

Guest editorial

Inclusion and exclusion of ethnic-minority populations in research on the effectiveness of interventions

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The concepts of migration, ethnicity and race imply major differences in environment and culture, and some differences in biology, which lead to inequalities in health that are easily demonstrated by proxy variables such as country of birth and self-reported ethnic group (Davey Smith *et al*, 2000; Bhopal, 2007). Therefore we need research and actions to tackle such inequalities. Once these differences have been identified and described, the next tasks are to understand why they occur, to develop ideas about how they may be reduced, to design appropriate interventions, and finally to evaluate the effectiveness of these interventions and through that process refine them prior to routine implementation. Efforts to reduce these inequalities will require, among other things, social and fiscal changes and public health interventions. In this editorial we wish to re-examine a debate (Bhopal, 2007) on the following difficult questions:

- 1 How are we going to advance research in ethnic-minority populations on the effectiveness of public health and medical care interventions?
- 2 What principles can we adopt to choose between such interventions in the light of gaps in knowledge?
- 3 What practical actions do we need to take in order to lay strong foundations for future health interventions research?

In the European community a policy consensus has emerged surprisingly quickly on the need to integrate the needs of ethnic-minority communities within the broader health and healthcare agenda, and to use this to deliver equity (Bhopal, 2009). In the UK, a major spur to policy was the Race Relations Amendment Act (RRAA) 2000, implemented in 2002, with its heavy emphasis on institutional responses, especially in the

public sector (Home Office, 2001). In England, the Department of Health's Chief Executive action plan of 2004 (www.dh.gov.uk/en/Publicationsandstatistics/Bulletins/DH_4072494) and in Scotland the Scottish Executive (now Scottish Government) action plan of 2002 (Fair for All HDL 2002) were partly coincidental with, and partly responsive to, the RRAA (Scottish Executive, 2002). Inequalities are centre stage in health policy, and ethnic inequalities have rather neatly and logically found their place within this agenda (Stronks and Kunst, 2009). Although this is a welcome development, it is important to keep mind that, in this era of evidence-based medicine and public health, we also need data on the effectiveness of interventions to advance action.

The question of what works is clearly crucial, but is usually difficult to answer because of a lack of appropriate high-quality data. The placebo-controlled, randomised, double-blind trial provides the most solid evidence for the effectiveness of initiatives. However, these trials are expensive, time consuming and difficult to conduct, particularly for complex interventions, where contextual considerations can be of considerable importance.

Repeated systematic reviews on interventions among ethnic-minority populations have highlighted two main points. First, there are substantial descriptive data emphasising need, at least for some topics (e.g. coronary heart disease (CHD), stroke, infections, blood pressure, smoking, alcohol and obesity) and some populations (South Asian, Chinese, African and Caribbean origin) (Gill *et al*, 2007). Secondly, with the exception of the USA, there is a dearth of data on effectiveness, and randomised trials are a rarity (Bartlett *et al*, 2003; Sheikh *et al*, 2004). Few robust effectiveness data exist for Europe.

Research on ethnicity and health is generally small-scale. Ethnic-minority groups are often invisible in large-scale studies, particularly European cohort studies (Ranganathan and Bhopal, 2006) and trials (Bartlett *et al*, 2003; Sheikh *et al*, 2004). However, such studies underpin the rationale and basis for interventions. The exclusion of minority populations tends to be quite striking. For example, Bartlett and colleagues reported that only 8 of 47 trials on statins reported data on ethnic groups specifically; all of those 8 trials were based in the USA (Bartlett *et al*, 2003). Hussain-Gambles and colleagues have shown very low rates of participation of South Asian populations in six trials led by the Clinical Trials Research Unit in Yorkshire (Hussain-Gambles *et al*, 2004). Sheikh and colleagues examined the reporting of ethnicity in 154 trials, and found that 23 of 59 trials in the USA reported ethnicity (39%), compared with 7 of 95 trials in Europe (7%) (Sheikh *et al*, 2004). Ranganathan and Bhopal showed that none of 40 cardiovascular cohort studies in Europe reported data on any ethnic group, whereas 15 of 32 such studies in North America did (Ranganathan and Bhopal, 2006). Yet ethnic-minority groups are willing participants in trials, with consent and response rates comparable with those for the population as a whole (Wendler *et al*, 2006). However, costs are higher for recruitment. This is in part driven by the preference for personal face-to-face approaches, but also by interpretation- and translation-related costs (Marquez *et al*, 2003).

Ideally, we would want trial-level evidence to inform decisions made about the target populations (ethnic-minority groups), but we know that (even in the USA, which leads the way) the trials and data that we need seldom exist. Thus we are left in a quandary. What do we do in these circumstances? Evidence to underpin interventions in ethnic-minority populations could, at least to some extent, come from the countries of origin of ethnic-minority groups. Unfortunately, the north-south gap in research, which mainly reflects the difference between economically developed and economically developing countries, means that there is a comparatively small evidence base in the relevant countries, although this situation is changing (Prabhakaran *et al*, 2009). Indeed, sometimes there is more research on the diaspora than on the source population.

Do we really need evidence from such trials to recommend an initiative in an ethnic-minority group? Certainly, within reason, a focused and substantial research programme is needed. Studies on general populations ought to include people from minority ethnic groups, and the ethical case has been made recently (Bhopal, 2008). Although we acknowledge that the numbers may be too small to allow meaningful subgroup analyses in the context of individual studies, in time meta-analyses will be possible if the ethnic composition of populations is logically, carefully

and consistently described. In addition, we need trials that are focused on ethnic-minority groups, often to replicate prior evidence of effectiveness, e.g. interventions to reduce cigarette smoking (for which there is now plenty of evidence for white populations), and sometimes to break new ground on specific issues, e.g. interventions to reduce oral tobacco use (West *et al*, 2004). However, compiling a database of this kind will be a multi-billion pound endeavour, and will take many years. This will therefore need to be an international exercise. In Europe, some steps are already being taken in this direction with, for example, the Migrant and Ethnic Health Observatory project (Rafnsson and Bhopal, 2009).

Pending the availability of such data, we need to use general principles. All health interventions, especially public health ones, are relevant to ethnic-minority groups, as the needs are remarkably similar, although the means of achieving them may differ (Gill *et al*, 2007). The needs of minority groups should be met simultaneously with those of the rest of the population, and not lag behind while awaiting a second wave of work, which may not materialise due to lack of expertise, energy and funds. If an intervention works in a white population, it makes sense, we believe, to also try it in ethnic-minority groups. This roll-out should involve making common-sense modifications to adapt the intervention for minority ethnic groups (Netto *et al*, 2008). Involving minority health professionals in the teams that are developing and implementing health initiatives can help to achieve this. Netto *et al* have distilled five principles to guide adaptation (Netto *et al*, 2008, 2009), and a project funded by the Health Technology Assessment/Medical Research Council will develop these and other principles (www.ncchta.org/project/1745.asp). For simple interventions (e.g. folic acid supplementation for pregnant women to prevent congenital abnormalities), effectiveness will probably be transferable across ethnic groups. We should evaluate such interventions by monitoring uptake and outcome. If an intervention is complex (e.g. evaluating whether brief advice from the general practitioner will help Bangladeshi smokers to quit), we should evaluate the question in the context of a formal trial. At least, if a trial is not feasible, we should research how to modify interventions to make them cross-culturally effective (Netto *et al*, 2008).

Health initiatives must cater for the ethnic-minority populations with work of equal potential effectiveness and sensitivity. To do otherwise promotes inequality, maintains inequity and is unethical and institutionally racist, if not illegal (Bhopal, 2009). To achieve this goal, we need institutional structures that include proactive strategies and stringent requirements of researchers. Institutional structures include the possibility of laws, policies, strategies, ethical guidance and services for researchers. Laws might be modelled on

the National Institutes of Health (NIH) Revitalisation Act 1993, which requires NIH-funded researchers to include women and ethnic-minority groups in research (Sheikh *et al*, 2009). Policies already exist, although they are not well known (McGuire, 2003). Funders do not tend to have strategies focused on ethnicity and health, although one is imminent, led by NHS Health Scotland (Scottish Ethnicity and Health Research Strategy Working Group, 2009). Ethical committees are taking an increasing interest in inclusion, although formal guidance is not available (Bhopal, 2008).

Researchers need to work to find solutions to the challenges, not least by mobilising and enthusing themselves, and subsequently ethnic-minority populations, to participate in the research process (Johnson, 2006). Research can help ethnic-minority groups to move out from the shadows and participate in a vibrant, healthy, multi-ethnic society (Johnson, 2006; Bhopal, 2007). In turn, ethnic-minority populations can also bring insights of interest to researchers and, in so doing, benefits to the population as a whole.

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