Is There a Universal Understanding of Vulnerability? Experiences with Russian and Romanian Trainees in Research Ethics

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ABSTRACT: vulnerability of participants in research and the provision of special protections for vulnerable research participants are key concepts in research ethics. Despite international consensus requiring special protections for vulnerable research participants, both the concept of vulnerability and the nature and adequacy of strategies to reduce vulnerability remain vague and, consequently, are subject to varying interpretations. We report on observations of the challenges faced in understanding this key concept by 20 Russian and Romanian trainees participating in a one-year M.A. training program in research ethics from 2000 through 2011. We describe how trainees' understanding of and appreciation for the need for special protections of vulnerable research participants was nurtured. This paper is part of a collection of papers analyzing the Fogarty International Center's International Research Ethics Education and Curriculum Development program.

KEY WORDS: bioethics, vulnerability, research ethics

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VULNERABILITY OF PARTICIPANTS IN RESE-arch and the attendant responsibility of researchers to provide special protections for vulnerable research participants are key concepts in research ethics (DuBois, 2006; Kipnis, 2001; Levine et al., 2004). Despite international consensus regarding the need for special protections for vulnerable participants in research, both the concept of vulnerability and the nature and adequacy of strategies to reduce it remain vague and, consequently, are subject to varying interpretation. Most guidelines have proposed a wide variety of (differing) categories of people who are vulnerable; e.g., some have proposed that pregnant women are vulnerable while others have not.

However, others such as Kipnis (2001) have argued persuasively that vulnerability is inherent in situations, not people; e.g., a pregnant woman may be vulnerable in some physical or biomedical procedures, but is not vulnerable in survey research about baby products. Hence, those who are to judge whether research participants are vulnerable and how their vulnerability can be reduced need to understand the nature of vulnerability as they cannot simply depend on existing guidelines.

Twenty international trainees from two countries of the former Soviet bloc—Russia and Romania—participated in a one-year M.A. training program in international research ethics during the period from 2000 through 2011. Almost universally, they appeared to be unable to comprehend the concept of vulnerability, its relevance in the context of research, and the associated need for special protections for vulnerable participants. We conclude that comprehension of vulnerability in others, often assumed to be a basic human intuition, is not. Or, in this case, the natural development of empathy for others may have been arrested by the sometimes brutal, sometimes subtle imposition of political ideologies and other attitudes that remain alive in their home countries, as we describe subsequently. Nevertheless, we suggest that empathy and comprehension of vulnerability can be nurtured pedagogically, in order to facilitate trainees' understanding of and appreciation for the need for special protections of vulnerable participants in research.

Conceptualizations of Vulnerability

INTERNATIONAL CONSTRUCTIONS

A variety of conceptualizations of vulnerability have been set forth. The 2002 CIOMS's *International Ethical Guidelines for Biomedical Research Involving Human Subjects* defines vulnerability as "a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group" and provides that "special provision must be made for the protection of the

rights and welfare of vulnerable persons." Additionally, the *Guidelines* interpret the ethical principle of justice to require that "research be responsive to the health conditions or needs of vulnerable subjects" and that the individuals recruited into research should "be the least vulnerable necessary to accomplish the purposes of the research" (CIOMS, 2002, p. 18).

Accordingly, "[v]ulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More specifically, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests" (Guideline 13). Several groups of individuals are specifically identified as vulnerable in research: children and "persons who because of mental or behavioural disorders are incapable of giving informed consent." Others may have attributes consistent with those classes of persons deemed to be vulnerable or potentially vulnerable. This may include medical and nursing students, subordinate hospital and laboratory personnel, employees of pharmaceutical companies, members of the armed forces or police, elderly persons, residents of nursing homes, people receiving welfare benefits or social assistance and other poor people and the unemployed, patients in emergency rooms, some ethnic and racial minority groups, homeless persons, nomads, refugees or displaced persons, prisoners, patients with incurable diseases, individuals who are politically powerless, members of communities unfamiliar with modern medical concepts, and individuals with serious, potentially disabling or life-threatening diseases. In essence, this large list of categories encompasses individuals who are or are likely to become dependent on others for a wide range of reasons (CIOMS, 2002).

No guidance is provided within either the *Guidelines* or commentary to the *Guidelines* to aid researchers in determining whether specific groups lack absolute or relative power in a specific context, thereby warranting classification as vulnerable. Furthermore, vulnerability is not always a static state of being; assessment of vulnerability and the need for and adequacy of special protections may consequently require periodic revisiting. As an example, immigrants may be considered to be vulnerable as a group due to language differences, lack of familiarity with a new homeland, reduced access to medical care, and possibly legal status. Long-term immigrants may not have these characteristics and so may not be vulnerable for the purposes of research protections. Though often treated as a binary classification (one is either vulnerable or not), it is open to debate whether vulnerability is better conceptualized as a spectrum of attributes with greater and lesser vulnerability.

In view of the lack of specificity in guidelines regarding these issues, it is not surprising that a cursory survey of various jurisdictions reveals considerable variation in the extent to which the concept of vulnerability is operationalized in both law and praxis. For example, U.S. regulations specifically enumerate only children, prisoners, and pregnant women as vulnerable populations. In practice, however, U.S. institutional review boards frequently consider mentally ill persons, students, non-English speakers, sexual minorities, and HIV-infected persons to be vulnerable (Backlar, 2000; Delano, 2006; Levine, Dubler, & Levine, 2001; Tickle & Heatherton, 2006; Perry, 2011; White, 2007; Yanos, Stanley, & Greene, 2009). Uganda's 2007 *National Guidelines for Research Involving Humans as Research Participants* enumerates the following additional groups as vulnerable in the context of research: mature and emancipated minors; fetuses; persons who are homeless; and members of the armed forces (Uganda National Council for Science and Technology, 2007). Australia provides that the following classes of persons are vulnerable: children and some young people; persons in dependent or unequal relationships, such as caretakers and people with chronic conditions or disabilities, including long-term hospital patients; governmental authorities and refugees; employers or supervisors and their employees; and service-providers (government or private) and especially vulnerable communities to whom the service is provided (National Health and Medical Research Council, Australian Research Council, and Australian Vice Chancellors' Committee, 2007). The policy further suggests that the following categories of persons may be vulnerable as a consequence of specific circumstances: neonates, terminally ill individuals, individuals in need of emergency care, and persons engaged in an illegal activity (ibid.).

TRAINEE UNDERSTANDINGS

Perspectives relating to vulnerability at the initiation of training were voiced in the context of an advanced seminar designed specifically for international research ethics trainees. Russian and Romanian trainees voiced perspectives that displayed considerable variance from international conceptualizations of vulnerability and special protections. As one example, trainees were asked to provide written comment on the methodological and ethical issues raised in a study designed to "investigate changes in nutritional status and morbidity over time among pre-school slum children" (Rao, Joshi, & Kelkar, 2000, p. 1060). The investigators concluded from a longitudinal observational study that under-nutrition resulted in increased risk

of infection and decreased growth. No intervention, including information relating to proper nutrition, was provided to parents of the children during or after the study. The question to be discussed by the trainees was whether the study should have been conducted in view of the state of knowledge about the consequences of malnutrition and, if it were to be conducted, whether any sort of intervention was warranted.

The view of one trainee from Russia typified that expressed by many Russian and Romanian trainees who participated in this seminar over the 11 years of the training program. In his/her written response to the published paper, that trainee distinguished between what he/she viewed as "strict" and "non-strict" harm. He/she argued that because it was an observational study, no strict harm, meaning death or harm due to the action of the investigators, occurred even though the investigators witnessed the worsening condition of many of the children. In contrast, one of the trainees from an African country likened the study to the Tuskegee syphilis study, arguing in his/her paper that "[the denial of] effective treatment as was done for denial of penicillin for the Alabama men is also reflected in the lack of a concrete plan to give these hapless Indian kids any food … But I argue that observing hungry children as they waste away for a two-year period is a significantly harmful procedure that society would scarcely condone."

Another assigned manuscript involved a questionnaire study to "investigate the well-being of gays, lesbians and bisexuals … in Botswana, how this level of well-being could be promoted and whether their health care needs were met by health care professionals" (Ehlers, Zuyderduin, & Oosthuizen, 2001, p. 848). Homosexuality was—and continues to be—illegal in Botswana. The views that one Romanian trainee expressed in his/her paper typified the views expressed by other Russian and Romanian trainees over time. The trainee argued that "a violation of human rights is not an issue for health care providers" regardless of the nature of that violation and that "health care providers would be stigmatized" if they were to become concerned with human rights. Other trainees offered comments during class discussion of the paper; these comments were recorded verbatim in writing by one of the authors (SL). During discussion, one trainee from Russia argued that because the principle of justice means that there should be "equal treatment, equal risks, and equal benefits for all participants," the recognition of gays and lesbians as a vulnerable population needing special protections in research would "give them privileges that the majority population does not have." This trainee asserted that research should be designed "to attend to the needs of the majority." Another

Romanian trainee argued, "accommodating these minorities [in research] would be infringing on the rights of the majority." Yet another trainee from Russia declared, "In collectivistic post-Soviet culture, we see that no one should be treated in a special way as this would place these people higher than the majority group, 'us' versus 'them.'"

Recent scholarship emphasizes the contextual nature of the determination of vulnerability (Kipnis, 2003; Levine et al., 2004). Accordingly, depending on the nature of the research, individuals who may be vulnerable in the fulfillment of everyday activities as the result of a personal characteristic, such as the loss of a limb, may be no more or less vulnerable as a research participant than anyone else. The trainees introduced to this literature appeared to have significant difficulty applying this conceptualization in their country contexts. For example, one recent trainee from Russia suggested that someone could not be viewed as being more vulnerable in research than others regardless of personal characteristics and the focus of the research because "If we say that someone is vulnerable, it is like excluding them from the group."

We hypothesize that the views expressed by many trainees from Russia and Romania may be causally associated with several factors specific to their experiences in their home countries. These include political ideology, religious beliefs, social norms, and widespread prejudice against members of specific subpopulations.

Various factors argue in favor of a pedagogical intervention to increase sensitivity to and acceptance of the internationally accepted concepts of vulnerability and special protections in research. First, appreciation of the meaning and sources of vulnerability is foundational to the conduct of ethical research. Without this understanding, investigators may be unable to recognize the potential for exploitation and violation of rights in research, whether in their own research or in their review of others' research. If, taking an extreme view, individuals are only assigned value as a result of the contribution they are able to make to narrow conceptions of public welfare, the meaning of "respect for persons" is substantially diminished and there is little reason to be overly concerned with processes such as obtaining informed consent.

Second, the ability to define, identify, and respond to vulnerability in the context of research constitutes one component of professionalism and integrity among scientists, whether engaged in biomedical, social science, or laboratory-based research. In this context, professionalism comprises not only a testable set of skills, but also an attitudinal competency (cf. Mahan, 2011).

Third, research is increasingly collaborative and international in nature. As an example, there has been increasing involvement of individuals in Russia as either researchers or participants. As of September 2009, 1.4% of the 29,740 clinical trials worldwide were being conducted in Russia, including 61 pediatric clinical trials (Lichterman, n.d.). In 2006, Russia initiated 151 international multicenter trials that recruited approximately 154,000 patients (Synergy Research Group, 2007). In the six-month period from January to June 2009, 242 new clinical trials were initiated in Russia, including 19 new pediatric trials. It has been estimated that approximately 5% of the Russian population participates in clinical trials. These clinical trials focus on various areas of medicine, including psychiatry, neurology, hematology, oncology, and cardiology, among others (Lichterman, n.d.). If those ostensibly trained in research ethics are unable to identify potentially vulnerable research participants, it is more likely that unethical research will be permitted to proceed.

Factors Potentially Contributing to the Nonrecognition of Vulnerability

POLITICAL IDEOLOGY SHAPING SOCIAL NORMS AND BELIEFS

The political ideology of a government may impact its citizens' understandings of conceptions of self, sense of personal security, required contributions to the state, and approaches to perceived difference and potential vulnerability. The political ideology of the government of the former Soviet Union illustrates well how this might occur.

The former Soviet republic has been characterized as "one of the largest and most complex multinational states in the world" (Lapidus, 1984b, p. 98). The country comprised approximately 100 identified nationalities, of which 22 had populations of more than one million (Lapidus, 1984a). National identity was determined by birth, inscribed in passports for use within the USSR, and institutionalized physically through the creation of ethno-territorial units (Zaslovsky, 1992). Accordingly, nationality became the basis for the Soviet Union's policy of double assimilation: the assimilation of diverse cultural groups into government-defined nationality categories and the assimilation of these categories into the Soviet state (Hirsch, 2000, p. 213).

During the Khrushchev era, efforts were made to promote rapid assimilation of non-Russian nationalities (Low, 1963). Soviet leaders professed the state to be "a unitary body whose underlying principle, proletariat internationalism, allowed no room for national differences and aspirations" (Dunlop, 1983). At the same time

the Soviet central government devised a system of social stratification by dividing the population into functional groups and redistributing wealth and privilege to those who were deemed to be critical to the maintenance of the federation's stability (Zaslovsky, 1992, p. 106).

Preferential treatment by the government of minorities in education and politics within their territories was utilitarian, designed to solidify loyalty to the central government and reduce the likelihood that ambitious minorities would foment dissent and organize separatist movements (Zaslovsky, 1992, p. 102). Rather than being perceived as vulnerable due to their difference, these minorities were instead regarded as privileged, or special, akin to trainees' initial belief that the receipt of special protections within the context of research rendered those individuals inappropriately privileged or special in comparison with others.

Assimilation policy was furthered in pervasive propaganda, and accompanied by corrupt practice in which a few benefitted but most did not. The state was able to demand loyalty and punish its apparent absence because the state held a monopoly on all needed services, including employment, education, and housing (Casier, 1999, p. 48). Dissenting views were often met with swift punishment (Zaslovsky, 1992, p. 103), so fear of expressing such views publicly was the norm. Despite the succession of one government administration to the next, differentness today is similarly subject to drastic repercussion, including swift and violent government response. Human rights activists, homosexuals, and immigrants, for example, face ongoing government indifference to other citizens' overt discrimination and physical assault, as well as active government repression and abuse (Amnesty International, 2012; Amnesty International USA, 2012).

The ideology that prevailed during Romania's Communist era similarly gave rise not only to intolerance of difference, but the eradication of civil society and the suppression of empathic response. All of the Romanian trainees were products of the education system that was instituted during this era. Nicolae Ceauşescu's regime spanned a 23-year period from his 1965 assumption of the presidency to his violent overthrow in 1989. His almost-absolute control was fostered and maintained through the arbitrary and often violent actions of the Romanian State Security Police (*Securitate*) and the widespread surveillance of Romania's populace to suppress all internal dissent. This surveillance was often effectuated through the coerced recruitment of family members and neighbors as informants for the benefit of the state. As a consequence, an atmosphere of extreme distrust surrounded most personal and social

relationships, rendering cooperation difficult at best (Deletant, 1995). (Several of the Russian trainees reported similar pressures experienced by their families and friends under the previous Soviet regimes to inform the KGB about their neighbors' families in order to avoid difficulties themselves.) The ability of individuals to forge cooperative alliances was reduced even further through Ceauşescu's abolition of nongovernmental organizations, resulting in the eradication of Romanian civil society.

The deep intrusion of government into private life is demonstrated by the increasingly severe interventions around sex and procreation. Following World War II, the government and communist party extended the traditional patriarchal attitudes that had prevailed in more rural areas (Gilberg, 1979). These newly fashioned measures included: the prosecution and conviction of unmarried women as prostitutes for any participation in sex outside of marriage (Harsanyi, 1993); the inculcation of the belief that sex without procreation as its objective was both immoral and a cause of insanity (David & Baban, 1996); a progressive increase of restrictions in the availability of birth control and abortion (Ceauşescu, 1966, 1985), cessation of the importation of contraceptives (David & Wright, 1971), and the eventual banning of birth control altogether (Hord et al., 1991); imposition of disincentives on childless couples and unmarried adults; lengthening of the divorce process; imposition of monthly birth quotas on physicians and other employees; conduct of investigations by the Securitate of alleged abortions; posting of agents in all maternity wards and obstetrical-gynecological clinics; and imposition of prison terms on physicians who violated the abortion restrictions (David, 1990a,b). Ceauşescu declared "the fetus [to be] the socialist property of the whole society. Giving birth is a patriotic duty. Those who refuse to have children are deserters, escaping the law of natural continuity" (Ceauşescu, 1986, pp. 217–218). The abuse and neglect of unwanted children abandoned to orphanages as a result of these policies has been well documented (Ames & Carter, 1992; Johnson & Groze, 1993; McMullan & Fisher, 1992). The Ceauşescu rule may have ultimately led to a ubiquitous sense of vulnerability and insecurity, which may have made it difficult to accept the notion that vulnerability is relative, existing along a spectrum of increased or decreased power.

In both Russia and Romania, the governments under which trainees came of age held sway over the church, an institution to which one might ordinarily look for moral teachings and examples of compassion and charity that could be applied in one's own life. Historical evidence suggests that this was not the case. Under the earlier Stalin regime in the former Soviet Union,

Orthodox clergy were targets for persecution; evidence suggests that at least some of those who survived did so by collaborating with the infamous KGB security force, resulting in the torture and deaths of those they denounced (Davis, 1995). The persecution of Orthodox clergy continued through the Khrushchev era from 1959 to 1964. It was alleged that not a single candidate for a high office in the Orthodox Church was able to move forward without the endorsement of the Communist Party and the KGB (Albats & Fitzpatrick, 1994). It was not until the 1990s that the Orthodox Church started to regain some independence from the state. In Romania, during the Ceauşescu regime, priests were known to collaborate with members of the Securitate, leading to the torture and deaths of parishioners who had confided in them (Anon., 2008; Bachman, 1989). One bishop acknowledged following the fall of the Ceauşescu regime "the church's prostitution with the Communist party" (Witte & Alexander, 2007, p. 313). Even now, in the face of austerity measures recently imposed on Romania's populace, the Orthodox Church has been criticized for "pocket[ing] all it can while leaving its mission to perform good works to the NGOs" (Anon., 2011).

SOCIAL NORMS

Beliefs are "not held in isolation, but [are] part of a system" (Glover, 1999, p. 265). Accordingly, social norms that prevailed in the former Soviet Union and Communist-controlled Romania continue to prevail to some degree today. It is conceivable that these environments played a large role in the development of trainees' initial understandings of and attitudes toward the concept of vulnerability and those groups that are widely believed to be vulnerable in research.

In today's Russia, there exists considerable dissonance between Russia's stated legal standard and praxis. Although Russian law recognizes specified groups as vulnerable in the context of clinical trial—pregnant women, orphans, and military personnel (EFCGP, 2010)—public pronouncements by government officials suggest that there continues to be a lack of understanding regarding the concept of vulnerable populations and the need for special protections. For example, Vladimir Zhrinovsky, the deputy chairman of the Russian Parliament, opined in 2009 that "Those condemned to capital punishment according to their wishes might be sent to mines or subjected to clinical trials. The latter would be useful for everyone: it would give them [the criminals] 5–6 additional years of life and would bring us new drugs" (Zhrinovsky, 2009). Not only are these pronouncements consistent with the views of many of the Russian trainees, but it is possible that such

statements are reflections of beliefs that are prevalent to some degree within the larger population.

In Romania, as noted above, children were often not perceived as vulnerable and instead were viewed as property, more precisely the property of the state with thousands turned over to state institutions. Current estimates suggest that currently 40% of Romania's children are subject to parental abuse (Williamson, 2002), which may partly explain Romania's large and growing numbers of runaway children (Gamble, 2009; United Nations Committee on the Rights of the Child, 1994). A frequently repeated Romanian saying aptly reflects the status of children in the eyes of many parents: "Eu te-am facut, eu te omor," which means, "I made you, I will kill you."

The Pedagogical Intervention

DEVELOPMENT OF THE INTERVENTION

Trainees in the program made a commitment to further education in the field of research ethics; therefore, it was assumed that they wanted to examine how to act in an ethical manner. Based on the program's experience with trainees and knowledge of their political and social backgrounds, lapses in the identification of vulnerability of the kind described above were generally predictable. These observations argued in favor of a pedagogical intervention, rather than criticism. Accordingly, it was hypothesized that an effective intervention required the development of (1) emotional self-awareness, which includes an ability to assess one's own responses and behaviors, (2) social awareness, including the ability to understand others' perspectives and an understanding of political forces that may be at play in specific situations (cf. Martin 2011), and (3) adequate judgment skills (cf. Lucey, 2011). Because the identification of vulnerability in research and the formulation of appropriate protections is a complex competency, it was further hypothesized that the promotion of this competency would follow a developmental curve. The intervention comprised content that is standard in the teaching of research ethics. Emphasis was given to the political and personal factors that might have contributed to the abuse of research subjects. An innovation was the introduction of personal diaries as described more fully below.

Examples of research widely recognized for their abuse of research subjects were examined in course work on health research ethics and a seminar designed solely for the Fogarty trainees. Discussions focused on the research methodology utilized; risks and benefits to research subjects; the extent to which subjects were informed;

historical and political contexts of the research; and the attitudes of the investigators towards the research subjects, their own role in society, and their retrospective understandings of the ethics of their research, to the extent that information was available. Trainees were asked to consider the researchers' situation, what pressures they faced professionally and personally, and the range of responses possible or probable. Such self-examination, it was hypothesized, might assist trainees to recognize and overcome conscious biases and perhaps recognize unconscious prejudices. Discussion also focused on possible motivations of errant researchers for their conduct as well as biases and assumptions that likely served as factors in their actions. Because each study was explored in the context in which it occurred, trainees were able to explore the role that political forces played in the initiation, continuation, and termination of these studies and the kinds of political pressures confronted as scientists or ethicists.

Trainees were also required to analyze a study of their choosing in the same manner. Because of the breadth and depth of the required analysis, trainees worked in groups with locally based U.S. students enrolled in the same course. This experience exposed the trainees to widely divergent views. Each group was required to submit a written paper and a PowerPoint presentation used to present their analysis orally to the class. This increased the exposure of trainees to differing views.

More recently, trainees were required to maintain a journal to record initial reactions, challenges experienced, and changes in perspectives related to the program and more broadly. Journal content is not shared with anyone other than the principal investigator of the program (SL) unless the trainee chooses to do so. These journals serve as a guide to help the trainee understand his or her evolving understandings and how others in his or her home country might respond to new ideas that the trainee introduces. The journal content provides valuable information in addition to individual discussions that enables the principal investigator to better understand the challenges and adjustments that trainees must face. As an example, one trainee confided that he/she had never understood prejudice against Black people. However, when the trainee came to the United States and saw a Black person for the first time, the trainee immediately felt a sense of fear. Discussions and the trainee's journal writing focused on what gave rise to that sense of fear, the range of possible responses when feeling fear, how such feelings might interfere with one's treatment of others, and how the trainee wished to respond in such situations.

Learning styles and the range of emotional responses vary across individuals. Some trainees were unable or unwilling to explore the emotional aspects of abuse of vulnerability in research participants through case studies or through journal keeping. For them, a focus on international norms for the conduct of research and the relationship between these norms and human rights provided another means of exploring this issue. Course work and class discussion on international standards examined the historical and political contexts in which they were developed. This material was relied on to address potentially difficult personal situations that trainees might encounter on their return home when seeking to effectuate change in attitudes and systems in order to promote these standards.

ASSESSMENT OF THE INTERVENTION

Comments from a number of trainees confirm that these class discussions and self-reflection promoted through the use of journals facilitated the development of an appreciation of vulnerability in others and ethical responses to it. As an example, one trainee from Russia later wrote:

> I believe that the "civil society" is slowly emerging in Russia. It has only passed 20 years since the complete mess that our country turned into after the collapse of the Soviet Union. That's why the society is only at the early stage of developing human rights awareness, and the value of informing people in medical care and research settings is only emerging here. It takes time to change the mentality of people. If we read books about US in the '30s, there was no official recognition of the value of human rights and treating every person with respect. It took 50–80 years in the US for such a type of mentality to emerge. My guess is that it'll take a half of a century in Russia too. More and more people with time will bring a new type of thinking here.

Another trainee from Russia explained why she believed this aspect of the training is necessary:

> To make real change, there has to be change on the cognitive level and the affective level before there is real change in behavior. I strongly believe that empathy must be taught. Otherwise, students don't know. I believe it must be done. In Soviet times values were about communism, but after Soviet times other values must fill in. It is an important part. When you get a Ph.D. in Russia, the Ph.D. stands for theory and methods and values, it is a social contract with other people. It is the teacher's

responsibility to teach values. After you finish your education, there is no one to teach you that. It is teacher's responsibility.

She explained the impact that the training had had on her:

> Russian/Soviet academic tradition requires from the scientist objectivity and dictates that the scientist should be impartial meaning he/she has no personal connection with the subject of the study. Otherwise, scientific results won't be "pure." For a Russian trainee, after some training there would be a contradiction between this requirement to distance from subjects and the new learnt ethical obligation to care … so I think of "third culture" place theory, that I am like between these two ideas and can understand them both.

One trainee from Romania wrote in response to the same question:

> The source of perception of vulnerability [should] be easily understood, which is obviously extremely important … We must examine our own biases and assumptions … which I think summarizes it all.

Another Romanian trainee commented,

> I believe that since Romania has joined the EU, there is a lot of progress in human rights protection. Yet, much has to be done to protect to a higher degree the rights of minorities, disabled and mentally ill. Stigma and lack of public awareness campaigns, insufficient public debate and lack of ethical committees in the medical facilities are among the main impediments.

Discussion

Experience gained with Russian and Romanian research ethics trainees over an 11-year period indicates that an understanding of vulnerability in the context of research cannot be assumed to be universal. This awareness was gained as a result of unguarded trainee statements in their written papers and in oral class discussions rather than by the findings of a systematic study of the concept among the trainees. As a result, we suggest that it cannot be assumed that trainee conceptions of vulnerability are uniform (or those of any student for that matter). To address this meaningfully, pedagogical intervention must go beyond a discussion of the enumerated groups of individuals traditionally designated as vulnerable in research. Rather, teaching must encompass both cognitive

elements designed to encourage an understanding of the intellectual and moral reasons underlying the development of international standards for the conduct of human research and exercises to facilitate trainees' development of self-awareness and appreciation of vulnerability in others.

In addition, to address issues of vulnerability and encourage increased self-awareness among the trainees, the faculty must be willing to serve as role models in the process. Faculty demeanor and responses to questions and comments must indicate the willingness to engage continuously in an examination of faculty and trainee biases and assumptions about populations, cultures, and science.

Romania's newly introduced curricular materials related to Roma populations in its bioethics and medical training programs (Astărăstoae et al., 2011) and student responses to these materials lend some credence to this recommended approach. Several former Romanian trainees were instrumental in the development of these materials and now participate in teaching this curriculum. Students in Romania who were presented on a cognitive level as an intellectual exercise with this new curricular material reported being bored by it. They believed it to have no relevance to them or to their professional obligations or encounters. In contrast, the trainees' students who were challenged to examine their experiences and values and who were provided with opportunities to exchange perspectives with self-identified Roma individuals reported new understandings of Roma culture, of themselves, and of how they might better communicate with Roma individuals in both clinical and research settings. Similarly, Russian scholars have been engaged in formulating integrated approaches for the development of intercultural understandings (Lebedeva & Tatarko, 2012).

Recent scholarship on the concept of emotional intelligence suggests that integration of cognitive and emotional components in a curriculum may be of value. Whether the various elements that comprise emotional intelligence—empathy, self-awareness, social skill, and self-regulation—are capabilities that can be developed or are innate traits that lie outside the taxonomy of cognitive ability continues to be disputed (Goleman, 1998; Petrides & Furnham, 2000; Petrides, Pita, & Kokkinaki, 2007). Nevertheless, emotion and affect have been consistently found to play a critical role in moral decision-making (Berkowitz, 1985; Nucci, 1989; Turiel, 1983, 1998; Zeidler & Schafer, 1984; Zeidler et al., 2002). Indeed, it has been noted that

teaching in bioethics contexts needs to use pedagogies that engage students in participating and emergent activities … to enable the development of multiple dimensions of knowledge. These dimensions include the scientific content as well as the personal, social, and emotional aspects associated with any bioethical issue" (Conner, 2008, p. 1).

Again, we do not suggest by the focus on Russian and Romanian trainees that their perspectives on vulnerability are either common to all individuals from these countries or that they are not held by trainees of other countries, including the United States. Indeed, it is likely that similar attitudes can be found everywhere, although the specific factors that give rise to them may differ. It is precisely because a lack of understanding or sympathy for vulnerability along a spectrum and as part of the human condition exists across societies and cultures that a pedagogical intervention is needed.

Finally, we must be mindful of the potential risks involved in the recommended process of self-examination. We often cannot know how individual trainees will respond to discussions of vulnerability, regardless of their country of origin; their emotional and cognitive responses are likely to vary as a function of their own histories of trauma, discrimination, and privilege. As educators, it is incumbent upon us to develop and maintain a safe environment in which these explorations can occur. Additionally, because we cannot predict what difficulties the trainees may encounter in their home countries as a result of their changed beliefs and/or behaviors, it is critical that we remain available to them for support.

Best Practices

The concepts of vulnerability and special protections for vulnerable research participants are foundational concepts in research ethics. However, whether and the extent to which individuals understand these concepts is likely shaped by a variety of factors in their countries, including political ideology, religious beliefs, social norms, and prejudice or discrimination against identifiable subgroups. Accordingly, it can be assumed that diverse understandings and levels of acceptance of these key concepts exist within any group of students or trainees.

Experience with a group of Russian and Romanian trainees in research ethics over a period of 11 years suggests that trainee understandings of these concepts and their responses to them must be addressed proactively. Our experience further suggests that increased understanding and integration of these concepts is best fostered through

the use of a multi-level, multi-component approach that encompasses cognitive components designed to familiarize trainees with the moral underpinnings of these concepts, exercises to increase trainees' self-awareness and foster empathy, and role modeling by faculty to demonstrate actual application of these concepts.

Acknowledgments

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Authors' Biographical Sketch

Sana Loue is a professor in the Department of Bioethics of Case Western Reserve University. She has directed the Fogarty-funded training program for 14 years. Her research interests include HIV risk and prevention, severe mental illness, family violence, research ethics, and forensic epidemiology. She was responsible for the recording of trainees' comments and the formulation of the pedagogical intervention described in the paper. She collaborated with Bebe Loff on the literature review and the drafting of the manuscript.

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