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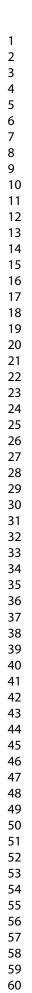
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Neurosurgeons' experiences of conducting and disseminating clinical research in low- and middle-income countries: A qualitative study protocol.

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Title Page

Full Title: Neurosurgeons' experiences of conducting and disseminating clinical research in low- and middle-income countries: A qualitative study protocol.

SHORT STUDY TITLE: Conducting and disseminating research in LMICs

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ABSTRACT

Introduction: Low-and middle-income countries (LMICs) face the greatest burden of neurotrauma. However, most of the research published in scientific journals originates from high-income countries, suggesting those in LMICs are either not engaging in research, or are not publishing it. Evidence originating in high-income countries may not be generalisable to LMICs, therefore it is important to nurture research capacity in LMICs so that a relevant evidence base can be developed. However, little is published about specific challenges or contextual issues relevant to increasing research activity of neurosurgeons in LMICs. Therefore, the aim of this study was to understand neurosurgeons' experiences of, aspirations for and ability to, conduct and disseminate clinical research in low- and middle-income countries.

Methods and analysis: This is a pragmatic qualitative study situated within the naturalistic paradigm using focus groups and interviews with a purposive sample of neurosurgeons from LMICs. First, we will conduct asynchronous online focus groups with 36 neurosurgeons to broadly explore issues relevant to the study aim. Second, we will select 20 participants for follow-up semi-structured interviews to explore concepts in more depth and detail than could be achieved in the focus group. Interviews will be audio-recorded and transcribed verbatim. A thematic analysis will be conducted following Braun and Clarke's six stages and will be supported by NVIVO software.

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confidential. The findings of the study will be shared with relevant stakeholders and disseminated in conference presentations and journal publications.

Registration: N/A

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Strengths and limitations of this study

- First qualitative study to explore the challenges of neurosurgeons conducting and disseminating clinical research in LMICs
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- Knowledge generated from this study will inform recommendations to enhance the research capacity of neurosurgeons in LMICs
- It will not be possible to represent all LMICs in this study
- Excluding non-English speaking neurosurgeons will mean any additional barriers that these neurosurgeons may face in conducting and disseminating research will remain unexplored.

Key Words

- Traumatic brain injury
- Neurosurgery
- Qualitative research
- Developing countries

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INTRODUCTION

In 2017 the UK Department of Health and Social Care provided over £160 million of funding for global health research¹. From this funding the NIHR Global Health Research Group on Neurotrauma was established with the overall aim of improving outcomes from neurotrauma in low- and middle income countries ² (LMICs). In addition to improving outcomes, the group also aims to increase the participation of LMICs in high quality clinical research³. The low proportion of published scientific papers from authors in LMICs is stark ⁴⁵. The limited participation of LMICs in research contrasts sharply with their disproportionately high incidence of neurotrauma⁶. In a recent study of research productivity in LMICs, as evidenced by publication in journals, Servadei, et al. ⁵ found that only 4.52% of 6708 published reports had an LMICs affiliation. In a further bibliometric study Africa and Southeast Asia were found to be responsible for less than 3% of publication productivity⁷. If journal publication is a reliable indicator of the quality and quantity of research, then LMICs are severely underrepresented in an international context⁵. In addition, Kolias, et al. ³ asserts that multicentre trials are typically conducted in high-income countries making generalisability of these studies to environments with different treatment practices particularly problematic. A recent review to identify randomised trials of neurosurgical procedures used in cranial and spinal neurosurgical practice found only 8.8% of studies (excluding China) were LMICs led studies⁸. Low-and middleincome countries need to develop an evidence-base that is relevant to the treatments and interventions accessible to them³⁷. Nurturing an environment that promotes high quality neurotrauma research is a fundamental part of this.

Little is written in the academic literature about the reasons why there are so few studies conducted, and/or published, by neurosurgeons in LMICs, although lack of time and resources are a likely factor ⁵. More specifically Langer, et al. ⁴ suggested poor research production; poor

preparation of manuscripts; poor access to scientific literature; poor participation in publicationrelated decision-making processes and bias of journals all exacerbate low engagement. However, there is little empirical data to underpin these assumptions, therefore it is important to understand this so that any recommendations for enhancing research capacity in the future are context specific and borne out of an in-depth understanding of the problem. A review by Franzen⁹ examined health research capacity development in LMICs suggesting power relationships effected capacity development, that stronger links between research, policy and practice were required and that a systems response was necessary if capacity was to be improved. However, only 20.8% of the papers included in the review were sourced from empirical primary research.

Aim & Objectives

The aim of this study is to understand neurosurgeons' experiences of, aspirations for, and ability to, conduct and disseminate clinical research in low- and middle-income countries.

Objectives

- 1. Explore the types of clinical research neurotrauma physicians from low- and middleincome countries are engaged in.
- 2. Understand the contextual challenges to conducting and disseminating clinical research in low- and middle-income countries.
- 3. Identify ways in which research and dissemination activities can be facilitated in lowand middle-income countries.

METHODS and ANALYSIS

Study design

We propose an exploratory pragmatic qualitative study situated within the naturalistic paradigm. Pragmatic qualitative research, also referred to as descriptive or generic qualitative research, is particularly useful when little is known about a topic and when researching populations from other cultures¹⁰. Pragmatic qualitative studies are not philosophically informed allowing the study to be designed in a way that is feasible, achievable and appropriate for the aim of the study¹¹. The naturalistic paradigm, explicated by Lincoln and Guba¹², also known as the constructivist paradigm in more recent texts (although many authors still prefer this original description), reject methods which are reductionistic¹³. Naturalistic inquiry tries to stay true to the nature of the phenomena under investigation and commits to the existence of multiple realities and working with subjectivity¹⁴.

Data collection

As there is little written in the empirical literature, we were cautious about developing an a priori interview schedule to guide data collection. Therefore, we have designed a study that will explore neurosurgeons' experiences within a focus group first as a means to understand the nature of the problem initially and then conduct semi-structured interviews with a smaller sample to explore the research question in more depth than may possible in a focus group setting. In addition, we propose collecting a small amount of demographic data.

Specific demographic data will be collected from each participant to include age, gender, country of residence, job title and experience. In addition, we will ascertain specific exposure to research training, research participation and the relevance of research to job role and job progression. This data is required if we are to interpret the context of the data correctly.

Online focus groups have a number of advantages over more traditional focus group formats¹⁵. First, they allow people who are in different geographical places to contribute to a group discussion where a face-to-face focus group is not possible¹⁶. Second, there is a heightened level of anonymity which

may mean people feel more able to be honest and or share sensitive information. Third, data is immediately available without the necessity for transcription ¹⁵. In addition, the asynchronous format allows participants the ability to contribute at a convenient place and time making the research more accessible to participants who may be in different time zones with competing demands on their time¹⁷.

The focus group questions were discussed with members of the research team, particularly those from LMICs, to ensure these were appropriate (Box One).

- 1. What are your personal experiences of conducting clinical research and what personal and/or organisational factors motivate you to conduct research?
- 2. What specific barriers are there to you conducting clinical research within your hospital?
- 3. In what ways is research shared between colleagues, the public, and the wider academic community?
- 4. What would help you to conduct and publish good clinical research?
- 5. What unique factors are there that should be considered to nurture research capacity in low and middle income countries?

Box One: Focus group questions

Selection of the online platform to facilitate the focus group was informed by a number of strict criteria informed by principles of safe data storage and accessibility. Each participant will be given a unique username and individually assigned password allowing them to contribute anonymously to the focus group. We propose three separate focus groups: Group One (lower income); Group two (lower-middle income); Group 3 (upper middle-income). We will try to have representation from a wide range of countries but will be affected by the number of people who respond to the initial call for participants. Questions will be posted online every seven-ten days in the order listed. Members of the UK research team, will regularly check the forum during this time, respond to direct questions if necessary, ask additional follow-up questions where appropriate or request clarification of points made.

Following completion of the online focus groups we will invite 20 participants to complete online video or telephone semi-structured interviews. We will select participants based on their demographic data and their contribution to the online focus group to ensure we capture a range of views and experiences. The specific interview schedule will be developed following preliminary analysis of the focus group data. The interviews will last approximately 30-60 minutes, will be conducted by the UK based research team and will be recorded with a digital recorder.

Sample

Non-random sampling is used in qualitative studies and here we use a purposive approach. Persons eligible to participate in this study are neurosurgeons working in a country defined as low- or middle-income, self-declared fluency in written and spoken English, have access to, and able to use, a personal computer or smart phone and able to provide informed consent. Participants will be identified in countries participating in the NIHR Global Health Research Group on Neurotrauma listed in Box Two. However, new collaborators in the group, including Zimbabwe and the Philippines, and participants from institutions based in other LMICs, will be added if necessary, to achieve the required sample size.

1. BRAZIL	7. MYANMAR
2. COLOMBIA	8. NIGERIA

3.	ETHIOPIA	9. PAKISTAN
4.	INDIA	10. SOUTH AFRICA
5.	INDONESIA	11. TANZANIA
6.	MALAYSIA	12. ZAMBIA

Box Two: LMICs in the NIHR Global Health Research Group on Neurotrauma

Qualitative studies do not make any claims about generalisability so a sample size calculation is not appropriate. Instead qualitative studies use the concept of data saturation to assess the completeness of findings which is the point reached when researchers are confident that new data will reveal no new information ^{18 19}. In this study we aim to recruit 36 participants for the online focus groups and then 20 participants for the individual semi-structured follow-up interviews when we expect data saturation to be reached.

Data analysis

There will be three phases to analysis in this study mirroring the stages outlined under study design. Phase one will analyse the focus group data; phase two will analyse the semi-structured interview data and phase three will triangulate findings from all methods to determine final findings for the study.

Phases one and two will use a Braun and Clarke ²⁰ thematic analysis (see Box Three) which is commonly used in pragmatic qualitative studies^{20 21} that do not require "highly abstract rendering of data" ^{22p.3}. Audio files will be transcribed verbatim by a transcription service and checked for accuracy by the research team. Online focus groups will be downloaded from the online platform and transferred to a Microsoft Word file. Given the nature of the research question it would be wrong to enforce an a priori framework on the analysis. Analysis will therefore be inductive and in vivo coding will be used. Analysis will be supported by the use of NVIVO software allowing researchers to organise the data, share coding decisions and confirm the origins of interpretation.

- 1. Familiarising yourself with your data
- 2. Generate initial codes
- 3. Searching for themes
- 4. Reviewing themes
- 5. Defining and naming themes
- 6. Produce the report

Box Three: Braun and Clarke ¹⁸ thematic analysis framework

Phase three will involve triangulation of data obtained from interviews and focus groups. The benefits of data triangulation include developing a more comprehensive understanding of the phenomena under investigation through the use of multiple methods²³.

Rigour

This study uses multiple methods and triangulation to increase its depth and accuracy of understanding. Preliminary findings from the focus group will be explored within the individual interviews which will increase credibility of the final findings. Critical reflexivity will also safeguard against naïve assumptions and possible hidden biases within the analysis. Peer debriefing and respondent validation will also be used in this study to increase rigour.

ETHICS and DISSEMINATION

The University of Cambridge Psychology Research Ethics Committee reviewed this study in January 2020 (REF PRE.2020.006). The University of Cambridge is the sponsor and appropriate insurance is in place. Participants will be informed fully about the study methods, risks and benefits through the participant information Sheet. A cooling off period of 48 hours will be given to all those who express an interest in the study and then electronic consent will be taken. Participants will be able to withdraw at any time. Data cannot be withdrawn from the focus groups, however participants can request their data is withdrawn from the interviews for up to one week following their completion. After this period this data cannot be withdrawn as analysis will have commenced.

All information will be kept strictly confidential and comply to principles of UK data protection law and General Data Protection Regulation. Participants will be advised not to share any personal information in the online focus group. When the focus groups have been completed, we will anonymise the data prior to data analysis. Similarly, all interview data will be anonymised upon transcription. Participants will be told that anonymised quotes will be published in the findings of this study. We will also be seeking consent to disclose region and level of income associated with their country of origin against any quotes used in the publication of findings as this will be important to the contextual understanding of the study.

Patient & Public involvement

Our research question asks for the views of neurosurgeons and therefore we do not intend to include patients or public in the design of, or data collection for, this study. However, we did ask for peer review of the study by collaborating members of the GHRGN. Their comments informed the final study design.

Dissemination

Participants in this study will be sent a summary of the findings once analysis has been completed. The findings of the study will then be shared through the NIHR GHRGN network, and other relevant stakeholders, including the World Federation of Neurosurgical Societies. This study will also be disseminated in conference presentations and journal publications.

Study Limitations

Generalisibility of the findings may be limited, as we do not expect to have participating neurosurgeons from all LMICs. However, we hope to include participants from a variety of LMICs with broad spread in terms of geography and income status. Unfortunately, due to the resources available we had to exclude non-English speaking neurosurgeons. Any additional experiences that this specific population have in conducting and disseminating research will remain unexplored, therefore, we will need to be cautious in our final conclusions for this study.

Conclusion

This is the first study, that we know of, to explore the challenges of neurosurgeons conducting and disseminating clinical research in LMICs. This qualitative study will provide a rich and in-depth understanding of how engagement in research could be improved for this population. This understanding will facilitate the development of appropriate recommendations with the aim of nurturing research capacity for neurosurgeons in LMICs in the future.

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REFERENCES

- 1. Department of Health and Social Care. Government awards over £120 million for global health research 2017 [Available from: <u>https://www.gov.uk/government/news/government-awards-over-120-million-for-global-health-research</u> accessed 21/10/19.
- 2. Neurotrauma.world. NIHR Global Health Research Group on Neurotrauma 2016 [Available from: <u>http://neurotrauma.world/</u> accessed 21/10/2019.
- 3. Kolias AG, Rubiano AM, Figaji A, et al. Traumatic brain injury: global collaboration for a global challenge. *Lancet Neurol* 2019;18(2):136-37. doi: 10.1016/S1474-4422(18)30494-0 [published Online First: 2019/01/22]
- 4. Langer A, Diaz-Olavarrieta C, Berdichevsky K, et al. Why is research from developing countries underrepresented in international health literature, and what can be done about it? *Bull World Health Organ* 2004;82(10):802-3. [published Online First: 2005/01/13]
- Servadei F, Tropeano MP, Spaggiari R, et al. Footprint of Reports From Low- and Low- to Middle-Income Countries in the Neurosurgical Data: A Study From 2015 to 2017. World Neurosurg 2019;130:e822-e30. doi: 10.1016/j.wneu.2019.06.230 [published Online First: 2019/07/12]
- 6. Mock C, Lormand JD, Goosen J, et al. Guidelines for essential trauma care. Geneva, 2004.
- 7. Tropeano M, Spaggiari R, Ileyassoff H, et al. A comparison of publication to TBI burden ratio of low- and middle-income countries versus high-income countries: how can we improve worldwide care of TBI? *Neurosurgical Focus* 2019;47(5):E5 p.1-6.
- B. Griswold DP, Khan AA, Chao TE, et al. Neurosurgical Randomized Trials in Low- and Middle-Income Countries. *Neurosurgery* 2020 doi: 10.1093/neuros/nyaa049 [published Online First: 2020/03/15]
- 9. Franzen SR, Chandler C, Lang T. Health research capacity development in low and middle income countries: reality or rhetoric? A systematic meta-narrative review of the qualitative literature. *BMJ Open* 2017;7(1):e012332. doi: 10.1136/bmjopen-2016-012332 [published Online First: 2017/01/31]
- 10. Sullivan-Bolyai S, Bova C, Harper D. Developing and refining interventions in persons with health disparities: the use of qualitative description. *Nurs Outlook* 2005;53(3):127-33. doi: 10.1016/j.outlook.2005.03.005 [published Online First: 2005/07/01]
- 11. Smith J, Bekker H, Cheater F. Theoretical versus pragmatic design in qualitative research. *Nurse Res* 2011;18(2):39-51. doi: 10.7748/nr2011.01.18.2.39.c8283 [published Online First: 2011/02/16]
- 12. Lincoln YS, Guba EG. Naturalistic inquiry. Beverly Hills, Calif. ; London: Sage 1985.
- 13. Beuving J, de Vries G. Doing Qualitative Research: The Craft of Naturalistic Inquiry. Amsterdam: Amsterdam University Press, 2015.
- 14. Bowen GA. Naturalistic inquiry and the saturation concept: a research note. *Qualitative Research* 2008;8(1):137-52. doi: 10.1177/1468794107085301
- 15. Zwaanswijk M, van Dulmen S. Advantages of asynchronous online focus groups and face-to-face focus groups as perceived by child, adolescent and adult participants: a survey study. *BMC Res Notes* 2014;7:756. doi: 10.1186/1756-0500-7-756 [published Online First: 2014/10/25]
- Harmsen IA, Mollema L, Ruiter RA, et al. Why parents refuse childhood vaccination: a qualitative study using online focus groups. *BMC Public Health* 2013;13:1183. doi: 10.1186/1471-2458-13-1183 [published Online First: 2013/12/18]
- 17. De Groot K, Maurits EEM, Francke AL. Attractiveness of working in home care: An online focus group study among nurses. *Health Soc Care Community* 2018;26(1):e94-e101. doi: 10.1111/hsc.12481 [published Online First: 2017/07/22]
- 18. Polit DF, Beck CT. Resource manual for Nursing research : generating and assessing evidence for nursing practice. Tenth edition. ed. Philadelphia: Lippincott Williams & Wilkins 2016.

- Moser A, Korstjens I. Series: Practical guidance to qualitative research. Part 3: Sampling, data collection and analysis. *Eur J Gen Pract* 2018;24(1):9-18. doi: 10.1080/13814788.2017.1375091 [published Online First: 2017/12/05]
- 20. Braun V, Clarke V. What can "thematic analysis" offer health and wellbeing researchers? *Int J Qual Stud Health Well-being* 2014;9:26152. doi: 10.3402/qhw.v9.26152 [published Online First: 2014/10/19]
- Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nurs Health Sci* 2013;15(3):398-405. doi: 10.1111/nhs.12048 [published Online First: 2013/03/14]
- 22. Bradshaw C, Atkinson S, Doody O. Employing a Qualitative Description Approach in Health Care Research. *Glob Qual Nurs Res* 2017;4:2333393617742282. doi: 10.1177/2333393617742282 [published Online First: 2017/12/06]
- 23. Thurmond VA. The point of triangulation. *J Nurs Scholarsh* 2001;33(3):253-8. [published Online First: 2001/09/13]

Author Contributions

PJA & AK conceived the research idea. CW, AK and BS designed the study. CW wrote the first draft of the protocol and paper for publication. TB, INE, CK, MK, DJFS all contributed to the study protocol and edited the final paper

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Competing interests statement.

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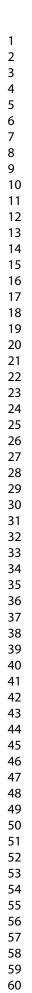
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Title Page

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INTRODUCTION

In 2017 the UK Department of Health and Social Care provided over £160 million of funding for global health research¹. From this funding the NIHR Global Health Research Group on Neurotrauma was established with the overall aim of improving outcomes from neurotrauma in low- and middle income countries² (LMICs). In addition to improving outcomes, the group also aims to increase the participation of LMICs in high quality clinical research³. The low proportion of published scientific papers from authors in LMICs is stark ⁴⁵. The limited participation of LMICs in research contrasts sharply with their disproportionately high incidence of neurotrauma⁶. In a recent study of research productivity in LMICs, as evidenced by publication in journals, Servadei, et al. ⁵ found that only 4.52% of 6708 published reports had an LMICs affiliation. In a further bibliometric study Africa and Southeast Asia were found to be responsible for less than 3% of publication productivity⁷. If journal publication is a reliable indicator of the quality and quantity of research, then LMICs are severely underrepresented in an international context⁵. In addition, Kolias, et al. ³ asserts that multicentre trials are typically conducted in high-income countries making generalisability of these studies to environments with different treatment practices particularly problematic. A recent review to identify randomised trials of neurosurgical procedures used in cranial and spinal neurosurgical practice found only 8.8% of studies (excluding China) were LMICs led studies⁸. Low-and middleincome countries need to develop an evidence-base that is relevant to the treatments and interventions accessible to them³⁷. Nurturing an environment that promotes high quality neurotrauma research is a fundamental part of this.

Little is written in the academic literature about the reasons why there are so few studies conducted, and/or published, by neurosurgeons in LMICs, although lack of time and resources are a likely factor ⁵. More specifically Langer, et al. ⁴ suggested poor research production; poor preparation of manuscripts; poor access to scientific literature; poor participation in publication-related decision-making processes and bias of journals all exacerbate low engagement. However, there is little empirical data to underpin these assumptions, therefore it is important to understand this so that any recommendations for enhancing research capacity in the future are context specific and borne out of an in-depth understanding of the problem. A review by Franzen⁹ examined health research capacity development in LMICs suggesting power relationships effected capacity development, that stronger links between research, policy and practice were required and that a systems response was necessary if capacity was to be improved. However, only 20.8% of the papers included in the review were sourced from empirical primary research.

Aim & Objectives

The aim of this study is to understand neurosurgeons' experiences of, aspirations for, and ability to, conduct and disseminate clinical research in low- and middle-income countries.

Objectives

- 1. Explore the types of clinical research neurotrauma physicians from low- and middleincome countries are engaged in.
- 2. Understand the contextual challenges to conducting and disseminating clinical research in low- and middle-income countries.
- 3. Identify ways in which research and dissemination activities can be facilitated in lowand middle-income countries.

METHODS and ANALYSIS

Study design

We propose an exploratory pragmatic qualitative study situated within the naturalistic paradigm. Pragmatic qualitative research, also referred to as descriptive or generic qualitative research, is particularly useful when little is known about a topic and when researching populations from other cultures¹⁰. Pragmatic qualitative studies are not philosophically informed allowing the study to be designed in a way that is feasible, achievable and appropriate for the aim of the study¹¹. The naturalistic paradigm, explicated by Lincoln and Guba¹², also known as the constructivist paradigm in more recent texts (although many authors still prefer this original description), reject methods which are reductionistic¹³. Naturalistic inquiry tries to stay true to the nature of the phenomena under investigation and commits to the existence of multiple realities and working with subjectivity¹⁴.

Data collection

As there is little written in the empirical literature, we were cautious about developing an a priori interview schedule to guide data collection. Therefore, we have designed a study that will explore neurosurgeons' experiences within a focus group first as a means to understand the nature of the problem initially and then conduct semi-structured interviews with a smaller sample to explore the research question in more depth than may possible in a focus group setting. In addition, we propose collecting a small amount of demographic data.

Specific demographic data will be collected from each participant to include age, gender, country of residence, job title and experience. In addition, we will ascertain specific exposure to research training, research participation and the relevance of research to job role and job progression. This data is required if we are to interpret the context of the data correctly.

Online focus groups have a number of advantages over more traditional focus group formats¹⁵. First, they allow people who are in different geographical places to contribute to a group discussion where a face-to-face focus group is not possible¹⁶. Second, there is a heightened level of anonymity which may mean people feel more able to be honest and or share sensitive information. Third, data is immediately available without the necessity for transcription ¹⁵. In addition, the asynchronous format allows participants the ability to contribute at a convenient place and time making the research more accessible to participants who may be in different time zones with competing demands on their time¹⁷.

The focus group questions were discussed with members of the research team, particularly those from LMICs, to ensure these were appropriate (Box One).

- 1. What are your personal experiences of conducting clinical research and what personal and/or organisational factors motivate you to conduct research?
- 2. What specific barriers are there to you conducting clinical research within your hospital?
- 3. In what ways is research shared between colleagues, the public, and the wider academic community?
- 4. What would help you to conduct and publish good clinical research?
- 5. What unique factors are there that should be considered to nurture research capacity in low and middle income countries?

Box One: Focus group questions

Selection of the online platform to facilitate the focus group was informed by a number of strict criteria informed by principles of safe data storage and accessibility. Each participant will be given a unique username and individually assigned password allowing them to contribute anonymously to the focus group. We propose three separate focus groups: Group One (lower income); Group two (lower-middle income); Group 3 (upper middle-income). We will try to have representation from a wide range of countries but will be affected by the number of people who respond to the initial call for participants. Questions will be posted online every seven-ten days in the order listed. Members of the UK research team, will regularly check the forum during this time, respond to direct questions if necessary, ask additional follow-up questions where appropriate or request clarification of points made.

Following completion of the online focus groups we will invite 20 participants to complete online video or telephone semi-structured interviews. We will select participants based on their demographic data and their contribution to the online focus group to ensure we capture a range of views and experiences. The specific interview schedule will be developed following preliminary analysis of the focus group data. The interviews will last approximately 30-60 minutes, will be conducted by the UK based research team and will be recorded with a digital recorder.

Sample

Non-random sampling is used in qualitative studies and here we use a purposive approach. Persons eligible to participate in this study are neurosurgeons working in a country defined as low- or middle-income, self-declared fluency in written and spoken English, have access to, and able to use, a personal computer or smart phone and able to provide informed consent. Participants will be identified in countries participating in the NIHR Global Health Research Group on Neurotrauma listed in Box Two. However, new collaborators in the group, including Zimbabwe and the Philippines, and participants from institutions based in other LMICs, will be added if necessary, to achieve the required sample size.

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1.	BRAZIL	7. MYANMAR
2.	COLOMBIA	8. NIGERIA
3.	ETHIOPIA	9. PAKISTAN
4.	INDIA	10. SOUTH AFRICA
5.	INDONESIA	11. TANZANIA
6.	MALAYSIA	12. ZAMBIA

Box Two: LMICs in the NIHR Global Health Research Group on Neurotrauma

Qualitative studies do not make any claims about generalisability so a sample size calculation is not appropriate. Instead qualitative studies use the concept of data saturation to assess the completeness of findings which is the point reached when researchers are confident that new data will reveal no new information ^{18 19}. In this study we aim to recruit 36 participants for the online focus groups and then 20 participants for the individual semi-structured follow-up interviews when we expect data saturation to be reached. If saturation is not reached, and increasing the sample size is feasible, we will request approval from the ethics committee to increase the sample to a more appropriate size.

Data analysis

There will be three phases to analysis in this study mirroring the stages outlined under study design. Phase one will analyse the focus group data; phase two will analyse the semi-structured interview data and phase three will triangulate findings from all methods to determine final findings for the study.

Phases one and two will use a Braun and Clarke ²⁰ thematic analysis (see Box Three) which is commonly used in pragmatic qualitative studies^{20 21} that do not require "highly abstract rendering of data" ^{22p.3}. Audio files will be transcribed verbatim by a transcription service and checked for accuracy by the research team. Online focus groups will be downloaded from the online platform and transferred to a Microsoft Word file. Given the nature of the research question it would be wrong to enforce an a priori framework on the analysis. Analysis will therefore be inductive and in vivo coding will be used. Analysis will be supported by the use of NVIVO software allowing researchers to organise the data, share coding decisions and confirm the origins of interpretation. CW will lead on the analysis, supported by BS in the initial coding and exploration of the data. CW is an experienced qualitative researcher and nurse academic with clinical experience of neurosurgery. BS is a PhD student and fourth year medical student who has undertaken training in qualitative methods and analysis. Once initial themes are identified these will be discussed with co-authors alongside supporting data. Themes will then be returned to participants so they can provide further insight. Any comments will be built into the process of defining and naming final themes.

- 1. Familiarising yourself with your data
- 2. Generate initial codes
- 3. Searching for themes
- 4. Reviewing themes
- 5. Defining and naming themes
- 6. Produce the report

Box Three: Braun and Clarke thematic analysis framework

Phase three will involve triangulation of data obtained from interviews and focus groups. The benefits of data triangulation include developing a more comprehensive understanding of the phenomena under investigation through the use of multiple methods²³.

Rigour

This study uses multiple methods and triangulation to increase its depth and accuracy of understanding. Preliminary findings from the focus group will be explored within the individual interviews which will increase credibility of the final findings. Critical reflexivity will also safeguard against naïve assumptions and possible hidden biases within the analysis. Peer debriefing and respondent validation will also be used in this study to increase rigour.

ETHICS and DISSEMINATION

The University of Cambridge Psychology Research Ethics Committee reviewed this study in January 2020 (REF PRE.2020.006). The University of Cambridge is the sponsor and appropriate insurance is in place. Participants will be informed fully about the study methods, risks and benefits through the participant information Sheet. A cooling off period of 48 hours will be given to all those who express an interest in the study and then electronic consent will be taken. Participants will be able to withdraw at any time. Data cannot be withdrawn from the focus groups, however participants can request their data is withdrawn from the interviews for up to one week following their completion. After this period this data cannot be withdrawn as analysis will have commenced.

All information will be kept strictly confidential and comply to principles of UK data protection law and General Data Protection Regulation. Participants will be advised not to share any personal information in the online focus group. When the focus groups have been completed, we will anonymise the data prior to data analysis. Similarly, all interview data will be anonymised upon transcription. Participants will be told that anonymised quotes will be published in the findings of this study. We will also be seeking consent to disclose region and level of income associated with their country of origin against any quotes used in the publication of findings as this will be important to the contextual understanding of the study.

Patient & Public involvement

Our research question asks for the views of neurosurgeons and therefore we do not intend to include patients or public in the design of, or data collection for, this study. However, we did ask for peer review of the study by collaborating members of the GHRGN. Their comments informed the final study design.

Dissemination

Participants in this study will be sent a summary of the findings once analysis has been completed. The findings of the study will then be shared through the NIHR GHRGN network, and other relevant stakeholders, including the World Federation of Neurosurgical Societies. This study will also be disseminated in conference presentations and journal publications.

Study Limitations

Generalisibility of the findings may be limited, as we do not expect to have participating neurosurgeons from all LMICs. However, we hope to include participants from a variety of LMICs with broad spread in terms of geography and income status. Unfortunately, due to the resources available we had to exclude non-English speaking neurosurgeons. Any additional experiences that this specific population have in conducting and disseminating research will remain unexplored, therefore, we will need to be cautious in our final conclusions for this study. However, given that this is the first study, that we know of, to explore the challenges of neurosurgeons conducting and disseminating clinical research in LMICs this qualitative study will provide a rich and in-depth

understanding of how engagement in research could be improved for this population. This understanding will facilitate the development of appropriate recommendations with the aim of nurturing research capacity for neurosurgeons in LMICs in the future.

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REFERENCES

- 1. Department of Health and Social Care. Government awards over £120 million for global health research 2017 [Available from: <u>https://www.gov.uk/government/news/government-awards-over-120-million-for-global-health-research</u> accessed 21/10/19.
- 2. Neurotrauma.world. NIHR Global Health Research Group on Neurotrauma 2016 [Available from: <u>http://neurotrauma.world/</u> accessed 21/10/2019.
- 3. Kolias AG, Rubiano AM, Figaji A, et al. Traumatic brain injury: global collaboration for a global challenge. *Lancet Neurol* 2019;18(2):136-37. doi: 10.1016/S1474-4422(18)30494-0 [published Online First: 2019/01/22]
- 4. Langer A, Diaz-Olavarrieta C, Berdichevsky K, et al. Why is research from developing countries underrepresented in international health literature, and what can be done about it? *Bull World Health Organ* 2004;82(10):802-3. [published Online First: 2005/01/13]
- Servadei F, Tropeano MP, Spaggiari R, et al. Footprint of Reports From Low- and Low- to Middle-Income Countries in the Neurosurgical Data: A Study From 2015 to 2017. World Neurosurg 2019;130:e822-e30. doi: 10.1016/j.wneu.2019.06.230 [published Online First: 2019/07/12]
- 6. Mock C, Lormand JD, Goosen J, et al. Guidelines for essential trauma care. Geneva, 2004.
- 7. Tropeano M, Spaggiari R, Ileyassoff H, et al. A comparison of publication to TBI burden ratio of low- and middle-income countries versus high-income countries: how can we improve worldwide care of TBI? *Neurosurgical Focus* 2019;47(5):E5 p.1-6.
- B. Griswold DP, Khan AA, Chao TE, et al. Neurosurgical Randomized Trials in Low- and Middle-Income Countries. *Neurosurgery* 2020 doi: 10.1093/neuros/nyaa049 [published Online First: 2020/03/15]
- 9. Franzen SR, Chandler C, Lang T. Health research capacity development in low and middle income countries: reality or rhetoric? A systematic meta-narrative review of the qualitative literature. *BMJ Open* 2017;7(1):e012332. doi: 10.1136/bmjopen-2016-012332 [published Online First: 2017/01/31]
- 10. Sullivan-Bolyai S, Bova C, Harper D. Developing and refining interventions in persons with health disparities: the use of qualitative description. *Nurs Outlook* 2005;53(3):127-33. doi: 10.1016/j.outlook.2005.03.005 [published Online First: 2005/07/01]
- 11. Smith J, Bekker H, Cheater F. Theoretical versus pragmatic design in qualitative research. *Nurse Res* 2011;18(2):39-51. doi: 10.7748/nr2011.01.18.2.39.c8283 [published Online First: 2011/02/16]
- 12. Lincoln YS, Guba EG. Naturalistic inquiry. Beverly Hills, Calif. ; London: Sage 1985.
- 13. Beuving J, de Vries G. Doing Qualitative Research: The Craft of Naturalistic Inquiry. Amsterdam: Amsterdam University Press, 2015.
- 14. Bowen GA. Naturalistic inquiry and the saturation concept: a research note. *Qualitative Research* 2008;8(1):137-52. doi: 10.1177/1468794107085301
- 15. Zwaanswijk M, van Dulmen S. Advantages of asynchronous online focus groups and face-to-face focus groups as perceived by child, adolescent and adult participants: a survey study. *BMC Res Notes* 2014;7:756. doi: 10.1186/1756-0500-7-756 [published Online First: 2014/10/25]
- Harmsen IA, Mollema L, Ruiter RA, et al. Why parents refuse childhood vaccination: a qualitative study using online focus groups. *BMC Public Health* 2013;13:1183. doi: 10.1186/1471-2458-13-1183 [published Online First: 2013/12/18]
- 17. De Groot K, Maurits EEM, Francke AL. Attractiveness of working in home care: An online focus group study among nurses. *Health Soc Care Community* 2018;26(1):e94-e101. doi: 10.1111/hsc.12481 [published Online First: 2017/07/22]
- 18. Polit DF, Beck CT. Resource manual for Nursing research : generating and assessing evidence for nursing practice. Tenth edition. ed. Philadelphia: Lippincott Williams & Wilkins 2016.

- Moser A, Korstjens I. Series: Practical guidance to qualitative research. Part 3: Sampling, data collection and analysis. *Eur J Gen Pract* 2018;24(1):9-18. doi: 10.1080/13814788.2017.1375091 [published Online First: 2017/12/05]
- 20. Braun V, Clarke V. What can "thematic analysis" offer health and wellbeing researchers? *Int J Qual Stud Health Well-being* 2014;9:26152. doi: 10.3402/qhw.v9.26152 [published Online First: 2014/10/19]
- Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nurs Health Sci* 2013;15(3):398-405. doi: 10.1111/nhs.12048 [published Online First: 2013/03/14]
- 22. Bradshaw C, Atkinson S, Doody O. Employing a Qualitative Description Approach in Health Care Research. *Glob Qual Nurs Res* 2017;4:2333393617742282. doi: 10.1177/2333393617742282 [published Online First: 2017/12/06]
- 23. Thurmond VA. The point of triangulation. *J Nurs Scholarsh* 2001;33(3):253-8. [published Online First: 2001/09/13]

Author Contributions

PJH & AK conceived the research idea. CW, AK and BS designed the study. CW wrote the first draft of the protocol and paper for publication. TB, INE, CK, MK, DJFS all contributed to the study protocol and edited the final paper

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Competing interests statement.

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