Protected Characteristics Project (PCP) Report

Contents

Section 1:

Background:

Multiple studies have demonstrated marked inter-ethnic differences in efficacy and safety of many drugs used to prevent and treat a range of conditions include cardiovascular, respiratory and oncological diseases. Under-representation in research participation therefore reduces the generalisability of findings, exacerbates poor patient outcomes and increases treatment costs. This compounds the inequalities these individuals already face, which leads to poorer health and an increased risk of morbidity and premature mortality.

Little data on protected characteristics (PCs) (age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation), or caring responsibilities is routinely collected from research participants as part of study protocols or through clinical records. Without this data it is difficult to robustly identify which communities/groups are excluded from research studies for which they are eligible. It also means it is difficult to evaluate whether efforts to increase research inclusion are having an effect on the diversity of research participants.

The Protected Characteristics Project (PCP) aimed to:

- Establish an effective way of collecting PCs, caring responsibilities and deprivation (using the Index of Multiple Deprivation [IMD], which is based on postcode) for research participants across Bristol, North Somerset and South Gloucestershire (BNSSG)
- Co-design a suite of Key Performance Indicators (KPIs) that could be used to monitor participation by under-served communities in research.

Funding for this project was provided by West of England Clinical Research Network, now part of the NIHR Research Delivery Network (RDN), NHS England, BNSSG ICB (Bristol, North Somerset and South Gloucestershire Integrated Care Board), Bristol and Weston Hospitals Charity and participating NHS trusts.

Questionnaire development:

In the summer of 2023, members of the public were invited to participate in focus groups to co-develop a questionnaire focused on the characteristics of people who participate in research. Various approaches were used to attract members of the public, including social media advertising, community groups and word-of-mouth. Recruitment was focused on five protected characteristics: race, religion, disability, sexual orientation and maternity/pregnancy, recognising that the remaining four would intersect with the selected five characteristics. The advert used for recruitment welcomed inclusion from all protected characteristics groupings.

Twenty-nine people were recruited and participated in a series of focus groups to create a questionnaire (*ref to appendices 1 and 2 for details on focus group members).* NIHR User Guidance for the diversity data questions (2022) which was based on version 2 of the Diversity and Inclusion Survey (DAISY) Question Guidance, developed by (Equality, Diversity and Inclusion in Science and Health) EDIS and the Wellcome Trust, was used to create the initial PCP questionnaire. The questionnaire asked questions on all the nine protected characteristics, caring responsibilities and postcode. Explicit consent was also sought from participants to pseudo-anonymise their data and link their protected characteristics data to clinical data in the BNSSG ICS Shared Data system. Focus group members provided feedback on the wording of the questions and the wrap around text to explain the rationale for each question in relation to research. The format and background colour of the questionnaire was also discussed to ensure readability by those who have visual impairments and/or dyslexia.

Seven focus groups were held, employing an iterative process in which comments from one group were actioned and the updated version of the questionnaire presented to the next group. Participants were provided questionnaires at least 24 hours before the meeting, and they were paid £25 per hour to review and attend the meeting.

Additional focus groups were held with members of the Bristol Young People's Advisory Group (YPAG) and two parents to help tailor the questionnaire for participants aged 0-10 and 11-16.

Section 2:

Data collection

The PCP was conducted as a service improvement project with approvals from the Quality Improvement departments of participating organisations. In September 2023 the questionnaire was piloted by 585 participants in early-phase NIHR studies delivered between September 2021 and December 2023 by the University Hospitals Bristol and Weston NHS Foundation Trust Clinical Research Facility (UHBW CRF). This provided proof of concept and feasibility of the questionnaire. The completion rate was 69% and >98% provided postcode to calculate IMD.

Between September 2024 and February 2025, the questionnaire was rolled out across all acute trusts and GP surgeries in the BNSSG region. Participants in NIHR studies conducted between January 2022 and December 2023 at UHBW, North Bristol NHS Trust (NBT) and GP surgeries were invited to participate. The PCP team are UHBW employees and were granted honorary contracts for NBT so they could screen and approach participants directly from the research data management system EDGE. Study managers for GP trials contacted participants directly using their local database since the PCP team did not have access to participant details.

A REDCap server (a secure, web-based application that is used to capture customised research data) was used to distribute a URL link to the questionnaire via email. Twilio or DrDoctor (cloud-based messaging platforms) were used to send the URL link via text message for those participants without an available email address. Participants with no available email address or mobile number were sent the questionnaire by paper copy.

Results:

The questionnaire was distributed to 39,939 people, including children. Of those, 14,670 (37%) completed the questionnaire. All the questions had an option of “prefer not to say” and “prefer to self-describe” as an addition to selected possible answers.

	Sent	PCP respondents	%
Postal	452	244	54
Email	32,338	13,232	41
SMS	7,149	1,194	17
Total	**39,939**	**14,670**	**37**

Age

99.6% (N=14,611) of respondents shared their age, the youngest age group was between 0 and 10 years old (1.1%; N=158), while the oldest age group was 81+ years old (4.6%; N=676). The majority of participants (60.6%) were between the ages of 51 and 70, which was an over-representation when compared to the BNSSG population of the same age group of 21.5% (ONS, 2021).

Age in years	PCP respondents number	PCP respondents %	BNSSG population %
0 to 10	158	1.1	12.3
11 to 20	104	0.7	11.9
21 to 30	347	2.4	15.3
31 to 40	798	5.5	14.8
41 to 50	2019	13.8	12.3
51 to 60	4422	30.3	12.3
61 to 70	4429	30.3	9.2
71 to 80	1658	11.3	7.6
81+	676	4.6	4.2

Disability

98% (N=14,379) responded to the question, with 31% (N=4,449) reporting some form of disability.

Disability:	PCP respondents number	PCP respondents %
Prefer not to say	247	2
No	9683	67
Yes	4449	31
Missing	291	
Total (not missing)	14379	100

Mobility issues were reported by the majority of the respondents (N=2479) as the leading cause of disability in both children and adults. The second most commonly reported cause of disability was mental health (N=1157) (*unable to calculate the percentage as some participants selected more than one option for disability type*).

Disability type	PCP respondents number
Prefer not to say	96
Impairment not listed	938
Social or behavioural impairment	314
Learning disabilities	122
Mental health	1157
Age-related	765
Mobility	2479
Deafblind	4
Hearing	594
Vision	279

Ethnicity

96.5% (N=14,159) answered the question about ethnicity. The majority of participants were White (95.1%; 13,462), which was higher than the BNSSG population of 87.3% (ONS, 2021). Other recorded ethnicities for PCP were lower compared to the BNSSG population, Arab (0.1% vs 0.4%), Asian (1.3% vs 4.7%), and Black (1% vs 3.4%) (ONS, 2021).

Ethnicity	PCP respondents number	PCP respondents %	BNSSG population %
Prefer not to say	87	0.6	-
Ethnicity not listed	83	0.6	0.9
Arab	15	0.1	0.4
White	13462	95.1	87.3
Mixed or multiple ethnic groups	181	1.3	3.3
Black, Black British, Caribbean or African	141	1	3.4
Asian	190	1.3	4.7
Total	14159		
Missing	511		

Most participants surveyed who described themselves as White, selected the option of White British (81.8%; N=11,006).

White	PCP respondents	PCP respondents %
Prefer to self-describe	1296	9.6
English, Irish, Scottish and Welsh	11006	81.8
Roma	11	0.1
Traveller	13	0.1
White - but did not specify	1136	8.4

Religion/belief

95% (N=13,950) of respondents responded to the question. Christianity was the most commonly stated religion/belief (47.2%; N=6,925), with no religion coming second (36.1%; N=5,308). No religion was record as the most commonly stated religion in the BNSSG population at 48.4% (ONS, 2021).

Religion	PCP respondents number	PCP respondents %	BNSSG population %
Prefer not to say	288	2	-
Prefer to self-describe	159	1	-
Sikh	12	0	0.3
Muslim	69	0	3.9
Jewish	29	0	0.2
Hindu	25	0	0.7
Christian	6925	50	39
Buddhist	80	1	0.5
Agnostic	338	2	-
Atheist	717	5	-
No religion	5308	38	48.4
Missing	720		

Sex

96.2% (N=14,120) of participants responded to the question. Female (64.9%; N=9,157) was the highest reported sex. The least reported was intersex (0.01%; N=2).

Sex	PCP respondents number	PCP respondents %
Prefer not to say	21	0.1
Intersex	2	0.0
Male	4940	35.0
Female	9157	64.9
Missing	550	

Gender

95.7% (N=14,043) responded to the question. 64.8% (N=9,097) identified as women. Non-binary was the least reported gender, accounting for 0.2% (N=26) of the responders.

Gender	PCP respondents number	PCP respondents %
Prefer not to say	35	0.2
Non-binary	26	0.2
Man	4885	34.8
Woman	9097	64.8
Missing	627	

Gender reassignment

93% (N=13,651) of respondents responded to the question, with 99.4% reporting the same sex as at birth and 0.4% (N=49) reporting a different sex from birth.

Sexual orientation

The question on sexual orientation was removed from the under-10s questionnaire. 92.6% (N=13,599) responded to the question, with heterosexual as the most commonly reported (90.4%; N=12,375), and queer as the least commonly reported (0.3%; N=44).

Sexual orientation	PCP respondents	PCP respondents %
Prefer not to say	274	2.0
Straight/heterosexual	12375	90.4
Queer	44	0.3
Gay or lesbian	319	2.3
Pansexual	59	0.4
Bisexual	343	2.5
Asexual	271	2.0
Missing	1071	

Marriage and civil partnership

The question about marriage and civil partnership was only asked of participants over the age of 16, which is the legal age of marriage in the UK. 92.4% (N=13,552) of participants responded. The majority (56.9%; N=8,350) were married or in a civil partnership. The lowest reported status was separated, reported by 2% (N=230) of participants.

Marriage and civil partnership	PCP respondents	PCP respondents %
Prefer not to say	116	1
Single	1521	11
Separated	230	2
Widowed or a surviving partner from a civil partnership	776	6
Divorced or civil partnership dissolved	1010	7
Married or in a civil partnership	8350	60
In a committed relationship	1886	14
Missing	1118	

Pregnancy

The question on pregnancy was removed from the under-10s questionnaire. 92.1% (N=13,504) responded to the question with 1.5% (205) having been pregnant in the previous 12 months. No-one under the age of 16 reported having been pregnant.

Caring responsibilities

The question was asked of all age groups and divided into caring responsibilities for children or adults.

93.6% (N=13,736) responded to the question of caring responsibilities for children. The majority reported not to have any caring responsibilities for children (80.9%; N=11,118). 17.6% (N=2,577) reported they were the parent or carer of a child or children under 18, of whom 13.2% (N=361) had a disability/health condition/illness/temporary care needs.

93.3% (N=13,692) responded to the question of caring responsibilities for adults. 22.1% (N=3236) reported they had caring responsibilities for adults. 37.1% (N=1,201) of those, reported they were a primary carer or assistant for an older person or people who were 65 years and over. 16.3% (N=529) reported they were the primary carer or assistant for a disabled adult or adults (18 years to 65 years).

Index of Multiple Deprivation (IMD)

Participants were asked to provide their postcode which was used to calculate IMD (1 = most deprived and 10 = least deprived). 68.6% (N=10,075) provided a full postcode. 33.4% (N=4,655) were from the two least deprived areas (IMD index 9 and 10) and 9.5% (N=1,551) from the most deprived areas (IMD index 1 and 2). There are no combined IMD scores available for BNSSG, and as detailed in the table below, the IMD scores are very different for each local authority (BNSSG, 2022). It is likely that the majority of the research participants will reside in Bristol. Using the Bristol data there is a three-fold under-representation in participants from the two most deprived areas. In contrast, the rate of participation from the two most deprived areas is similar to the North Somerset data and is over-represented compared to South Gloucestershire.

IMD decile	**Bristol**	**North Somerset**	**South Gloucestershire**	**PCP**
1	15.4%	5.9%	0%	4.1%
2	14.4%	4.4%	1.2%	5.4%
3	11.4%	5.9%	3.0%	5.8%
4	11.8%	4.4%	8.5%	7.6%
5	10.3%	4.4%	8.5%	7.7%
6	6.1%	10.4%	9.7%	9.5%
7	11.4%	14.8%	15.8%	13.6%
8	7.2%	16.3%	10.9%	12.9%
9	5.7%	14.8%	11.5%	13.4%
10	6.1%	18.5%	30.9%	20.0%

Data sharing

In the initial phase of the PCP work at UHBW, explicit consent to pseudo-anonymise the data and link it to the BNSSG ICS Shared Data system was sought. However, when the questionnaire roll-out continued and different organisations were engaged, the project team's access to personal data was limited because they were not the primary custodians of the data. With limited ability to link questionnaire responses to participants who consented to data sharing, obtaining consent was no longer possible and the question was removed. The total number of participants approached for data sharing was 2808, and 88% (N=2469) provided consent.

Summary

Using the PCP questionnaire enabled the collection of a dataset on protected characteristics, caring responsibilities, and postcodes for 14,670 research participants across BNSSG. The key findings revealed a fourfold under-representation in participants from ethnicities other than White compared to the BNSSG population. There is a threefold under-representation of those living in the most deprived areas of Bristol compared to the least deprived deciles. More females than males took part in research (65% vs 35%). Older adults (51-70 years old) were over-represented and younger adults (20-40 years old) were under-represented when compared to the BNSSG population.

Challenges to data collection:

The project included a number of different organisations and varying challenges were encountered:

- There were inconsistencies in the way consent was recorded on the research data management system EDGE, especially for studies that were approved through the Confidentiality Advisory Group (CAG).
- There was also a delay in updating notification of death on the patient administration system (from where contact details were sourced), which meant that some participants were contacted after death. Appropriate steps were taken to manage these issues.
- The capabilities of the REDCap servers varied between organisations, which required additional data agreements to transfer data between REDCap servers hosted by a different organisation.

Section 3:

One of the goals of the PCP was to establish locally defined key performance indicators (KPIs) to monitor research participation by under-served communities and to assess the effectiveness of current and planned interventions. A series of focus groups were held to co-design the KPIs in collaboration with members of the public from various community groups. We had members from religious groups, LGBTQ+, The West of England Centre for Inclusive (WECIL). Black Mothers Matter, Health Research Ambassadors, and YPAG Bristol participate.

In response to the PCP findings of under-representation in research participation among participants from Asian and Black participants, as well as people living in the most deprived areas, five broad themes from the focus group discussions arose:

1. Research must be directly linked to participant benefit. People with the greatest health needs should be represented in research.
2. Research participation should match the local geographical population and demographics.
3. The research workforce needs to be representative of the local geographical population to increase research study recruitment and retention.
4. Researchers should provide evidence of alternative recruitment methodologies that allow people from under-served communities, relevant to the local geographic population, to participate.
5. Participants’ experiences must be included in the analysis and implementation of all research.

A separate report on the KPI development is available from Bristol Health Partners.

Section 4:

Lessons learned from the development of the questionnaire

1) **Flexibility:**
   Successful recruitment from many communities frequently depends on word-of-mouth referrals. There is a need for flexibility in recruitment timelines and method used to contact people. Clarity on how information will be shared about potential research participants and/or those who join focus groups is critical from the outset.
2) **Data collection methods:**
   Allowing various methods for data collection is important. When the questionnaire was developed, feedback was primarily gathered through focus groups. However, a number of participants were unable to attend the scheduled meeting but were eager to provide input. Those people were invited to contribute comments by email, and valuable feedback was gathered that would have otherwise been missed.
3) **Payment:**
   - Including engagement costs in grant applications and project costing ensures participants are adequately compensated for their time.
   - Many participants in the focus groups did not have bank accounts and cash payments were used, while others chose vouchers from their favourite retailers.
4) **Recruitment timing:**
   Timing matters when recruiting members of the public and it is crucial to avoid school and public holidays.
5) **Reporting back to the participants:**
   Feedback to participants including the completed dataset and report is critical and allows them to feel valued for giving up their time and providing input. Below are a few remarks from participants in response to the feedback given.

“Thank you so much for sending this to us and taking onboard our comments. I’m delighted to see the cream/yellow background, use of simpler language, better phrasing regarding disabilities, and LGBTQ+ options.”

“I have gone through the final version of the questionnaire, and I believe everything discussed has been captured.”

“Thank you for your kind message and for sharing this exciting update. It’s wonderful to hear that the questionnaire has reached over 14,000 people—This is an incredible achievement! I am honoured to have been part of such a significant and impactful project. Thank you for allowing us to contribute.”

Conclusion

The PCP achieved its objective of collecting comprehensive data on protected characteristics, caring responsibilities and deprivation across BNSSG. The co-designed questionnaire was completed by 14,670 research participants. The main caveat to this study is the participation rate of 37%. REDCap proved to be an effective way of distributing the URL link to the questionnaire in large numbers and simplified data analysis. Postal questionnaire ensured that eligible participants with limited digital abilities/access were given the chance to participate.

Co-designing local KPIs ensured that information on what matters to members of the public was captured. This will inform how initiatives will be targeted to increase participation from groups that were shown as under-represented.

The PCP has provided baseline data that will be used to measure the effectiveness of current initiatives such as the Health Research Ambassadors programme which is helping to increase access to research in many local communities. Bristol Health Partners has been instrumental in increasing training for our research workforce, using trauma informed approaches to anti-racism and finding better ways to engage with diverse communities/ groups who are under-represented in research studies.

Acknowledgement:

We thank all participants who completed the questionnaire and the R&D teams at the participating sites for their help with data provision. We would also like to thank our funders who made this project possible.

Appendixes:

Appendix 1- Organisations and participants involved in the development of the questionnaire:

Organisation and protected characteristics:	**Number of participants:**
WECIL – disability	5
LGBTQ+ community	6
UWE faith group	5
Research Patient and Public Involvement members (NBT and People in Health West of England)	5
Caafi Health	2
Horfield community group	4
Maternity	1
Plain English reviewers	2
Bristol Health Partners public contributor	1

Appendix 2: Protected characteristics of focus group members involved in developing the questionnaire.

Participants:	Age:	Ethnicity:	Gender:	Sexual orientation:	Disabilities reported:
1	71	White British	Female	Heterosexual	None
2	70	White British	Male	Heterosexual	Blind and Wheelchair user
3	70	White Irish	Male	Heterosexual	none
4	68	White Irish	Female	Heterosexual	none
5	60	Black Caribbean	Female	Heterosexual	none
6	49	Black Caribbean	Female	Heterosexual	none
7	47	Asian Pakistani	Female	Heterosexual	None
8	46	Asian Pakistani	Female	Heterosexual	None
9	42	White Polish	Female	Heterosexual	None
10	40	Black African	Male	Heterosexual	None
11	40	White British	Male	Gay	None
12	40	Black Caribbean	Female	Heterosexual	None
13	38	Black African	Female	Heterosexual	None
14	36	Asian Chinese	Female	Queer, Pansexual, Asexual	None
15	33	White Irish	Non-binary	Bi-sexual	None
16	16	Mixed Asian/White/Black	Male	Heterosexual	None
17	15	Black African	Female	Heterosexual	None
18	13	White British	Male	Heterosexual	None
19	12	Asian Pakistan	Male	Heterosexual	None
20	Prefer not to say	White British	Female	Heterosexual	Wheelchair user

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