that verbal information from healthcare professionals in a clinic setting remains a cornerstone for patient education about clinical trials. This is an ideal opportunity for trial education and recruitment in appropriate patients, and standardisation of pathways may help to improve this. Unique to the clinic environment is the ability for healthcare professionals to have an open dialogue with patients. This provides an opportunity for patients to ask questions about potential clinical trials and for healthcare professionals to check patient understanding before enrolment. These are key factors in the successful recruitment of patients to clinical trials.[25]

Findings in the context of the literature

Despite its widespread use in the engineering industry, process mapping remains underutilised in developing patient pathways in healthcare. Previous work has shown that process mapping can effectively identify key timepoints for structured data entry in pituitary surgery, revealing that operation notes and neurosurgical ward round entries were the highest yield.[7] Additionally, process mapping applied to spine surgery identified that the preoperative surgical clinic was a crucial point where most patients learnt about their upcoming elective surgeries through verbal consultations with their surgeons.[15] Both studies successfully used process mapping to gain novel insights into the patient pathway.

To our knowledge, this study is the first to use process mapping to identify timepoints for potential clinical trial recruitment. Unlike previous studies, it also incorporated feedback from patients who had first-hand experience with the patient pathway into the process map design.

Strengths and limitations

The key strength of this study is the novel methodology used in the development of the process map. This involved integration of feedback from key stakeholders in the patient pathway, including clinicians and patients,

thus limiting the influence of bias in the creation of the process map. This resulted in the development of a comprehensive process map, which was qualitatively validated using EHR. The methodology used is established for constructing process maps and has been used in other medical use cases such as spine and pituitary surgery.[7 15] Also, the patient population used to quantitatively validate the process map included a heterogeneous sample. This would have resulted in cohort characteristics which are representative of other neurosurgical centres.

The process map was developed at a single centre, which limits the generalisability of the results when applied to other centres. We propose that other neurosurgical centres mirror our methodology to construct their own process map for the patient pathway at their centre. This will help guide local quality improvement interventions. In addition, the patient cohort used to validate the cohort was limited to 200 patients for the quantitative validation and 25 patients for the cross-sectional questionnaire. These small sample sizes limit the generalisability of the study. In addition, the cohort of patients present in the cross-sectional survey was taken from postoperative neurosurgical clinics. This cohort of patients represents a low morbidity subset of the overall population of patients with brain tumours and would have resulted in a selection bias influence on our results. Patients who were enrolled in clinics outside of the trust that used a different EHR were not identified in the study. This commonly happens when patients with non-operative management are referred to specialist oncology centres for further chemoradiotherapy or palliative care. Future work aims to address these limitations by reproducing the methodology across multiple centres using a collaborative model.

CONCLUSIONS

This study used process mapping to illustrate the patient pathway after a brain tumour diagnosis and investigate the resources used by patients to learn about their disease and ongoing clinical trials. The study identified that preoperative imaging and neurosurgery procedures are key timepoints in the patient pathway where a high proportion of the population are present, and therefore provide high-yield opportunities for automated data retrieval. Finally, the study demonstrated that patients mostly rely on self-directed internet searches to learn about ongoing clinical trials. Automation of high-quality resource linkage may help to improve this situation.

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Contributors JB serves as the guarantor for this project. JB, JP, JGH, NN, SS, SCW and HJM contributed to conceiving and designing the study. JB and JP contributed to data extraction, curation and analysis. JB, JP, NF, JGH, MK, NN, SS, SCW, LT, CSH and HJM drafted the manuscript. CSH and HJM provided supervision of the study. All authors were involved in the writing and approval of the final version of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study was categorised as a service evaluation and did not alter the care patients received or collect patient identifiable information. The study was registered with our local clinical governance committee.

Provenance and peer review Not commissioned; externally peer-reviewed.

Data availability statement Data are available upon reasonable request.

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