Recruitment of minority ethnic groups into clinical cancer research trials to assess adherence to the principles of the Department of Health Research Governance Framework: national sources of data and general issues arising from a study in one hospital trust in England

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Recruitment of minority ethnic groups into clinical cancer research trials to assess adherence to the principles of the Department of Health Research Governance Framework: national sources of data and general issues arising from a study in one hospital trust in England

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ABSTRACT

Background This article describes the issues encountered when designing a study to evaluate recruitment of minority ethnic groups into clinical cancer research in order to monitor adherence to the principles for good practice set out in the Department of Health, Research Governance Framework, England.

Methods (i) A review of routine data sources to determine whether their usefulness as a source of data on prevalence of cancer in the population by ethnic category. (ii) A local case study at one hospital trust to ascertain whether the ethnicity of cancer trial participants was representative of admitted cancer patients.

Results (i) The lack of a comparator population makes it problematic to assess recruitment levels by ethnic group in clinical research. (ii) The odds of being in a trial were 30% lower for a member of a minority ethnic group compared to a white cancer patient after adjusting for disease, age and gender, OR 0.70 (0.53 to 0.94). These results differed for each ethnic group; Asian patients did not appear under-represented while Black and Chinese did so. However, there are important caveats to the findings based on the limited recording of ethnicity.

Conclusions The lack of available data on the ethnicity of participants in clinical research and the prevalence of cancer in the population according to ethnicity makes it difficult to design a study to monitor representation of minority ethnic groups. This information is necessary to assess adherence to the Research Governance Framework principle that research evidence reflects the diversity of the population.

INTRODUCTION

In England, the Research Governance Framework published by the Department of Health in 2001 established a duty to ensure appropriate representation of minority ethnic groups in clinical research.[1] Participation of all groups is important as inclusion ensures generalisability; that is, that results are based on a representative population and so can be applied to the population as a whole (external validity).[2] For example there may be differences in risks and adverse drug reactions[3] or in the toxicity and efficacy of drugs for different ethnic groups.[4] Further, exclusion on the basis of ethnicity is an important equity issue, undermining the principles of the NHS.

In the US legislation mandated guidelines that all minority groups are to be represented in research samples unless there are specific grounds not to.[5] However, there is no such legislation in the UK.

Nevertheless, the Research Governance Framework (2.2.7), states:

> Research and those pursuing it should respect the diversity of human culture and conditions and take full account of ethnicity, gender, disability, age and sexual orientation in its design, undertaking, and reporting … It is particularly important that the body of research evidence available to policy makers reflects the diversity of the population.[1]

This statement was modified in the second 2005 edition of the Framework, diminishing its role to "Whenever relevant … should take account of age, disability, gender, sexual orientation, race, culture and religion in its design, undertaking, and reporting."[6] The shift from 'ethnicity' to 'race, culture and religion' is likely to create practical problems in monitoring adherence to the principles of the Framework since such data are not routinely collected.

More detailed guidance for research ethics committees requires that they "need to take into consideration the principle of justice" (2.4).[7]

To take full account of diversity in the population, we chose to investigate participation by minority ethnic groups in cancer research trials because of the burden that it places on the population, accounting for one in four deaths in the UK. While our focus was ethnicity, we acknowledge the need to monitor other aspects cited in the Framework, for example, gender and disability. We reviewed the literature on participation by minority ethnic groups in clinical research and identified the following main themes.

i. **Under-representation of minority ethnic groups in clinical research**
US studies on representation in clinical research show that ethnic groups other than white are less likely to be recruited to clinical trials.[8–10] In the UK too studies have found evidence of under-representation of participants from some ethnic groups.[11 12]

ii. **Reasons for under-representation**
Possible barriers to participation include: costs, language and communication barriers, health

provider attitudes, and socio-cultural barriers.[2] In the USA, a legacy of distrust deterred participation in clinical research by minority groups following the suspension of the notorious Tuskegee syphilis study in the 1970s, under which diagnosed African-American subjects remained untreated effectively with penicillin for many years to study the diseases' progress. Fortunately however, in recent times some studies from both the USA and the UK have indicated that people from minority ethnic groups are as willing as others to participate in clinical research.[13 14]

iii. **Quality and completeness of coding of ethnicity**
In England, ethnicity is not well recorded in routine data. There are limited data sets which include ethnicity, with long-standing concerns about completeness, accuracy and timeliness that inhibit analysis to identify ethnic disparities in healthcare.[15]

With regard to clinical research, it was reported in 2003 that less than 1% of randomised controlled trials recorded on the NHS National Research Register referred to minority ethnic or non-English speaking groups.[16] American randomised controlled studies are five times more likely than European studies to report information on ethnicity of participants.[17] This under-recording is important because of the underlying variations among different groups in the prevalence of disease and differences in responses to treatment.

THE RECORDING OF ETHNICITY IN ROUTINE DATA

Our primary aim was to explore the feasibility of designing a study to evaluate representation of minority ethnic groups in clinical cancer research trials. To do so we needed to profile representation by ethnic group of participants in cancer research trials (numerator data) and compare this with the prevalence of cancer in the population by ethnic group (denominator data). We reviewed a variety of population data sources to determine whether they could be used to provide denominator data as follows:

i. **National census**
The decennial census undertaken in England and Wales by the Office for National Statistics (ONS) provides the main data source on the ethnic status of the whole population. The 2001 census expanded the 1991 initial nine ethnic categories to comprise a 16 code national standard to be used in NHS and social care, grouped under five broader headings.[18] Though the census provides invaluable data and defines the ethnic categories to be used, it was an unsuitable comparative source for our study. This is because prevalence of the various cancer diseases varies according to ethnicity, so simply using the proportion of people in each ethnic category according to the census as a denominator would not reflect such variations.

ii. **Cancer Registry data**
We considered whether cancer registry data would provide comparative data that reflected prevalence of cancer by ethnicity in the population. However, although the cancer minimum dataset records individual tumours, ethnicity is an optional item and not well completed. In 2006, only 39% of Thames Cancer Registry (TCR) data (which covers South East England) contained a valid code (personal communication TCR, 2008). TCR data derive from a number of sources, most of which do not include ethnicity and of these only hospital data recorded on the Patient Administration System (PAS) are likely to record ethnicity and be accessible to data collection staff.[19]

iii. **Ethnicity recording in hospital data**
As described, hospital administrative data has the potential to provide information on both cancer and ethnicity. It has been a requirement to record ethnicity in the NHS hospital inpatient contract minimum dataset since 1995–1996. However, by 2002–2003, ethnicity coding was complete for only 69% of Hospital Episode Statistics data from the 241 English trusts,[20] though more recent analysis from London trusts indicates this is improving.[21]

iv. **ONS mortality registration data**
Cancer mortality registration data collected by ONS has been a legal requirement in England and Wales since 1837. However, ethnicity is not recorded.

v. **ONS Longitudinal Study**
This study which began in 1971 links census and vital event data for 1% of the population of England and Wales. Through formal application to ONS we obtained an extract of data but it was aggregated in such a way as to make detailed comparisons difficult. It was presented as incidence rates per 1000 person years for three broad ethnic groups plus 'other' and could not be directly compared to the data used in our study.

From this review of data sources we concluded that it is problematical to assess recruitment levels by ethnic group in clinical research as there is no satisfactory comparative population although the Longitudinal Study and hospital administrative data offer the best potential.

LOCAL CASE STUDY

In light of this finding, we devised our own unique method which we demonstrated in a local case study to ascertain the level of involvement of minority ethnic groups in clinical cancer research undertaken at University College London Hospital (UCLH) NHS Foundation Trust. The Trust is an amalgamation of seven specialist hospitals in London and serves patients locally, regionally and nationally. The Trust's Joint UCL/UCLH/Royal Free Biomedical Research Unit maintains a database comprising 5300 research projects.

METHODS

The ethnicity of the following populations were sampled and compared:

i. Participants of cancer research trials recorded on the Biomedical Research Unit database.
ii. Patients admitted to the trust with a primary diagnosis of cancer.

The rationale for comparing ethnicity between these two groups was that the vast majority of those recruited to clinical trials will be drawn from the same geographic population. Therefore UCLH admitted cancer patients were used as a proxy to ascertain the prevalence of cancer in the general regional population. However, we acknowledge that for some rare diseases where there are few studies, those in trials may be referred from wider geographical areas as tertiary referrals. This includes sarcoma for which UCLH has one of the few centres in the country. It also applies to a small number of patients with more common cancers participating in early phase drug trials.

Determining ethnicity of participants in cancer trials

The method of determining the ethnicity of trial participants was as follows.

The initial sample comprised 1112 cancer research trial participants from 64 studies, identified by the Cancer Clinical Trials Manager and staff in December 2004 from the Research Unit database, classified by disease group as follows:

- Bone tumours/sarcoma
- Breast
- Genito urinary
- Gynaecological

- Haemotology
- Head and neck
- Lung
- Upper/lower gastrointestinal/colorectal

The selection of studies included in the sample was made opportunistically, that is, those for whom documentation and 'log files' were available from the UCLH Oncology Research Office and comprised trials that were both still open and closed. However, we are unaware of any reason why this selection should not be representative.

Ethnicity was not routinely recorded in clinical trial records. To overcome this, individual hospital patient numbers of participants were recorded from log files and then used to interrogate PAS which includes a data field for ethnicity. In this way we were able to identify the majority (98%) of trial participants. As some PAS records were coded to 1991 ethnic census categories and others to 2001, these were 'collapsed' to the five broad headings of the 2001 census, plus a category for 'unknown' as shown in table 1. It is acknowledged that had the full range of 2001 census categories been consistently available, more detailed analysis would have been permitted. However, Department of Health guidance states that these five headings may be used to feed back broad findings.[18]

Some participants had taken part in more than one trial in the sample (ranging from one to four). Therefore an individual-based data set was derived representing 1011 participants and this was the final sample that was analysed.

Determining ethnicity of patients admitted to UCLH

PAS data were extracted for 11 655 inpatients and day case patients at UCLH hospitals with a primary cancer admission over the 5-year period, 1 April 2000 to 31 March 2005 (ICD codes C00-C97). As for the trial sample, subsequent occurrences were removed for people admitted more than once in order to construct a data set which only counted ethnicity once for each individual (though this means that only the first diagnosis would be captured for a person presenting with more than one type of cancer over the period).

Admitted patients were categorised to the same broad ethnic classifications and disease groups as trial participants.

Once both samples of trial participants and admitted patients were organised into a person-based format, data matching across the two files was undertaken based on the unique patient number. Sometimes matched records showed differences in certain details, for example of disease group. For consistency, details were taken from the inpatient extract. The completeness of ethnicity was improved manually if recorded as 'unknown' for an individual patient for one admission but captured in a subsequent admission, or missing in the trial sample but available from the inpatient sample.

Table 1 How ethnic categories were aggregated for the study

Ethnic category used in study	Ethnicity coding recorded on PAS	
	Ethnic description	Ethnic code
White	White, white British, white Irish, any other white background	0, A, B,C
Mixed	White and black Caribbean, white and black African, white and Asian, any other mixed background	D, E, F, G
Asian	Indian, Pakistani, Bangladeshi, any other Asian background	4, 5, 6, H, J, K, L
Black	Black Caribbean, black African, Caribbean, African, black other, any other black background	1, 2, 3, M, N, P
Chinese or other	Chinese, any other ethnic group	7, 8, R, S
Unknown	Missing, not stated	9, Z

PAS, Patient Administration System

RESULTS

Characteristics of the sample of UCLH admitted cancer patients

Ethnicity is not routinely recorded in clinical research.

Table 2 describes the characteristics of the sample of admitted patients in our study and of the subset identified as participating in a research trial. The three disease groups of 'upper/lower gastrointestinal/colorectal', 'haematology' and 'genitourinary' cancer account for nearly half (47%) of admissions over this time. The majority (82%) of diseases in the 'other' category comprised the following: 39% malignant/secondary neoplasms without specification or other and ill defined site, 23% brain and 20% skin cancers.

Slightly more men (51.3%) were admitted compared to women (48.7%). There was a wide range of ages with 39.8% patients aged over 65, and 36.2% aged between 45 and 64.

The highest proportion of cancer inpatients whose ethnicity was recorded was white (84.9%). There are very similar numbers whose ethnicity was coded as Asian, black, or 'Chinese or other' (4.4–5.1%). However, there are also a large proportion of people admitted for whom ethnicity is missing or not stated (n=2561, 22%).

Table 2 Characteristics of patients admitted to University College London Hospital from 1 April 2000 to 31 March 2005 with a primary diagnosis of cancer, and of the subset of patients identified as being part of a research trial

Factor	Level	Admitted patients (%)	Research patients (%)
Gender	Men	5978 (51.3)	257 (55.3)
	Women	5677 (48.7)	208 (44.7)
Ageband	0–4	115 (1.0)	2 (0.4)
	5–14	404 (3.5)	39 (8.4)
	15–24	517 (4.4)	80 (17.2)
	25–44	1758 (15.1)	125 (26.9)
	45–64	4222 (36.2)	166 (35.7)
	65–74	2613 (22.4)	44 (9.5)
	75+	2026 (17.4)	9 (1.9)
Ethnicity*	Asian	423 (4.7)	29 (6.9)
	Black	399 (4.4)	18 (4.3)
	Chinese or other	464 (5.1)	14 (3.3)
	Mixed	86 (0.9)	4 (0.9)
	White	7722 (84.9)	358 (84.6)
	Unknown	2561	42
Disease	Bone tumours/ sarcoma	955 (8.2)	179 (38.5)
	Breast	933 (8.0)	33 (7.1)
	Genito urinary	1386 (11.9)	12 (2.6)
	Gynaecological	1070 (9.2)	13 (2.8)
	Haematology	1965 (16.9)	136 (29.2)
	Head and neck	544 (4.7)	0 (0)
	Lung	999 (8.6)	17 (3.7)
	Other	1698 (14.6)	25 (5.4)
	Upper/lower Gastrointestinal/ colorectal	2105 (18.1)	50 (10.8)
Total		11655 (100)	465 (100)

*To aid comparisons, 'unknown' ethnicity was excluded when calculating percentages for ethnicity.

Results from matching trial participants to admitted cancer patients

From record matching, we were able to identify 465 trial participants in the inpatient sample representing 46% (n=465) of the 1011 people in the clinical trial extract and 4% of the 11 655 people in the inpatient extract. Possible reasons for identifying less than half of the trial participants in the inpatient extract include:

1. Trial participants were admitted with a primary diagnosis other than cancer
2. Trial participants were admitted before April 2000, predating the time period covered by the inpatient data sample. This applied to 26 of the 64 studies in the sample and the start date could not be identified for a further six trials.
3. Patients were treated on an outpatient basis—outpatient data was not used in the study as clinical coding was not undertaken making it not possible to identify those treated for cancer

Comparison of inpatients identified in research trials with the remainder

Initially we compared the characteristics of inpatients identified as participating in trials (n=465) to the rest of the inpatient sample (n=11 190) using simple cross-tabulations. It should be noted that as the study is based on samples, it is to be expected that some inpatients that actually took part in a trial were not identified in our trial sample, thus an undercount of the number of inpatients in trials. This is an acknowledged limitation of the study design.

Comparison by disease group

Table 2 shows that the majority of matched trial patients were admitted for either the bone tumours/sarcoma (38.5%) or haematology (29.2%) cancer disease groups. Conversely, none were admitted for cancers of the head and neck. This suggests that an analysis of the relationship between ethnicity and the chance of admittance to a clinical trial should be adjusted for type of cancer since the latter may be a confounder.

Comparison by age and gender

There are also clear differences in the age of patients known to be in a trial compared to the remaining admitted patients. The mean (SD) of the 465 inpatients identified in a trial is 41.1 (19.1) years, compared to 57.1 (19.5) years for the remainder, indicating that trial patients tend to be younger. Additionally there are slightly more men amongst the 465 trial participants (55.3% cf 51.1%) suggesting that analysis of the relationship between ethnicity and the chance of admittance to hospital should also be adjusted for age and gender.

Comparison of ethnicity

Table 2 shows the numbers and proportions of admitted patients by ethnic group who were trial participants. Patients for whom ethnicity was unknown were omitted from the calculations of the relative percentages: 2561 (22.0%) and 42 (9.0%) admitted and trial patients respectively. Asian patients appear to be more highly represented amongst trial participants compared to admitted patients (6.9% vs 4.7%), whereas 'Chinese or other' patients appear under-represented (3.3% vs 5.1%). A χ^2 test suggests that there may be real differences between distributions of ethnic groups between admitted and trial patients (p=0.11). To simplify this initial analysis we dichotomised patients into either 'white' or 'combined minority ethnic groups' to investigate whether overall, ethnic minority groups are adequately represented in trials. From this we found that 4.6% (358/7722) of white admitted patients participated in trials, compared with 4.7% (65/1372) from minority ethnic groups. This difference is not statistically significant (p=0.87).

Unadjusted analysis

Both analyses were repeated using logistic regression since the latter may be used to adjust for potential confounders. The ORs for being in a research trial, relative to white patients, are 1.51 (95% CI, 1.02 to 2.24) for Asian patients, 0.97 (0.60 to 1.58) for black patients, 0.64 (0.37 to 1.10) for Chinese patients, and 1.00 (0.37 to 2.75) for mixed race patients. The simplified analysis produced an OR of 1.02 (95% CI, 0.78 to 1.34). This represents the odds of a patient from a minority ethnic group being in a research trial compared to a white patient. This suggests that the odds of being in a trial are very similar for both white patients and those from other ethnic groups.

Adjusted for disease, age and gender

When the analysis was repeated, adjusting for disease, age and gender, the ORs change substantially (table 3).

These results suggest that there are differences between ethnic groups regarding the chance of being in research trial (p=0.01). In particular, Asian patients appear to have a very similar chance of being in a research trial as white patients, with black patients and Chinese patients under-represented, black patients did not reach significance. This analysis also reveals a tendency for older patients to be less likely to appear in research trials (OR (age, years)=0.978 (0.973 to 0.983), p<0.001), but there is little evidence that men and women have different rates of representation (OR (women)=0.93 (0.74 to 1.16), p=0.51).

The simplified analysis suggests that patients from minority ethnic groups (combined) have a lower chance of being in a research trial than white patients (OR=0.70 (0.53 to 0.94), p=0.01). This now suggests that minority ethnic groups are less likely to be involved in trials after taking account of age, gender and disease characteristics. Note that all the adjusted analyses remove head and neck patients from the analysis, and effectively down-weighting patients with diseases for which there are few trials.

Sensitivity analysis

A problem is the high proportion of patients (22%) with missing ethnicity information. To investigate this we performed some simple sensitivity analyses. If we assume that all the patients with missing data come from minority ethnic groups the simple adjusted analysis produces a reduced OR of 0.58 (0.46 to 0.72) for patients from minority ethnic groups. The OR decreases because relatively few patients with missing data take part in clinical trials (1.6% of patients with missing ethnic data take part in trials compared with 4.7% with completed data). If we assume the other extreme situation where all the patients with missing ethnic data are white, the simple adjusted analysis produces an OR of 0.85 (0.64 to 1.12) for patients from minority ethnic groups which hints at under-representation but is not statistically significant (p=0.24).

Table 3 Adjusted ORs for being in a research trial relative to white patients

Ethnic category	OR (95% CI)
Asian	1.07 (0.70 to 1.62)
Black	0.64 (0.39 to 1.06)
Chinese or other	0.46 (0.26 to 0.81)
Mixed	0.61 (0.21 to 1.74)

DISCUSSION

We set out to identify and describe the issues encountered in designing a study to evaluate recruitment of minority ethnic groups into clinical cancer research in order to evaluate adherence to the principles of the Research Governance Framework. Having reviewed the potential of relevant data sources to provide population denominator data on cancer prevalence by ethnic category, we went on to devise a methodology to address this question through a local case study.

Our main focus was the issue of how to assess the representation of minority ethnic groups in clinical research, a problem that the English health system must confront if it intends to honour the commitments expressed in the Research Governance Framework.

Results from our case study indicated that the proportion of members of minority ethnic groups enrolled into a sample of clinical cancer research trials is significantly lower than expected compared to hospital admissions after taking account and adjusting for disease, age and gender. Within our overall finding there were differences for specific ethnic groups, that is, while Asians do not seem to be under-represented, black and 'Chinese or other' patients may be. It is essential however to consider the extent of missing data, and that some cancer types are represented to a much greater extent in the trial group than the admissions group (particularly sarcoma). We explored a range of possible effects on the results through simple sensitivity analyses which still suggested under-representation though results did not always reach statistical significance.

Given these limitations further research is required to confirm whether results are real or artefact. As the study was purely quantitative no conclusions are drawn as to the reasons for lower participation or barriers.

Primarily, this study highlights the methodological difficulties involved in attempting to evaluate appropriate representation of minority ethnic groups in clinical research trials. We were able to demonstrate a potential method to overcome these difficulties, although it required considerable effort and availability of data to yield useful results.

Our main recommendation is for improved coverage and quality of ethnicity recording in routine data, though the difficulties involved are recognised. It is acknowledged however that the Thames Cancer Registry has been able to overcome limitations in its work to assess breast cancer incidence in different ethnic groups using information derived from Hospital Episode Statistics data.[22]

In summary, without good quality recording of patient characteristics in both research trials and in routine health and population data, it is not possible to monitor whether the guidelines of the Research Governance Framework are being adhered to, and whether the body of research evidence available to policy makers reflects the diversity of the population.

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