CLINICAL STUDY PROTOCOL

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Executive summary

In May 2017, 2018 and 2019, and over an extended screening period of several months in 2021, 2022, 2023 and 2024, a global cross-sectional blood pressure (BP) screening survey (May Measurement Month [MMM]) was carried out in more than 120 countries overall, collecting data from over 7 million adult participants to raise awareness of the health issues surrounding raised BP. Due to the COVID-19 pandemic, the survey was deferred in 2020.

An eighth BP campaign (MMM25) is now planned. As per previous years, it will involve the opportunistic screening of volunteer adults (aged ≥18 years). The MMM25 survey is expected to be conducted in approximately 90 countries each incorporating a variable number and type of screening sites. Basic demographic and clinical information as well as BP measurements will be collected by trained volunteer investigators throughout the month of May. The campaign period may be extended for up to four months for logistical or other reasons.

BPs will be measured with participants in the sitting position and recorded in triplicate according to standardised specified methods. The data will be anonymised, coded and transferred electronically (through a purpose-designed application or using an Excel spreadsheet) to a central Amazon Web Services (AWS) DynamoDB database. Screenees whose BP readings are consistent with the current definition of hypertension (≥140 mmHg systolic and/or ≥90 mmHg diastolic and/or taking BP-lowering medication) will be provided with written dietary and lifestyle advice. They will also be provided with advice regarding referral to receive medications and/or follow up support, according to local facilities.

As per MMM24, in 2025, a select number of countries will be invited to conduct atrial fibrillation (AF) screening at MMM sites in addition to the standard BP screening procedures.

1. Rationale

Raised blood pressure (BP) is the biggest single contributing risk factor to global death[1] and to the global burden of disease[1]. This impact is largely mediated through increased rates of cardiovascular (CV) disease, specifically coronary artery disease, heart failure, stroke and renal disease. Because CV disease affects approximately one third of adults globally, it represents the largest epidemic ever experienced by mankind. Raised BP currently causes approximately 10.9 million deaths each year worldwide[1] and this figure is expected to rise, given an expanding and aging global population. The

aetiology of raised BP is largely explicable by identified environmental factors such as obesity, excessive intake of alcohol and dietary salt, and insufficient exercise[2]. However, several drug classes have been shown to provide cost-effective BP lowering for the prevention of the adverse CV sequelae of raised BP. Despite the availability of these antihypertensive medications, global data suggest that less than half of those classified as hypertensive are aware of their problem[3,4,5]. Furthermore, less than a third of those who are treated for hypertension get their BPs controlled to currently recommended targets[3,4,5]. Even assuming treatment and control rates are maximised among those currently diagnosed as being 'hypertensive'[3,4,5] it is clear that a huge beneficial impact on morbidity and mortality, and a massive reduction in the burden of disease attributed to raised BP, can be achieved by increasing awareness through enhanced screening for raised BP.

Successful BP screening campaigns, entitled May Measurement Month (MMM) were carried out in 2017[6], 2018[7], 2019[8], 2021[9], 2022[10], 2023 and 2024. These campaigns included 120 countries in total up to at least 70 countries each year, and in total over seven million adults have been screened.

2. Aims

The aims of the May Measurement Month 2025 campaign are as follows:

1) To highlight the importance of measuring BP.

2) To identify and facilitate the reduction of BPs of those people who require intervention to lower their BP according to current guidelines.

3. Objectives

The objectives of the May Measurement Month 2025 campaign are as follows:

1) To target at least 1 million people aged ≥ 18 years for BP screening

2) To supply diet and lifestyle treatment advice to all those screened who have BPs in the high normal (130-139 / 80-89 mmHg) and hypertensive (≥140/90mmHg) ranges.

3) To provide advice on further follow-up of raised BP according to local facilities.

4) To use the data on untreated and inadequately treated hypertension to motivate governments to improve local screening facilities and policies, and thereby reduce the global burden of disease associated with raised BP.

4. Methods

4.1 Inclusion criteria

i. Any adult aged ≥ 18 years

ii. Informed consent provided by participants according to local requirements.

4.2 Patient materials

All written materials presented to screenees will use vocabulary in a language that is clearly understood at the study sites. These materials will be provided in several core languages (English, French, Spanish, Chinese, Arabic, Hindi, Portuguese) and will be available to download from the maymeasure.org website.

4.3 Collection of site information and basic demographic information

a) All questionnaire information should be collected prior to BP measurements

b) Where the app is used, data that will remain the same throughout the screening session will only need to be entered once (e.g. date, location).

c) The following anonymised data will be collected on all screenees via approximately 26 questions:

- Location eg. country/town/site ID
- Basic demographic information eg. age, gender and ethnicity
- Relevant medical history eg. any previous history of hypertension, diabetes and adverse CV events.
- Relevant medication history eg. use of BP medications, aspirin, anticoagulants and statins
- Lifestyle information eg. exercise habits, smoking and alcohol use
- Three sitting BP and pulse readings

4.4 Collection of BP measurements

4.4.1 Type of BP machine

- BP should preferably be measured by an automated electronic device. However, if this is not available, a conventional sphygmomanometer using a stethoscope can be used.
- If a sphygmomanometer is used, the first and fifth Korotkoff sounds (the appearance and disappearance of sounds) will be recorded as the systolic and diastolic BP respectively.
- The brand of BP machine (OMRON/other) used to measure BPs will be recorded.

4.4.2 Cuff size

Measure the circumference of the arm (at the mid upper-arm level) and ensure where possible that the correct size of arm cuff is used:

- For arms with circumference <22 cm use paediatric cuff
- For arms with circumferences 22 – 32 cm, use regular cuff
- For arms with circumference 32 – 42cm, use large cuff (or medium/large cuff [22 - 42cm])
- For arms with circumference > 42cm, use extra-large cuff

4.4.3 Taking BP measurements

- BP should be measured on the upper arm of one arm only, preferably left. The cuff should be placed at the heart level
- The patient's arm being used for the measurement should rest comfortably on a table
- Prior to measurement:

  The participant should be seated with their backs supported, legs uncrossed and feet flat on the ground for five minutes

  Participants should not have smoked immediately before or during the measurement and should not talk during and between BP measurements.
- Three BP readings should be taken with one minute between readings and recorded using one of the methods described below in Section 5.1.
- For each BP reading, the automated BP devices also provide data on heart rate, and this information should also be captured using one of the methods described below in Section 5.1. If the auscultatory method/sphygmomanometer is used, the heart rate should be established during the one minute after each BP reading, and also recorded via the app or other chosen data collection method.

4.5 Advice for high normal and 'hypertensive' BPs

Definition of high normal:

- the average SBP (mean of the last 2 of 3 readings) = 130-139 mmHg and/or
- the average DBP (mean of the last 2 of 3 readings) = 80-89 mmHg

Definition of hypertension:

- being on at least one antihypertensive medication taken for raised BP or
- the average SBP (mean of the last 2 of 3 readings) ≥ 140 mmHg and/or
- the average DBP (mean of the last 2 of 3 readings) ≥ 90 mmHg

Dietary and lifestyle information provided to those with high normal and 'hypertensive' BPs to include:-

a) reduce salt intake

b) don't drink too much alcohol – stick to local recommendations

c) don't smoke

d) reduce caffeine intake

e) reduce saturated fat and sugar intake

f) engage in regular physical exercise for at least 30 minutes on at least five days of the week

g) eat plenty of fruit and vegetables daily (including nitrate rich foods e.g. beetroot, green leafy vegetables, apples and grapes etc)

h) maintain a healthy body weight

i) avoid stress where possible and allow time for relaxation

A generic package of advice will be provided centrally for local adaptation and can be translated locally if required.

4.6 Atrial Fibrillation Sub-study (for participating countries/sites only)

Raised blood pressure (BP) and atrial fibrillation (AF) are both major risk factors for stroke and AF is more common among those with raised BP. Both conditions, if detected and well-treated, can reduce the risk of stroke and other cardiovascular disorders (e.g. dementia).

Both conditions are relatively easy to detect by routine screening and recently-produced medical devices allow for the detection of AF via a single lead ECG incorporated into a BP measuring device (eg. the OMRON M7, Complete device or Omron Intellisense).

The AF-Screen International Collaboration is a group of global experts with an interest in AF. Their aim is to promote discussion and research about screening for unknown or under-treated AF as a way to reduce stroke and associated death. They provide advocacy for implementation of AF-screening programs, tailored to the medical systems of individual countries. Following collaborative pilot studies between AF-Screen and MMM personnel in 2021, 2022, 2023 and 2024, the AF-Screen International Collaboration will work with the May Measurement Month (MMM) campaign in 2025 to carry out combined AF and BP screening in a subset of countries participating in MMM, in order to raise awareness of undiagnosed AF and evaluate the efficacy of combined screening for raised BP and AF.

4.6.1 Methods

Approximately 37 countries that participate in MMM have been identified as having active AF-Screen members. In a subsample of approximately 10 countries the MMM National Leads who are able to collaborate with their local AF-screen members will acquire ethics and agree screening sites that will participate in both the usual MMM protocol as well as the AF sub-study (see Appendix 1).

BP and AF screening will be carried out using the OMRON Complete, M7 devices and Intellisense on all BP screenees aged 60 and above.

The usual questionnaire administered with BP screening will be modified slightly by the addition of 3 extra questions as follows :-

Was Atrial Fibrillation detected in the current assessment? Yes, No

Have you ever been diagnosed as having Atrial Fibrillation by a health professional before? Yes, No

Which device(s) was/were used to check whether AF was present? Omron Complete, Intellisense, Omron M7, None

The final question links to a YES response to the question ‘Was Atrial Fibriliation detected in the current assessment? Yes, No

Those detected as having AF will be advised of their condition and provided written information about the causes and consequences of AF.

Those detected with AF will be referred to relevant medical facilities to arrange confirmation and management of the AF diagnosis as required.

4.6.2 Unique Reference Numbers

Where possible, a link between the MMM AF detection service and a clinic/consultant will be set up in order to refer participants for linkage to care with targeted follow up, where required. In order to understand the impact this detection study is having in each country, MMM will provide each participant with a unique reference number (URN) to enable follow up with the linked AF follow up facility. A full breakdown of the participant journey is provided to each participating country for guidance. (Appendix 2).

Data regarding the treatment and follow up of those patients detected initially as having AF will be collected and analysed as part of the MMM25 sub study (MMM/AFS 2025).

5. Data Management

5.1 Source Data

- Data will be collected directly from screenees and entered onto the bespoke MMM App (produced by Clarifi media) before and immediately after BP measurements. The data collected are anonymous, with no personally-identifiable information collected from the screenees.

- Investigators collecting or uploading data will to be given a set of reference numbers which will be included on each participants' record in order to establish the location of each screening site.

- The MMM App can be used where internet facilities are not available but will then need to be downloaded and registered in an area with internet connection. Where online access is available at the screening site, data will be uploaded automatically from the app to the central AWS DynamoDB database.

- If working offline, data will be uploaded by the app once internet access is available.

- Where a laptop or mobile device is not available, data can be collected, handwritten on to a template form, provided by the MMM project team, and then transferred into the database via manual input into the app. The app will be available in 8 languages: English, Arabic, Chinese (Cantonese/Mandarin), French, Hindi, Portuguese, Polish and Spanish.

- If use of the MMM app is not at all possible, then an Excel spreadsheet will be provided by the MMM project team and data can be recorded either directly, or via entry from paper forms. These will be submitted to the MMM project team and stored in the same AWS Dynamo DB database.

5.2 Database

BP data records will be stored on Amazon Web Services (AWS). Data collected via the app will be stored in raw form in an AWS DynamoDB database and exports of the collected data will be stored as Comma Separated Value (CSV) files within AWS Simple Storage Service (AWS S3).

5.3 Access to Data

Access to AWS will be restricted to authorised users only who will require to use 2-factor authentication to sign into their accounts. Access to this password-protected drop-folder and to DynamoDB will be provided to the MMM statistician, project manager and those nominated by the MMM Trustees for the purposes of data analysis, for the duration of analysis.

The Study Principal Investigator on behalf of MMM will be the custodian of the data on behalf of all collaborating national investigators. National Lead MMM Investigators in each country may request the raw data via email to the project manager, which will be made available as soon as possible and ideally within 10 working days. Following cleaning of the data centrally, cleaned data will also be available to Lead MMM Investigators in each country on request as soon as possible and ideally within 10 working days. Access to the data for any other 3rd parties for research purposes is granted by the MMM Publication committee on application via mail to the MMM Trustees.

5.4 Data Quality

Accurate data collection and reporting is critical for ensuring the validity of the MMM campaign results as well as to uphold ethical standards to participants. Data checks will be undertaken centrally by the MMM management team in order to identify any potential invalid data, errors or anomalies - this may include missing or duplicate data. Should any concerns arise, the National Leader or appropriate delegate will be contacted to rectify the issue.

Should the checks or associated modelling suggest that the data may be invalid, this will be escalated urgently to the National Lead for input and investigation, and to any relevant country-level ethics committees as appropriate. If the outcome of any investigation still suggests that the data are invalid, then all or any data from that country may be removed, and any individuals who may be linked to the invalid data will not be permitted to participate in any further MMM campaigns.

6 Statistical Analysis

6.1 Sample size

The total of >1 million adults (18+years) was selected on the basis of including a large enough sample of BP data in each participating country, sufficient to raise awareness at a national level.

6.2 Data Analysis

Analyses will include but not be restricted to:

i) The proportion of screenees with previously undiagnosed hypertension at a national, regional, global and ethnic level.

ii) Age and sex stratified and standardised levels of systolic (S) BP, diastolic (D) BP, BP variability and the proportion of screenees with known and newly diagnosed hypertension generated at a national, regional and global level.

iii) The proportion of screenees on treatment for hypertension with uncontrolled BP.

iv) The association between the same BP parameters and site of data collection, age, sex, ethnic group and treatment status will be evaluated at a regional and global level.

v) The association between the same BP parameters and other co-variants reported including previous CV disease, pulse rate, BMI, pregnancy, diabetes, smoking, socio-economic status, exercise output and alcohol intake.

7 Ethical Considerations

7.1 Informed Consent

In accordance with local requirements, informed consent will be acquired from all screenees having received a simple verbal explanation of what data are to be collected and why, including that collected data will be used for research purposes.

7.2 Ethical/Regulatory Authority approval

In those countries or regions where ethics approval is required for an anonymised screening project such authorisation will be obtained from the relevant authority before BP screening begins.

Logistics including legacy effects of COVID-19, may require adaptation of the screening period within each local setting.

7.3 Subject Confidentiality

All screenee data collected for MMM is anonymous and not traceable to the individual screenees.

7.4 Local COVID-19 compliance

National leaders and their delegates will be responsible for ensuring that the running of MMM25 within their country, is in line with all local laws and guidance measures regarding COVID-19, if required.

8 Study Management

8.1 Overall management structure

The Trustees of the MMM charity will provide global oversight for the project, collection, processing, analysis and interpretation of the data. They will be supported by the project management team to form the MMM Management Board. The MMM Management Board will also receive advice from external advisors appointed to the board for a defined period. These advisors will meet with the MMM Management Board twice per year plus on an ad-hoc basis if required. The recruitment will be initiated, monitored and supervised by the national leaders (at least 1 per country). They will be responsible for identifying recruitment sites, each with a centre lead (experienced clinician/nurse/pharmacist). The national leaders will report directly to the MMM Management Board via the Project Manager at harsha@maymeasure.org.

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Appendix 1

Atrial Fibrillation Screening Countries

In the first instance, the countries listed below are anticipated to be invited to participate in our Atrial Fibrillation Screening Programme in 2025.

1. Armenia
2. Australia
3. Bahrain
4. Bulgaria
5. Canada
6. China
7. Georgia
8. Greece
9. Kyrgyzstan
10. Mexico
11. Mozambique
12. Nepal
13. Nigeria
14. Philippines
15. Poland
16. Portugal
17. Slovakia
18. Thailand
19. UK and RoI
20. Vietnam

The list above is tentative and may be subject to change. Any countries that participate in the AF screening programme will gain all relevant local approvals.

Appendix 2

Atrial Fibrillation Participant Journey