Beta-blockers Or Placebo for Primary Prophylaxis of oesophageal varices (BOPPP Trial). A blinded, UK multi-centre, clinical effectiveness and cost-effectiveness randomised controlled trial (BOPPP).

Publication and Dissemination Policy

Scope: This document relates to outputs arising from the BOPPP trial, including both written and oral presentations, and publications.

Publication Policy

A significant number of people will contribute to the BOPPP trial during its course, including many outside the trial management or steering committees. This document addresses how individuals contribute to the publication process to ensure timely study outputs in an equitable, efficient and transparent manner.

Principles regarding authorship and writing

- A lead author and wider writing team will be established for each identified paper.
- All potential contributors will have the opportunity to opt into a writing team.
- It is the responsibility of the Chief Investigator (CI) and Chief Scientific Investigator (CSI) to ensure balance and inclusivity in writing teams across the range of likely study publications, to ensure everyone is appropriately acknowledged and has the opportunity to be involved as an author.
- It is the responsibility of the CI to decide authorship order, usually in discussion with the lead author and CSI.
- All named authors must meet authorship criteria (detailed below).
- A timetable for publication will be agreed with each lead author and approved by the BOPPP TMG and will include a start date (for drafting) and target submission date.
- Publication timetabling must account for appropriate review by the funding body and sponsor. For any one paper, each substantive new draft/version will be circulated by the lead author to the writing team to ensure appropriate opportunities to contribute. The lead author will be in charge of version control.
- The TMG welcome proposals for additional outputs from any member of the BOPPP team at all sites - All proposals for publications using BOPPP trial data will require approval by the BOPPP TMG which convenes monthly.

Presentations

- Submission of abstracts for conference presentation should be agreed in advance with the BOPPP TMG. Authors should allow sufficient time for their request to be reviewed. This may be completed via email.
- However, if there is insufficient time for the BOPPP TMG to review such a request, the CI or delegate can make a decision on behalf of the BOPPP TMG.

Authorship & contributorship

The following criteria based on BMJ rules on *authorship* and *contributorship* (see http://www.bmj.com/about-bmj/resources-authors/article-submission/authorship-contributorship) will be used to acknowledge the level and nature of contribution of key individuals in publications arising from the project. Note that this states:

Authorship

The uniform requirements for manuscripts submitted to medical journals state that credit should be based only on substantial contribution to (see http://www.bmj.com/about-bmj/resources-authors/article-submission/authorship-contributorshipauthorship):

- The conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All these conditions must be met. Participation solely in the acquisition of funding, collection of data or recruitment does not justify authorship.

The lead author and/or senior author will be identified as guarantors of the paper. The guarantor accepts full responsibility for the work and/or the conduct of the study, has access to the data, and has controlled the decision to publish.

Publication level

Publications fall into three categories which will be agreed by the BOPPP TMG:

Level 1
Publications which relate to the main purpose of the study and the funding received.

Level 2
Publications relating to the main study, but not the main questions. For example, this may include some exploratory analysis of collected data.

Level 3
Publications which utilise the study but need additional resources to deliver.

Consideration should be given as to whether or not the study should be referred to in the authorship (e.g. and the BOPPP trial team).

Contributorship and acknowledgements

Contributorship
Contributors to the BOPPP trial will be acknowledged on each publication and, once available, on the study website. Where journal restrictions apply, it may be that readers are simply directed to the study website for full details of contribution. Contributorship relates to the BOPPP trial as a whole, not necessarily individual study outputs. Contributors may also be already listed as authors on individual papers.

The contributorship statement would be drafted by the lead author (in conjunction with the CI and CSI) and circulated as part of the draft manuscript for endorsement / modification by the other authors.

Acknowledgements
The lead author shall acknowledge all others who have played a part in the study but do not fulfil the criteria for authorship or contributorship. This may include groups who have contributed to design or staff in sites which have delivered the study.

All outputs should acknowledge the study funders and sponsor and carry the appropriate disclaimers. If the sponsor or funding body requires advance notification of submission this must be noted and built into the dissemination timetable accordingly.

All publications should be considered for wider dissemination in liaison with funders or sponsors where appropriate and should be fed back to participants (see Public Involvement Policy POL/003/1) and the wider public as appropriate.

Access to/use of study data

- Any use of study data, including process and outcome data, beyond the study team must be subject to prior approval from the BOPPP TMG, which must include both CI and CSI.
- Use of data may also need Sponsor and Funder approval
- Such requests must be in writing and clearly describe the purpose for which the data is required and how it is to be used.
- All output from such work must acknowledge the source of the data, and its use must be consistent with ethical and governance approval, (either existing of subsequently sought).
- Where appropriate authorship opportunities should be allocated to the CI and relevant study staff.

- The BOPPP team would like the authorship of the main publications to be inclusive, and will be largely reflective on recruitment metrics.
- As a guide, for each 10 participants a site recruits an additional named author can be added to the main trial publication in addition to site PIs. This can be discussed on a site-by-site basis and can include any member of the site BOPPP study group as defined below. Non-medical authorship is encouraged.

  <u>BOPPP study group definition:</u>
  - Principal Investigators
  - Research nurse(s)/practitioner(s)
  - Sub-investigator(s)
  - Associate Principal Investigator(s)

Table of planned publications – authorship is subject to ongoing study activity

Level 1 publications						
Study component / outline paper	**Aims of paper / notes**	**Possible target journal/s (Impact factor)**	**Lead writers**	**Other writers**	**Priority**	**Status**
Protocol paper (group authorship)	Offer external authorship – those actively involved, Bristol team (BOPPP study group) Definitions of involvement – delivery staff Named authors – Site PIs - >10 patients - API scheme providing writing input – Spring 2021	BMJ open	Trial Manager, Junior Statistician, Qualitative Researcher	BOPPP study group	High	Draft: Spring 2021
Qualitative Research paper Optimising recruitment to the BOPPP trial: a qualitative study exploring patient and staff perspectives	Barriers and facilitators (from the perspectives of trial participants and recruiting staff) Identifying factors that influence recruitment to the BOPPP trial – and opportunities for tailored interventions to improve recruitment.	PlosMedicine	Qualitative Researcher, Dr Vanessa Lawrence, Dr Haroon Ahmed, Research Nurse,		High	Draft: Spring 2021
Baseline paper	Describes population that we have recruited, feeds into main outcomes paper, but doesn't have outcome. This is the cohort that we have generated in the BOPPP recruits.	BMJ open PlosOne	Trial Manager, Junior Statistician, Qualitative Researcher, Research Nurse, Dr Vishal Patel			TBC

Main Clinical Outcomes paper		Lancet (3500 words), New England Journal of Medicine	Dr Vishal Patel, Dr Ben Carter, Dr Mark McPhail	BOPPP study group		TBC
M-BOP mechanistic paper		Lancet, New England Journal of Medicine	Dr Mark McPhail, Dr Vishal Patel, Dr Ben Carter			TBC
Health economics paper			Health Economist, Dr Huajie Jin	BOPPP study group		TBC
GP data – implementation in primary care Additional GP data required to make paper viable	Factors that influence successful implementation in primary care	Implementation Science	Qualitative Researcher, Dr Vanessa Lawrence, Dr Haroon Ahmed, Dr Vishal Patel, Dr Mark McPhail	BOPPP study group	High	Draft: Summer 2021

All members of BOPPP study team have ability to propose Level 2 and 3 publications.

Level 2 publications						
Study component / outline paper	**Aims of paper / notes**	**Possible target journal/s (Impact factor)**	**Lead writers**	**Other writers**	**Priority**	**Status**
Event rate paper (Natural history)	This is open to those who propose themselves and would ideally suit PIs/ Sub-Is/ A-PIs at sites.	**At local PI discretion**	PIs/ Sub-Is/ A-PIs			**Spring 2023**
Site level data - Abstract	Sites that have 50-80 BOPPP cases could generate a site level abstract.	**At local PI discretion**	Trainees/ A-PIs			**TBC**

Level 3 publications						
Study component / outline paper	**Aims of paper / notes**	**Possible target journal/s (Impact factor)**	**Lead writers**	**Other writers**	**Priority**	**Status**
Investigators	Access to local data – analyse Access data to ask additional questions of local relevance.	**At local PI discretion**	BOPPP study group			**TBC**

Conference Presentations							
Status	**Date of conference**	**Submission deadline**	**Conference**	**Venue**	**Title**	**Presenter**	**Type**

Contribution Log					
Initials	**Name**	**Dates of contribution to study**	**Description of contribution**	**Potential papers to be include on as author (by no)**	**Person responsible for ensuring engagement**

Public Engagement Log					
Date of event	**Name of event**	**Venue**	**Contribution type**	**Title**	**Presenter**

Appendix I

Site	Potential Named Authors
Royal London Hospital	Dr Vikram Sharma Louise Payaniandy Christopher Sivell
Royal Victoria Hospital, Belfast	Dr Roger McCorry Dr Johnny Cash Allison Lloyd Heather Lawther
Queen Elizabeth Hospital, Birmingham	Dr Dhiraj Tripathi Dr Neil Rajoriya Emma Burke Emma Eaves
Royal Sussex County Hospital, Brighton	Dr Khaleel Jamil Lorraine Shah-Goodwin He Zhengmei
Southmead Hospital, Bristol	Dr Zeino Zeino Charlotte Cranfield Rebecca Noller
Addenbrookes Hospital, Cambridge	Dr Jo Leithead/ Dr Victoria Snowdon Bill Griffiths Abigail Ford
Royal Derby Hospital	Dr Andrew Austin Marie Appleby
Royal Devon and Exeter Hospital	Dr Ben Hudson Victor Mariano Melanie Hutchings
Frimley Park Hospital	Dr Kuldeep Cheent Thanuja Weerasinghee Louise Rowe-Leete
Glasgow Royal Infirmary	Professor Adrian Stanley Lynne Turner Mhairi McIntyre Janet Johnstone
St Marys Hospital, Imperial	Dr Ameet Dhar Dr Nowlan Selvapatt Celia Diaz-Moore Gareth Hahn
King's College Hospital	Dr Mark McPhail Ane Zamalloa
Kingston Hospital	Dr Helen Matthews Andrew Swain Margaret Grout
Royal Liverpool University Hospital	Dr Edward Britton

	Dr Imran Patanwala Martina Lofthouse
Freeman Hospital, Newcastle	Dr Steven Masson Sarah Hogg Jasmin Snowdon Rachael Welton Lorna Brownlee
Queens Medical Centre, Nottingham	Dr Stephen Ryder Varinder Ryan Jan Hallas Julie Grundy
Derriford Hospital, Plymouth	Professor Matthew E Cramp Sue Inniss Sarah Griffee Charlotte Orr
Queen Alexandra Hospital, Portsmouth	Dr Andrew Fowell Dr Richard Aspinall Beverley Longhurst Melanie Willcox
Princess Royal University Hospital	Dr Mayur Kumar Nicola Griffiths
Royal Free Hospital	Dr Jennifer Ryan Christine Eastgate
St Georges Hospital	Dr Sarah Hughes Joana Teixeira