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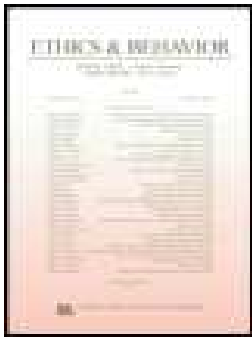
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National Human Research Ethics: A Preliminary Comparative Case Study of Germany, Great Britain, Romania, and Sweden

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Although international research is increasing in volume and importance, there remains a dearth of knowledge on similarities and differences in “national human research ethics” (NHREs), that is, national ethical guidelines (NEGs), Institutional Review Boards (IRBs), and research stakeholder’ ethical attitudes and behaviors (EABs). We begin to address this situation by reporting upon our experiences in conducting a multinational study into the mental health of children who had a parent/carer in prison. The study was conducted in 4 countries: Germany, Great Britain, Romania, and Sweden. Data on NHREs were gathered via a questionnaire survey, two ethics-related seminars, and ongoing contact between members of the research consortium. There was correspondence but even more so divergence between countries in the availability of NEGs and IRBs and in researcher’ EABs. Differences in NHREs have implications particularly in terms of harmonization but also for ethical philosophy and practice and for research integrity.

Keywords: ethical attitudes, ethical behavior, ethical guidelines, Institutional Review Boards, national human research ethics

INTRODUCTION

There is extensive agreement as to the principles—*respect for persons, beneficence, nonmaleficence, and justice*—by which research with human participants should be conducted to ensure it is ethical (A. J. London, 2007). Inconsistencies start to become apparent when efforts are made to interpret these principles and translate them into ethical procedures (Emanuel, Wendler, & Grady, 2000; Mishna, Antle, & Regehr, 2004). These inconsistencies are part of a much more extensive pattern of convergence and divergence in ethics, which exist in three main domains: ethical guidelines, Institutional Review Boards (IRBs), and research stakeholder’ ethical attitudes and behaviors (EABs; Carrington, Neville, & Whitwell, 2014). We refer to these three domains collectively as human research ethics (HREs). Intranational similarities, but more commonly differences, have been identified in the content and status of ethical guidelines (Powell & Smith, 2006), the membership and decision making of IRBs (Hedgecoe, 2008), and the EABs of research stakeholders (Graffigna, Bosio, & Olson, 2010).

Similarities and differences in HREs have been reported also at the international level. There are conflicting assessments as to the degree of overlap between national ethical guidelines (NEGs; Blake, Joffe, & Kodish, 2011). There is evidence of some conformity in the existence and organization of IRBs (Klitzman, 2008), but the indication from most research is of major variations between national IRB systems (Hearnshaw, 2004). Agreement but also notable discrepancy has been revealed in the EABs of different national research stakeholders (Ries, LeGrandeur, & Caulfield, 2010).

Although conformity and deviation in HREs are important at the intranational level, they are especially relevant in the international context. International research is subject to the same sociodemographic and organizational factors that produce divergence in HREs in intranational studies, but it is exposed to a range of additional social, political, economic, and cultural variables that can create divergence in HREs. The amount of international research being conducted is also burgeoning (Garrafa, Solbakk, Vidal, & Lorenzo, 2010).

There are contesting philosophical perspectives on the implications of similarities and differences in national HREs (NHREs; Benatar, 2004). Ethical Universalists argue that there are established ethical procedures that should be adhered to in all situations and that any deviation from these is unethical. Moral Relativists counter that the way in which ethical procedures are interpreted has to take account of local conditions, such as culture and values. Other writers, adopting a more applied stance, have claimed that differences in ethical behavior may signify unethical research practice (Hearnshaw, 2004). There has, within these critiques, been a particular concern surrounding research sponsored by organizations in high-income countries (HICs) but conducted in low- and medium-income countries (LMICs)—work that may involve “ethical imperialism” (Hyder et al., 2004). This charge of ethical imperialism has come to incorporate a series of fundamental ethical and political issues, including *equipoise* (Freedman, 1987), the *standard of care* (Edejer, 1999), and the *10/90 gap* (Garrafa et al., 2010). Variations in ethical procedures can lead to adverse consequences for research both methodologically (Graffigna et al., 2010) and practically (Hearnshaw, 2004).

There has been considerable debate over the appropriate response to differences in NHREs (Freed-Taylor, 1994). Much of this debate has revolved around the issue of harmonization, which has been discussed in relation to NEG (Freed-Taylor, 1994) but even more so IRBs (Hedgecoe, Carvalho, Lobmayer, & Raka, 2006). There have been a number of major initiatives toward harmonization, for example, the *International Conference on Harmonisation* (Hirtle, Lemmens, & Sprumont, 2000). Opponents of harmonization have challenged the basic premise that differences in EABs are problematic (Edwards, Ashcroft, & Kirchin, 2004), pointed out that there will always be variance in the extent to which research stakeholders support harmonization and interpret its associated directives (Hedgecoe et al., 2006), and suggested that harmonization may be incompatible with European law (Hedgecoe et al., 2006).

There is limited research on similarities and differences in NEG and IRBs, and even less on agreement and disagreement in research stakeholders’ EABs (Giacobbe & Segal, 2000). A large part of the extant research is based upon a small number of English-speaking countries, namely, Australia, Canada, New Zealand, the United Kingdom, and in particular the United States, and much of it is drawn from biomedicine (Leach & Harbin, 1997). Analyses of ethical procedures tend to be neither extensive nor in-depth (Fisher, 2006).

Our aim was to address some of this shortfall in knowledge. We intended, more specifically, to assess more fully than had been done before the extent and depth of similarities and differences in NHREs. This would then enable us to contribute to the debate surrounding convergence and divergence in NHREs, and in particular how they should be interpreted, what they might signify in terms unethical practice, and the response with which they should be met.

We sought to accomplish these aims by describing and analyzing the similarities and differences in NHREs that became apparent in the course of a study into the mental health of children and young people (hereinafter referred to as *children*) who had a parent/carer (*parent*) in prison in Germany, Great Britain (GB—England, Scotland, and Wales), Sweden, or Romania. The research was located in behavioral science and the social sciences (criminology and social

work); two distinct methods (questionnaire surveys and interviews) were employed; and a range of participants were used—comprising practitioners, policymakers, and members of the public (both adults and children). Members of this last group could be deemed vulnerable because they were children, imprisoned, and/or in families where a parent was imprisoned. We begin by examining the existence of NEGs and IRBs before turning to the main focus of the study—the researchers' EABs in respect of participant-related ethical procedures. There is an additional focus upon vulnerable groups because HREs are especially germane to them.

METHODS

Background

A substantial (Robertson, 2007) and increasing (Walmsley, 2008) minority of children experience parental imprisonment. Such loss of a parent can have adverse consequences on a child's development (Murray, Farrington, Sekol, & Olsen, 2009), but it appears that services for these children and families may be deficient (Jones et al., 2013). There is a paucity of data on how children are affected by parental imprisonment; what their subsequent needs are; and how these are being, and should be, met (Johnson & Easterling, 2012). The COPING (Children of Prisoners, Interventions and Mitigations to Strengthen Mental Health) project was designed to tackle some of this dearth of information.

COPING was an European Union–funded study, carried out across four member states between January 2010 and December 2012. It involved a consortium of six nongovernmental organizations and four research institutions from France (Children of Prisoners Europe), GB (the University of Huddersfield [project lead] and Partners of Prisoners and Families Support Group), Germany (Technische Universität Dresden, and Treffpunkt e.V.), Romania (Universitatea Alexandru Ioan Cuza and Asociația Alternativă Sociale), Sweden (the Karolinska Institutet and Bryggan), and Switzerland (Quaker United Nations Office, Geneva). COPING comprised a questionnaire-based survey conducted among children 7 to 17 years of age who had a parent in prison, and their nonimprisoned parent; interviews with a subsample of these children and their imprisoned and nonimprisoned parents; interviews with stakeholders; and a service mapping exercise.

Sample

The four study countries were chosen on the basis that they represented a diverse range of European states in terms of criminal justice policy and practice—including that relating to imprisonment (International Centre for Prison Studies, 2013)—and wider political, economic, social, and cultural characteristics (International Monetary Fund, 2013).

Data Collection

Data on NHREs were collected in three main phases. The first phase involved two linked seminars that were held for all members of the research consortium; the first at the launch of the project, and the second shortly before the onset of fieldwork. An *Ethical Protocol* was drafted following on from these seminars. The second phase consisted of ongoing communications in

which consortium members informed the first author of any ethical issue they encountered and/or any instances where they departed from the Ethical Protocol. The third phase comprised a questionnaire survey administered to the four national research leads toward the end of the COPING study. The survey was intended to check what ethical procedures had been followed and whether there had been any deviation from the Ethical Protocol.

Ethical Approval

Each research team abided by any institutional, professional, and legal requirements in its respective country regarding ethical approval.

FINDINGS

National Ethical Guidelines

The GB researchers were able to refer to at least one set of research relevant NEG for each of the disciplines and subdisciplines represented in the COPING project. These included the British Psychological Society's (2009) *Code of Ethics and Conduct* and the British Society of Criminology's (2006) *Code of Ethics*. These NEG contained only limited advice regarding vulnerable participants. Research relevant NEG did not exist in any of the three remaining countries.

IRBs

Researchers in Germany and Sweden are required by law to obtain ethical approval for studies with human participants (European Network of Research Ethics Committees, 2013). Ethical approval—through a local health-service-based IRB—is a legal requirement for most, but not all, biomedical research in GB. There is no corresponding legal requirement to achieve ethical approval for social research, although there are policy and professional expectations that this be done, usually via a university-based IRB (Health Research Authority, 2013). All of these IRBs expected special attention be paid to vulnerable groups, including child participants and imprisoned parents. There was no equivalent IRB system in Romania, but researchers in this country conducted their work in accordance with the major ethical procedures adopted by the three other research teams.

Researchers' EABs

The research consortium identified 16 participant-related ethical procedures that needed to be taken into account in the process of ensuring the COPING study was ethical. These procedures can be divided into three broad groups according to the degree of agreement or disagreement that existed between the four national research teams.

Similarities in researchers' EABs

Written, nongeneral informed consent was obtained from all adult participants (Table 1). Special care was taken when developing the written research materials for imprisoned parents and their

TABLE 1
Similarities in Researchers' Ethical Attitudes and Behaviors

<i>Ethical Procedure</i>	<i>Germany</i>	<i>Great Britain</i>	<i>Romania</i>	<i>Sweden</i>
Informed consent	Each adult taking part in the research did so only after giving fully informed consent.	Same	Same	Same
Child assent	Each child (i.e., younger than 18) taking part in the research did so only after giving assent.	Same	Same	Same—except this applied only to those younger than 15
Child dissent	If a child (i.e., younger than 18) stated that he or she did not wish to take part in the research, then this wish was respected—even if parental consent had been given.	Same	Same	Same
Withdrawal	Each individual taking part in the research was informed of his or her right not to answer particular questions or to withdraw from the research at any time without this having any adverse consequences for them or anyone else.	Same	Same	Same
Organizational permission or approval	<p>Permission for the research to take place was obtained from the head of the prisons in which some of the research took place.</p> <p>Approval for the research to take place was sought from the following federal ministries and agencies: The Bavarian Ministry of Justice and Consumer Protection; the Saxony Ministry of Justice; and the Bavarian Commission for Data Protection.</p>	<p>Permission for the research to take place was obtained from the head of the prisons in which some of the research took place.</p> <p>Approval for the research to take place was sought from the following national ministries, and national and regional government agencies: The Ministry of Justice, the NOMS, and Northwest England NOMS.</p>	<p>Permission was obtained from The National Administration of Prisons and the heads of prisons in which some of the research took place; Local Child Protection Services in Iasi, Botosani, Bacau, and Vaslui counties (to enable access to children in state care);</p> <p>Approval was required from the National Authority for Personal Data Processing, according to Law 677/2001 for the protection of persons with regards to personal data processing.</p>	A collaborative agreement was signed between the Swedish National Prison and Probation Service and the Swedish university.

Participant support	All individuals taking part in the research—and in particular children and their parents—were informed that they could obtain psychological and social support from the NGO that was involved in participant' recruitment. If a participant did not want this form of support or if they were not in contact with this NGO, then they were informed of alternative sources of support.	Same	Same	Same
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Note. NOMS = National Offender Management Service; NGO = nongovernmental organization.

family members, and in face-to-face meetings with them, to ensure they fully understood the nature and purpose of the study and the conditions under which it was being conducted.

The majority age in all four countries was 18 years. Written, nongeneral assent was obtained from all minors in GB, Germany, and Romania, and all participants younger than 15 in Sweden (even though Swedish IRBs did not require this). (The lower maximum age for assent in Sweden is explained by the particular rules in that country governing minor consent; see upcoming details.) A minimum age for gaining assent from children was not set, with the youngest participants at 7 years of age. Children were excluded from COPING if they did not know the reason for their parents' absence.

If a child dissented to take part in the research, then his or her wishes were always respected.

Every participant was informed that he or she could refuse to answer questions or could withdraw from the research, without adverse consequences. This assurance was made especially clear to members of prisoners' families.

Organizational permission or approval¹ for the research was sought from relevant research stakeholders. These stakeholders varied between the four countries, but they consisted of one or more of government departments or agencies, or local statutory services (Table 1). All members of the research consortium understood that it was particularly important to work with these stakeholders given the vulnerability of some of the participant groups, in particular the imprisoned parents and children who were in state care.

All the research teams provided participants with information on psychological and social support services—including the local collaborating NGO—and facilitated contact with these agencies where appropriate. These arrangements were considered especially important for prisoners' families, as it was anticipated that some of them might have unmet needs and/or might become distressed through their participation in the research.

Relatively modest differences in researchers' EABs

All research teams were committed to the principles of data confidentiality and participant anonymity, but they also concurred that disclosures should be made where they received information that a child was at risk of harm (Table 2). There were, in Sweden, no additional circumstances under which confidentiality or anonymity would be breached. Disclosure could, in GB and Romania, also occur if researchers were informed of a risk to prison security and in Germany if they were told of or any planned criminal offence. Each research team informed its participants of its respective disclosure policy. None of the fieldworkers, in any of the four countries, received information that they felt should be passed on to an authority.

Relatively major differences in researchers' EABs

Parental consent was gained for all minors in Germany, GB, and Romania (Table 3) but in Sweden only for those younger than 15. Parents in all four countries—with the exception of those in one particular situation in Sweden (see upcoming details)—had to give active consent.

¹“Permission” refers to situations where the head of an organization had to decide whether the research took place in the setting for which he or she was responsible. “Approval” refers to situations where a stakeholder expressed an opinion as to whether research should take place in the setting for which he or she had an advisory or regulatory role.

TABLE 2
Relatively Modest Differences in Researchers' Ethical Attitudes and Behaviors

<i>Ethical Procedure</i>	<i>Germany</i>	<i>Great Britain</i>	<i>Romania</i>	<i>Sweden</i>
Confidentiality	Participants were informed that the information they provided to the research would be treated in the strictest confidence—subject to the two exceptions given below.	Participants were informed that the information they provided to the research would be treated in the strictest confidence—subject to the two exceptions given below.	Participants were informed that the information they provided to the research would be treated in the strictest confidence—subject to the two exceptions given below.	Participants were informed that the information they provided to the research would be treated in the strictest confidence—subject to the one exception given below.
Anonymity	Participants were informed that they would not be identified or identifiable in any written or verbal report emanating from the research—subject to the two exceptions given below.	Same	Same	Same
Disclosure	Participants were informed that confidentiality and anonymity would be breached if they provided information that indicated (a) a person had been harmed or was at risk of harm, or (b) a serious crime was planned.	Participants were informed that confidentiality and anonymity would be breached if they provided information that indicated (a) a child (any person younger than 18) was at risk of coming to harm, or (b) there was a risk to prison security.	Participants were informed that confidentiality and anonymity would be breached if they provided information that indicated (a) a child (any person younger than 18) was at risk of coming to harm, or (b) there was a risk to prison security.	Participants were informed that confidentiality and anonymity would be breached if they provided information that indicated: A child's (any person younger than 18) physical or mental health was endangered.

TABLE 3
Relatively Major Differences in Researchers' Ethical Attitudes and Behaviors

<i>Ethical Procedure</i>	<i>Germany</i>	<i>Great Britain</i>	<i>Romania</i>	<i>Sweden</i>
Parental consent	Parental consent was obtained before any child (i.e., person younger than 18) was asked to take part in the research.	Parental consent was obtained before any child (i.e., person younger than 18) was asked to take part in the research.	Parental consent was obtained before any child (i.e., person younger than 18) was asked to take part in the research.	Parental consent was obtained before any child (i.e., person younger than 15) was asked to take part in the research.
Solo or joint parental consent	Consent was obtained from only one parent for his or her child to take part in the research. This was always the nonimprisoned parent.	Consent was obtained from only one parent for his or her child to take part in the research. This was always the nonimprisoned parent.	Consent was obtained from only one parent for his or her child to take part in the research. This was always the nonimprisoned parent.	Consent was obtained first from the nonimprisoned parent for his or her child to take in the research. Consent was assumed for the imprisoned parent except in cases where this parent opted out.
Minor consent	Minor consent was not obtained.	Minor consent was not obtained.	Minor consent was not obtained	Minor consent was obtained from young people 15–17 years of age inclusive.
Compensation	Each individual who took part in the questionnaire survey was given a €5 (US\$6) shopping voucher and each family that took part in an interview was given a €30 (US \$38) shopping voucher.	Each individual who took part in the questionnaire survey was given the equivalent of a €11 (US\$14) shopping voucher and each family that took part in an interview was given the equivalent of €29 (US\$36) shopping voucher.	Compensation was not given to any individual taking part in the research.	Each individual who took part in the questionnaire survey and each individual who took part in an interview was given a €7 (US\$9) cinema ticket.
Sensitive third-party information	Nonimprisoned parents were asked about the imprisonment record of the imprisoned parents.	Nonimprisoned parents were asked about the imprisonment record of the imprisoned parents.	Nonimprisoned parents were asked about the imprisonment record of the imprisoned parents.	Nonimprisoned parents were <i>not</i> asked about the imprisonment record of the imprisoned parents.
Ethnicity information	Researchers asked each participant about his or her ethnicity without prior specific consent and recorded ethnicity on the basis of the participant's nationality and the language(s) he or she spoke.	Researchers asked each participant about his or her ethnicity without prior specific consent and recorded ethnicity on the basis of the participant's physical appearance (i.e., skin color).	Researchers obtained specific consent from a participant in order to ask him or her about his or her ethnicity and recorded ethnicity on the basis of the participant's physical appearance (i.e., skin color).	Researchers did not ask respondents specifically about their ethnicity. Ethnicity data were collected in the form of child participants' and the parental country of birth.

Police checks	Requests were made of the police to ascertain whether they had any information in which there were indications that it would be inappropriate for a researcher to have contact with a child (a person younger than 18). The main concern would have been that the researcher would have harmed a child previously. These checks were carried out by the National Central Registration Registry.	Requests were made of the police to ascertain whether they had any information in which there were indications that it would be inappropriate for a researcher to have contact with a child (a person younger than 18). The main concern would have been that the researcher would have harmed a child previously. These checks were carried out by the Criminal Records Bureau, which is an agency of the national government (in England and Wales).	Police checks were not carried out.	Requests were made of the police to ascertain whether any information was available indicating that it would be inappropriate for a researcher to have contact with a child (a person younger than 18). The main concern was identifying prior criminal activity related to harming a child. These checks were carried out by the National Police Board.
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Consent was required of only one parent in GB, Germany, and Romania but of both parents in Sweden. The Swedish researchers were concerned that it might be difficult, for practical reasons, to obtain the consent of imprisoned parent. The Swedish IRB agreed to a streamlined consent process whereby imprisoned parents were informed of the research, of their right to remove their child, and that nonresponses would be taken as consent.

Researchers in Sweden obtained (autonomous) consent from minors 15 to 17 years of age.

Researchers in GB, Germany, and Sweden were generally quite positively disposed toward the idea of compensating nonimprisoned parents and their children. They also agreed that the amount, and form, of compensation had to be sufficient enough that it achieved its intended purpose but not be so generous that it had an unwarranted influence upon any participant. There were discrepancies even between these three teams as to the precise amount and form of compensation that was appropriate (Table 3). The Romanian researchers felt that it would be unethical to offer compensation, as the economic conditions of many of its families were such that this proposition would almost compel them to participate.

Researchers in GB, Germany, and Romania believed it was ethical to ask nonimprisoned parents about the incarceration record of the imprisoned parent. The Swedish researchers, by contrast, felt that this practice was unethical. All families taking part in the COPING study were vulnerable by virtue of their having a parent in prison, but the Swedish policy meant that it was not possible, in that country, to examine the relationship between parental incarceration history and children's mental health.

The GB and Romanian researchers asked participants to define their ethnicity according to their physical appearance. (The Romanian team was under a legal obligation to obtain participants' consent before asking them about their ethnicity.) The German and Swedish researchers were more cautious about collating information on ethnicity and believed that it should be categorized according to some aspect of a participant's culture, that is, their nationality, the language(s) they spoke, and/or their country of birth (or that of their parents). Membership of a Black or minority ethnic group can render an individual vulnerable, but it was not possible to make comparisons, across the four countries, as to the role of this variable, owing to the varying classificatory schemes.

Researchers in GB, Germany, and Sweden requested checks of official information sources (largely police based) to verify that it was not inappropriate for any given individual to have contact with children. These systems did not exist in Romania. There were, however, safeguards in place in Romania (and the other three countries) to help prevent untoward behavior on the part of any fieldworker. This included the supervision of fieldworkers and the setting up of systems for participants to report any concerns they might have.

DISCUSSION

NEGs were available in only one country, and IRB systems existed in three countries. The EABs of the four national research teams were similar in respect of six ethical procedures, but there were relatively modest or major differences between them in relation to three and seven ethical procedures, respectively. There was, in general, little consistency between particular countries and research teams in their NHREs.

National Ethical Guidelines

Many countries have NEGs, often covering biomedical research and sometimes other disciplines, but a considerable number do not. There does not appear to be any especially distinct patterns by country, although NEGs may be more common in English-speaking HICs (Alahmad, Al-Jumah, & Dierickx, 2012). There are other NEG dimensions that were not examined in the COPING research but for which either correspondence or divergence, between countries, has been reported—namely, the content (Mishna et al., 2004; Taylor, 2008) and specificity of codes (Powell & Smith, 2006), the positions that are taken within them (Elger & Caplan, 2006), and their status (Freed-Taylor, 1994). There is reference to vulnerable groups in some, but not all, NEGs. Children are especially likely to be discussed, but there is variation between the codes in the other groups that are mentioned (Alahmad et al., 2012). Coverage of vulnerable groups in NEGs is, overall, limited.

IRBs

Issues over the availability (Uys, 2006), use (Glickman et al., 2009), and operation (Calain, Fiore, Poncin, & Hurst, 2009) of IRBs are more likely to arise in LMICs. Some LMICs have effective IRB systems, and the number and quality of IRBs in these countries is increasing (Nyika et al., 2009). LMIC's IRBs sometimes work to more robust standards than their HIC equivalents (Klitzman, 2008). Commonalities and discrepancies have been identified in the IRB systems of HICs (Graffigna et al., 2010). There can be differences between countries in the types of research that are required to go to ethical review (Cleaton-Jones & Wassenaar, 2010). Many IRBs exhibit a special concern over vulnerable groups, but there is variation between them as to who is defined as vulnerable, the level of attention they receive, and the reason for this attention (L. London, 2002). HIC's IRBs tend to be more concerned with child participants (Balén et al., 2006), whereas their LMIC's counterparts are more anxious over participants who are in poverty or poor health (Nyika et al., 2009).

Researchers' EABs

Primary ethical procedures

We categorize ethical procedures into one of three groups: *primary*, *secondary*, or *tertiary*. Primary ethical procedures are the most prominent in discussions of HREs, and they have been subject to a fairly substantial amount of research. These ethical procedures are generally respected and followed by national researchers. Differences in EABs become apparent when the detailed implementation, and additional dimensions, of these procedures are examined.

Difficulties with informed consent are more likely to arise in LMICs, especially in relation to vulnerable groups (Emanuel, Wendler, Killen, & Grady, 2004; Glickman et al., 2009). These problems do not always arise in LMICs (Oduro et al., 2008), and differences with HICs should not be overstated (Allmark & Mason, 2006). Similarities and differences between national researchers have been highlighted in the breadth of the informed consent they obtain (Ries

et al., 2010) and the format in which they request it (Suhonen, Saarikoski, & Leino-Kilpi, 2009), but particular patterns by country have not been reported.

Researchers in HICs appear to attach equally high importance to “protecting respondent anonymity/confidentiality” and “maintaining client confidentiality” (Giacobbe et al., 2000). Disclosure in LMICs tends to be in the interests of the relatively powerful (Beyrer & Kass, 2002), whereas in HICs it is usually motivated by a concern for people who are at risk or who are a risk to others (Ensign, 2003). There can be disparities between HIC researchers in the precise circumstances in which they disclose and whether they inform participants of their disclosure policy (Fisher, 2006).

There is some inconsistency and even confusion as to what HIC’s researchers’ EABs are, or should be, regarding child-related ethical procedures (Helweg-Larsen & Bøving-Larsen, 2003). Many researchers in LMICs and HICs recognize the importance of parental consent (Powell & Smith, 2009) and routinely seek it in practice (Ries et al., 2010), but there are differences between national researchers in the likelihood of their seeking active consent (Bogolub & Thomas, 2005). There is a facility in many HICs for parental consent to be waived (Balen et al., 2006), but this is uncommon in LMICs (Ahsan, 2009).

Minor consent is particularly likely to be sought by researchers in HICs conducting psychosocial studies of sensitive topics with adolescents (Flicker, Haans, & Skinner, 2004), but there are differences in the conditions under which it is obtained (Moodley, 2007). There are distinctions between researchers in the minimum age for minor consent (Powell & Smith, 2006), but there does not appear to be any particular patterns by country (Taylor, 2008).

There is fairly extensive agreement between researchers in HICs that they should obtain assent from children (Mishna et al., 2004) and the criteria to be used in determining whether a child is capable of giving assent (Vitiello, 2003). There is a fair amount of variation between national researchers in their EABs in respect of the minimum age for child assent (Ries et al., 2010).

There is a consensus among researchers, especially those in Europe and the United States, that children should not be involved in a study if they have dissented (Sheahan, Da Silva, Czoli, & Shaul, 2012), although there are contradictions within the literature as to whether this holds for therapeutic research (Sheahan et al., 2012).

Secondary ethical procedures

Secondary ethical procedures are recognized by many—but not all—researchers and have received only modest coverage in the literature. There is agreement between HICs’ researchers concerning participants’ right to withdraw (Giacobbe & Segal, 2000) and the extent of withdrawal they should be offered (Ries et al., 2010). There is quite widespread recognition of the need to pay special attention to respecting the rights of vulnerable groups regarding withdrawal (Scheyvens, Scheyvens, & Murray, 2003).

There are conflicting views as to whether compensation is ethical (Singer & Bossarte, 2006; Thomas, 2007). There is particular disquiet over the use of compensation with vulnerable populations (including prisoners; Pont, 2008), and especially those who are disadvantaged (Denny & Grady, 2007) and even more so those living in LMICs countries (Creed-Kanashiro, Oré, Scurrah, Gil, & Penny, 2005).

Tertiary ethical procedures

Tertiary ethical procedures rarely feature in discussions of research ethics and have been subject to little research. The indication from reviews of NEGs and related instruments is that researchers from a range of countries obtain solo parental consent (Hens Nys, Cassiman, & Dierickx, 2009). In a small number of countries, researchers are expected to acquire joint parental consent (Vitiello, 2003)—an expectation that is greater where risks are higher, the research is therapeutic, and both parents are available (Axelin & Salanterä, 2008).

The United States is the only country where there has been any appreciable discussion concerning the collation of sensitive third-party information (Lounsbury, Reynolds, Rapkin, Robson, & Ostroff, 2007). U.S. researchers tend to be cautious about gathering third-party information without the consent of the individual in question.

Gathering information on participants' ethnicity and classifying ethnicity according to physical appearance are standard practices in English-speaking HICs (Afkhami, 2012). Researchers in continental Europe are more wary of collecting data on participants' ethnicity and tend to categorize ethnicity by the country of origin of, and/or the language spoken by, participants and/or their parents (Verkuyten, 2009). Ethnicity can be an important variable in terms of vulnerability, but these definitional inconsistencies raise issues over the validity of given categorizations and intercountry comparisons (Salway et al., 2011).

Researchers in many HICs seek permission from non-family member "gatekeepers" (Savage & McCarron, 2009). Some participant groups, including children and prisoners, may be deemed vulnerable and gatekeepers may have a safeguarding role in relation to them (Emmel, Hughes, Greenhalgh, & Sales, 2007). Researchers in a number of HICs complain that gatekeepers often present unwarranted impediments to legitimate studies, and more particularly do not respect participants' right to engage in research (Heath, Charles, Crow, & Wiles, 2007).

Many different national researchers believe they should identify sources of support for participants (Swain, Heyman, & Gillman, 1998), especially if the research involves vulnerable groups (Jewkes, Watts, Abrahams, Penn-Kekana, & García-Moreno, 2000) and sensitive topics (Lees, Procter, & Fassett, 2014).

There has been an increasing commitment among researchers from HICs toward requesting "police checks" on fieldworkers collecting data from vulnerable participants, particularly children but also people with disabilities and the elderly (Jacobs & Blitsa, 2012).

Limitations

The countries in the COPING study do not comprise necessarily a representative cross-section of all nations in Europe (Karamessini, 2007), let alone the world (Inglehart, 1997). The COPING countries make up a quite modest proportion (9%) of all European states ($n = 45$) and a very small proportion (2%) of all nations (estimated $n = 196$; Rosenberg, 2014). The data in this article were obtained from a single study, with a quite specific focus and restricted range of methods. The study was also limited in terms of the disciplines and subject areas it drew upon. NEGs and IRBs were examined in the course of this research but in relation only to whether they existed. There was a more detailed exploration of researchers' EABs, but this was in respect just of participant-related ethical procedures, and even this was not comprehensive (McGuire et al., 2008). It is likely that, had the research been more wide-ranging, more similarities but an even greater number of

differences in NHREs would have been identified, rendering this phenomenon yet more complex. There was no analysis to verify the exact factors that accounted for the similarities or differences in NHREs, or to establish the extent to which the prevailing EABs applied to all individuals within a given country's research team.

CONCLUSION

This work represents an important first step toward a broader recognition of the existence of similarities but even more so differences in NHREs. There is, within the wider literature, support for our findings but also an indication that there are other dimensions of NHREs where there is convergence but much more commonly divergence. Many of these differences exist between LMICs and HICs, but there is also variance within these groupings (Glickman et al., 2009), plus a number of other axes around which there are discrepancies, including Europe–United States, United States–other HICs, and continental Europe–English-speaking HICs.

Similarities in EABs lend support to the universalist view of ethics (Grodin, 1992), whereas differences in EABs reinforce a relativist stance (Gostin, 1991). A more appropriate response to IHREs might be that proposed by Mzayek and Resnick (2010), whereby “a middle-ground solution is offered in the form of ethical pluralism” (p.3). We did not feel that differences in behavior, within COPING, were a reflection of unethical research. Similar conclusions have been reached in reviews of other research (Blake et al., 2011). These differences have, instead, been interpreted as a product of legitimate distinctions between national researchers. Some actions by national researchers, though, have been adjudged to be unethical (Lurie & Wolfe, 1997). Further differences in ethical behavior and instances of unethical practice may be identified with the increasing focus on the conduct of national researchers.

The issue of ethical imperialism is complex. Some unethical practice in LMICs is perpetrated by local researchers as opposed to “visiting HIC” investigators. Unethical research has also been conducted in HICs (Blake et al., 2011). All research stakeholders will have to be more mindful of the risk of ethical imperialism as the volume of international research grows and the number of differences in ethical behaviors being revealed increases.

There are greater social, political, and cultural differences between LMICs and HICs than there are within HICs, which have been the focus of comparative HREs studies (Louw & Delpont, 2006). It is likely that as more complete knowledge of NHREs emerges, harmonization will be rendered even more challenging. This raises questions over the extent to which harmonization can be achieved and the degree of effort that should be invested in striving toward it.

The need for research on similarities and differences in NHREs is growing. This is a result of the dynamic nature of HREs and of research more generally, which is leading to ever-increasing situations for both convergence and divergence. There are three major sources for this dynamism: the emergence of novel areas of study, sources of data, and research methods (Sampson, Caldwell, Taylor, & Taylor, 2013); the rising amount of research being undertaken in an ever-wider range of countries (Kamalski & Plume, 2013); and “ethics creep” (Haggerty, 2004). We believe future work should be concerned with

- Africa, Asia, Central and South America, Eastern Europe (including Russia), and the Middle East (Alahmad et al., 2012);

- biomedicine, but even more so behavioral science, the social sciences, and the humanities (Leach & Harbin, 1997);
- multidisciplinary research, in order to determine the moderating effect, if any, of a discipline in the nation–HREs relationship;
- NEGs and IRBs, but even more so the EABs of researchers (in relation to participants, other researchers and stakeholders, and society more generally) and participants (Valdez-Martinez, Garduño-Espinosa, Martinez-Salgado, & Porter, 2004; Vitiello, 2003);
- the full range of ethical procedures and all dimensions of NHREs (Fisher, 2006); and
- the causes of similarities and differences in NHREs (Suhonen et al., 2009).

Researchers engaged in intranational or international studies more generally should be encouraged to report on HREs and NHREs, respectively. Existing efforts to build ethics awareness and capacity (Lavery, 2004) should be continued and expanded not only in LMICs but also in HICs (Zachariah et al., 2012).

The extent of the void that exists in the appreciation of NHREs is well illustrated, perhaps, through Pipi et al.'s (2004) account of the principles that underpin the Māori “code of conduct”:

It is important to remember that in Māori society knowledge and learning are associated with being tapu (sacred). In discussing learning and tapu, Te Uira Manihera (1992:9) of Tainui describes the sacredness of learning and the struggle elders have in “the handing down of knowledge”. The fear is that “by giving things out they could be commercialised. If this happens they lose their sacredness, their fertility . . .” (p. 151)

The study of NHREs is a major and challenging task, but it is also—for what it can reveal about the diversity and richness of human thought and action—a fascinating one.

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