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Representation of South Asian people in randomised clinical trials: analysis of trials' data

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ment in 23/26—88% (71% to 96%)—of cases. The discharge destinations recommended by the geriatrician were to a rehabilitation ward (eight patients), home with extra support (seven), nursing home (three), NHS continuing care (two), medicine for the elderly ward (one), hospice (one), and medical ward (one).

Comment

The study confirmed the reliability and validity of the instrument for the objective evaluation of the appropriateness of surgical bed occupancy in a colorectal unit. A Canadian report on the American appropriateness evaluation protocol showed a poor validity against a panel of experts ($\kappa=0.25$).² A European version of the protocol has been suggested but has not been validated in a substantial study.³ The validity of our instrument needs to be retested in other settings with a larger study population. Whether the instrument can be used as a

tool for clinical decision making or audit needs to be confirmed in future studies.

We thank R J C Steele and M Lavelle-Jones for assisting us with conducting this study.

Contributors: GBH had the original idea. AA, DZ, SLB, and KLC conducted the study. AA and GBH wrote the first draft of the paper, which was edited by all the other authors. All authors were involved in the design of the study. AC is the guarantor for the study.

Funding: None.

Competing interests: None declared.

Ethical approval: The local ethics committee approved the study.

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Representation of South Asian people in randomised clinical trials: analysis of trials' data

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Excluding patients of ethnic minority groups from clinical trials is unethical,¹ introduces substantial bias, and means that findings are based on unrepresentative populations.² The National Institutes of Health Revitalization Act 1993 requires that all minority groups be represented in the sample in research projects supported by the National Institutes of Health, unless there is a clear and compelling justification not to do so. In the United Kingdom no such legislation exists.

Participants, methods, and results

To determine the proportion of South Asian participants (the biggest minority ethnic group in Britain) included in clinical trials we investigated the ethnicity profile of six clinical trials recently conducted by the Northern and Yorkshire Clinical Trials and Research Unit, University of Leeds. All were phase III, multicentre, randomised, controlled trials and had recruited large numbers of participants and centres. Two were national breast cancer trials for which regional recruitment figures were available; two were national gynaecological trials (of different surgical techniques for hysterectomy and for ovarian cancer); one was a national, minimally invasive trial of surgery in colorectal cancer; and the sixth was a regional study investigating the eradication of *Helicobacter pylori* in general practice. None contained exclusion criteria that were directly related to ethnic origin, but all patients' information sheets and consent forms were in the English language only.

We identified ethnic origin in the baseline data of three trials and identified South Asian patients by an SQL programming query. For the three remaining trials, we analysed the names of the participants by using a computer program (Nam Pehchan) developed

by Bradford Health Authority. Researchers experienced in analysing South Asian names manually checked for discrepancies. The Nam Pehchan programme was not infallible. It did not differentiate between different Muslim surnames (for example, South Asian, Far Eastern, or Arabic). Therefore, forenames (which are often more specific to language or region than surnames) were needed to identify some South Asian participants.

South Asian (Indian, Pakistani, and Bangladeshi) people comprised up to 1.7% (mean 0.6%) of total participants in the six trials (table). A community trial in Leeds and Bradford recruited the highest number of South Asian participants, but this number was lower than expected compared with estimates of population figures from the Office for National Statistics.³

Comment

People of South Asian ethnic origin seem to be under-represented in clinical trials. Though not previously supported by data, this has been of concern to researchers. This under-representation might be due to investigator bias, inappropriate strategies for recruitment, or cost issues—for example, for translators or translations of information sheets.⁴

Such inequality in the ethnic origin of participants in trials has ethical and scientific ramifications because genetic predisposition, dietary intake, and exposure to environmental and occupational hazards lead to ethnic differences in susceptibility to diseases. Furthermore, patients' response to drugs, how they metabolise drugs, and their concurrent diseases, as well as the side effects of drugs, can vary between different ethnic groups.⁵

Our small survey used only the rather crude comparative data available for the expected South

Proportion of South Asian participants in six multicentre clinical trials

Trial type	Sex	Trial population		Recruitment	Recruitment figures	No (%) South Asian participants
		Age (years)				
Hysterectomy	Female	>18 (mean 41.2 (SD 8))		National	1380 randomised	8 (0.6%)
Cancer:						
Colorectal	Male and female	>18 (mean 69; range 25-94)		National	584 on whom ethnicity data are available	1 (0.2%)
Breast	Female (post-menopausal)	Mean 64		Regional	780 randomised	2 (0.3%)
Breast	Female (post-menopausal)	Most >55		Regional	133 randomised	0 (0%)
Ovarian	Female	>18*		Regional	480 registered (242 randomised)	3 (0.6%)
				National	559 registered (300 randomised)	4 (0.7%)
<i>Helicobacter pylori</i> eradication	Male and female	40-49		Regional	8407 participants	145 (1.7%)

Office for National Statistics' latest estimates of proportion of population that is of South Asian origin are 3.8% for the Yorkshire-Humber region and 3.4% for Great Britain as a whole.³

*Range and mean unknown.

Asian population. We would have liked to compare more precisely the trials' inclusion criteria of age range and sex with those of the expected South Asian population, but this information is not currently available. Trials that recruited older patients would not be expected to comprise a percentage of South Asian people equal to the overall figures of the Office for National Statistics because the number of elderly South Asian people in the UK population is small.

Increased awareness and monitoring of recruitment and retention of ethnic minority groups in clinical trials are needed, and analysis of data by ethnicity of subjects should be done consistently. More rigorous review by the research ethics committee of clinical trial protocols, payment for translation of information supplied to participants, community participation, and education of ethnic minority groups may contribute to attaining proportional representation of ethnic minorities in trials.

Contributors: SM had the idea to write the report, collated the data, helped to draft the report, and critically revised it. MH-G, JB, BL, and KA helped to formulate and revise the report. MH-G also helped to draft the report. All authors have seen and approved the final version. SM is the guarantor.

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RESEARCH POINTERS

Average energy intake among pregnant women carrying a boy compared with a girl

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The birth weight of boys is about 100 g heavier than the birth weight of girls, and this seems to be consistent across populations. No study, has examined whether the difference is because the pregnant woman has a higher energy intake or more efficient energy utilisation if she is carrying a male embryo than if she is carrying a female embryo. We report data to support the first hypothesis—that the pregnant woman carrying a boy has a higher energy intake.

Participants, methods, and results

We analysed data from an international prospective study on dietary and non-dietary predictors of

pregnancy hormones and outcomes among women in Boston, United States, and Shanghai, China.¹ Because the database of nutrients for the Chinese diet is incomplete, we present data on dietary intakes for the US women only.

Between March 1994 and October 1995, we identified 402 eligible pregnant women during their first routine prenatal visit at the Beth Israel Hospital in Boston and invited them to participate in the study. We followed throughout their pregnancies the 304 women who consented and did not have an early pregnancy termination or twin birth. The study population, study design, and methods have been described.¹

Pregnant women carrying boys have a 10% higher energy intake than those carrying girls

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