Helle Merete Nordentoft and Nanna Kappel

VULNERABLE PARTICIPANTS IN HEALTH RESEARCH: METHODOLOGICAL AND ETHICAL CHALLENGES

Ethical guidelines for conducting research are embedded in the Helsinki Declaration of 1964. We contend that these abstract and intentionally universal guidelines need to be appropriated for social and healthcare research, in which purpose and methods often deviate from medical research. The guidelines appear to be instrumental and over-simplistic representations of the often ‘messy’ realities surrounding the research process that is often guided by relational and local negotiations of ethical solutions. Vulnerable participants, for instance, challenge both professional and research ethics, leaving both professionals and researchers in ethical and moral dilemmas. In this article, we specifically focus on the methodological challenges of obtaining informed consent from drug users and terminally ill cancer patients in our PhD research. The question is how to illuminate the needs and problems of vulnerable patients and — at the same time — respect their integrity without exposing them unnecessarily. The article illuminates the interactional construction of roles and relationships and how they affect the contextual construction of vulnerability. In this respect, we demonstrate that both patients and researchers are at risk of being vulnerable. In conclusion, we outline and advocate for a more empirically informed ethics in research with potentially vulnerable participants.

Keywords vulnerable participants; ethics; informed consent; health research

Introduction

Obtaining informed consent is an inevitable demand and appears to be a simple procedure in the research process. According to the Helsinki Declaration of 1964, research participants are informed of the aims, methods, potential risks and benefits of the research project and ‘the discomfort it may entail’ (World Medical Association [WMA], § 24).

However, we experienced this procedure to be a complicated and challenging process in our PhD research on drug users and terminally ill cancer patients. We found that:
The tick-box approach to ensuring compliance in ethical standards surrounding the eliciting of informed consent is an oversimplistic representation of the often ‘messy’ realities surrounding the research process.

(Sin, 2005, p. 289)

Several researchers – particularly researchers using ethnographic methods – agree with Sin (2005) in terms of the complexity of working with and obtaining informed consent in social research (Burgess, 2007; Lawton, 2001; Parker, 2007; Miller & Boulton, 2007; Oeye et al., 2007; Aldridge & Charles, 2008). These researchers assert that the differences between medical and social research call for a reconstruction of the ethical guidelines into what is termed ‘a more empirically informed ethics’ (Parker, 2007, p. 2248). This article can be seen as a contribution to this reconstruction in that it explores the ways in which vulnerability can be assessed empirically and how the conception of vulnerability may affect the negotiations of informed consent in the context of our ethnographically inspired studies. In the article, we discuss case studies from the ‘messy’ reality in our research, in which vulnerable participants often challenge ethical standards of both researchers and professionals. Nordentoft (2007) has explored changes in how an interdisciplinary palliative team conducts emotion work at their weekly conferences before and after clinical supervision (CS). Her dissertation is based on 10 months of fieldwork. Nordentoft defines emotion work as talking about emotions, non-verbal display of emotions and the interactive work leading up to or following emotion talk or display as emotion work. This interactive work can, for instance, be performed through the telling of stories, the use of metaphors or the construction of reformulations. Kappel (2009) investigates the interaction between nurses and hospitalised patients who use illicit drugs. Her data derive from fieldwork over a 12-month period. This article specifically focuses on the methodological challenges of obtaining informed consent. The question is how you can illuminate the needs and problems of vulnerable patients and – at the same time – respect their integrity without exposing them unnecessarily.

In the first part of the article, we present two case studies from our PhD research followed by an analysis of their methodological implications for obtaining informed consent. Here, we discuss the concept of vulnerability and the ways in which the conception of vulnerability may affect the research process. The next section expands on this challenge by drawing on our empirical research. We discuss the ways in which participants’ roles and relationships in field research may affect the negotiation of vulnerability and informed consent. In conclusion, we summarize the main points of the article and make some recommendations for future research.

Two case studies

Most patients were happy to talk to us when we offered them time to listen to their story. De Raeve (1994, p. 303) describes this situation as ‘a godsend for anyone who happens to feel lonely or worried’. Iben, a patient in Nordentoft’s study, is an example of such a patient. Iben was in her sixties, diagnosed with an incurable cancer and terminally ill. Moreover, she was a teacher and an intellectually sharp woman. She
displayed an interest in Nordentoft’s work on several occasions and asked more questions than any other patient. She compared Nordentoft’s project to some of the topics she had taught as a teacher and initiated discussions about the perspectives of Nordentoft’s study. These conversations appeared to revive Iben’s professional background, including her personal dignity as a teacher, and helped her to forget her terminal condition and patient role for awhile. However, Iben was a challenge to the routines of the palliative staff in that she was demanding and critical of their care. In an interview, Iben told Nordentoft that she was very satisfied with the palliative ward in the beginning of her admission to the hospital. The positive atmosphere and head physician’s behaviour, including his way of pulling a joke once every now and then, gave her a sense of hope. After awhile, when she realized that she would not get well again, she got upset with the head physician because she felt that he had let her down somehow by giving her a sense of hope for recovery in his approach to her.

The palliative team categorized Iben as a difficult patient because of her critical behaviour (Li & Arber, 2006). In her relationship with the researcher, Iben gained a more independent, dignified and personal position than she had as a terminally ill patient, and was able to provide information that the researcher was interested in. Their relationship possibly enhanced Iben’s hope work and mental strength in keeping the hostile future at a certain distance – perhaps because she was active and in a ‘giving’ position and not only in a passive and submissive ‘receiving position’ as a patient. The concept of ‘hope’ from the study of Peräkyla argues that conversation at hospitals is important in constructing this hopefulness in terms of ‘just feeling better’ or ‘getting better’ (Peräkylä, 1991).

Several participants in Kappel’s study were also categorized as being difficult and demanding. They did not adapt to several of the daily routines in the ward; they could be messy, noisy and were non-compliant. It was unusual that someone took an interest in them, such as Kappel did in her study. In this respect, qualitative research can be said to give a voice to groups that are normally silent and marginalized (Dickson-Swift et al., 2008). Bente, a patient in Kappel’s study, belongs to this group. Bente was hospitalized due to malnutrition and a lung infection. Bente used illicit drugs; she was in her late thirties and was HIV positive. When Kappel approached her bed, she tried to inform Bente about the project and to obtain informed consent, and she saw that Bente was asleep. Kappel woke her up, but Bente had difficulty in staying awake and appeared to be sedated. Bente agreed to participate in the study by murmuring ‘yes’, but Kappel was not convinced about her consent and considered whether it was ethical to use these data in the study. Suddenly, Bente asked Kappel if it was a work day and when Kappel answered ‘yes it is’, she jumped out of bed in order to get some money from the bank. The following day Kappel repeated her request for informed consent and once again Bente agreed to participate.

Vulnerability, fieldwork relationships and informed consent

During fieldwork Kappel – like Nordentoft – experienced that her participants appreciated that someone took the time to listen to their story, gave them a voice and did not judge them beforehand. Several participants demonstrated their appreciation and willingness by telling Kappel that she was welcome back any time. Some even invited her to visit them after they had been discharged from the hospital.
Listening as researchers do can be seen as being similar to listening as a therapist or counsellor, apart from the fact that the researcher interprets what is being said. For that reason, both Nordentoft and Kappel experienced the role confusion De Raeve (1994) writes about. As described by other researchers, we got closer to some patients than others (Cannon, 1989; Allen, 2004). Close relationships with participants may result in staff and patients forgetting that you are in fact a researcher and obliged to look at events as possible data. This situation could lead to participants giving informed consent to and sharing confidential issues which are not meant for research purposes (Lawton, 2001). The process of obtaining informed consent should therefore be an ongoing process that needs to be repeated several times during a study — as the case story with Bente from Kappel’s study illustrates (Katz & Fox, 2004).

De Raeve (1994) is quite radical in her line of thinking because she questions whether it is at all ethical to conduct research in sensitive settings such as palliative wards. In addition, she asks if dying patients should ever be subjects for a scientific study. She is critical of the notion that the anticipated research outcomes are ‘undeniably good’ and questions the extent of the moral scrutiny which is practised. In this respect, De Raeve claims that there has historically tended to be a view that it is okay to perform research on the most vulnerable and disadvantaged people in society such as dying patients or drug abusers. Nevertheless, she frequently thinks that these research subjects in fact become a ‘means to an end’. Hereby, she says that it is ‘the completion of the research not the care of the individual’ which seems to be the researcher’s primary motivation. She also questions whether the free will of vulnerable groups is compromised because of their dependency and illness. In our research projects, we have given this issue careful consideration and excluded several categories of vulnerable patients in a dialogue with staff and fellow researchers. This means that patients with double diagnoses — physical/mental health diagnoses which potentially make them psychotic or suicidal, or patients who have visibly and physically deteriorated — have been excluded from our studies. None of the patients we have included have been unable to give us informed consent — some have done so over time — as described in the situation with Bente — others right away — as in the situation with Iben. Furthermore, there have been organizational restrictions in the sense that it is particularly difficult to obtain access to carry out research on vulnerable groups in and outside of hospitals in Denmark.

De Raeve’s opinion, however, collides with another view in which vulnerable groups, as exemplified by Bente from Kappel’s study, are often considered to be stigmatized and left out of research (Aldridge & Charles, 2008). For example, Raudonis (1992) asserts that there is a fine line between protecting vulnerable research subjects and making paternalistic decisions ‘supposedly in the patient’s best interests’ (Raudonis, 1992, p. 242). Ironically, the vulnerable groups most in need of attention and improvement in their condition may be the groups that are most frequently left out of qualitative research, possibly because the research process becomes ‘too messy’ (Sin, 2005, p. 289).

Still, patients with a poor prognosis may find some sort of comfort in being able to do some good and help others when they themselves are relying on help from others. Participating in a research project can be seen as a way of preserving one’s identity and autonomy and leaving some personal legacy behind (Raudonis, 1992). In this regard, participants similar to Iben in both our studies may have acquired a voice from being interviewed and observed.
Our research, however, reveals that vulnerable patients are often critical of and challenge the professional care they are receiving. Therefore, close relationships between vulnerable participants and researchers can be a risk to good relationships between staff members and researchers. Moreover, Kappel and Nordentoft depended on a good and trusting relationship with staff to access vulnerable participants. For this reason, Nordentoft decided not to visit Iben alone, but only together with other team members. This decision was not straightforward because Iben was apparently lonely and did not talk to anybody about her terminal condition. Several times, Nordentoft felt a moral obligation to go and talk to her. Even so, she did not visit Iben alone — after all she was a researcher, not a nurse or even a friend!

The cases of Bente and Iben reveal the complex nature of relationships that evolve in a field study. From this standpoint, informed consent can be seen as a concept which seeks to further ‘the appropriate relationship between researcher and research participant’ (Miller & Boulton, 2007, p. 2199). Informed consent emphasizes respect for the participants’ autonomy — ‘... that is participants right to self-determination and privacy’ (Raudonis, 1992, p. 241). This right encapsulates the participants’ choice in making decisions about who they talk to and tell their experiences, thoughts and feelings to. ‘Normal adults’ are seen as being capable of having ‘this appropriate relationship’, as well as making a decision whether or not to participate in a research project. Yet, as Sin (2005) points out:

> the assumptions behind what constitutes the ability to provide valid informed consent are clearly underlain by complex ideologies and social constructions of what ‘normal’, ‘competent’ and ‘informed consent’ constitute. These categories are often objectified despite the fact that they are not necessarily as unambiguous as they may first appear.

(Sin, 2005, p. 280)

Vulnerable individuals represent a broad and vaguely defined group of people. In fact, most participants in healthcare contexts can be said to be vulnerable to the extent that their ability to give informed consent may be affected by physical, mental or emotional responses to their situation. Silva (1995) asserts that vulnerable individuals often experience:

> diminished autonomy due to physiological/psychological factors or status inequalities. Examples of such persons are pregnant women; children; persons with mental retardation; mental disabilities or physical handicaps; persons in prisons; elderly persons; students and employees.

(Silva, 1995, p. 15)

These conditions imply a deficiency in their ability to make personal decisions and to understand the consequences of their decisions. These groups are likely to experience harm and must be protected by the special safeguard of ethical guidelines (Moore & Miller, 1999, p. 1034).

Our theoretical position implies that all expressions, including vulnerability, are seen as being local and time-bound, depending on the concrete situation the expression is a part
of, this notion is reflected in the concept of ‘indexicality’, thereby pointing to the uniqueness of an activity. Both of our PhD projects operate within a micro-sociological framework inspired by ethnomethodology (EM) and symbolic interactionism. This framework avoids theorized accounts and generalizations in order not to obscure local orders. Garfinkel argues that a sociology which is based on accounts or concepts blurs ‘the fundamental role of enacted practices in the constitution of social phenomena’ (Rawls, 2002, p. 21). The studies are therefore based on an inductive ethnographic approach. Rather than asking ‘How do participants see things?’ we ask ‘How do they do things?’ in anticipation of catching the ‘lived order’ of the settings and how participants orient to and conceive vulnerability (Garfinkel, 1967; Rawls, 2002). In other words, we have been looking out for ‘emic’ descriptions and meanings in our studies that provide us with ‘an internal view, with criteria chosen from within the system’ (Pike, 1967, p. 38) and how the processes of defining vulnerability, deviant behaviour, stigmatizing processes, and inclusion and exclusion operate (Goffman, 1963; Becker, 1966).

In wanting to study the ‘local order’ of the setting, an ethnometodological perspective is, however, confronted with a genuine methodological problem: how can something invisible such as the ‘local order’ be studied? Members of a given society have a practical more than a theoretical interest in their constitutive work. Consequently, they take common-sense understandings for granted as a resource they utilize in their daily lives. Inspired by one of the methodological strategies of EM we, therefore, conduct close studies of sense-making situations in which the sense making has been especially noticeable in order to direct a focus at the ordinary. Specifically, this means that we have included patients such as Bente and Iben for a closer analytic study because they have been challenging the routines and competences of the staff and, therefore, become particularly vulnerable. Irrespective of the context, we argue that some subjects, such as the research participants in our studies, may be seen as being particularly vulnerable. For example, those who use drugs, such as Bente, may be more vulnerable to stigma and discrimination because of their drug use (Goffman, 1963). This speaks directly to status inequities. Terminally ill cancer patients such as Iben may experience another type of stigmatization and process of exclusion: social isolation because of the taboo that surrounds death and dying (Li & Arber, 2006). Iben’s case also illustrates that health professionals taking care of vulnerable populations are at risk of becoming vulnerable themselves because they are emotionally affected (Nordentoft, 2007, 2008) and/or because their professional identities are challenged by critical patients such as Iben.

To summarize vulnerability from our theoretical position cannot be conceived as a static and predefined condition, but must be seen as indexical and situational – a condition ‘that must be understood as a construct of the purpose and the context of the study’ (Oye et al., 2007: 2305). Moreover, it is important to be aware of and study research participants’ and researchers’ orientations to and definitions of vulnerability and normal behaviour, since these orientations are constitutive of the setting. This feature of social action is called ‘reflexivity’ (Garfinkel, 1967) and implies that:

what actors ‘know about’ or ‘make of’ and ‘do in’ a setting is also itself constitutive of the setting and informed by it.

(Pollner & Emerson, 2001, p. 121)
This situational and contextual complexity – some might also add relativity – could, however, be used as an argument for the establishment and continuation of an ethically controversial research project. Thus, it seems appropriate to elaborate on and improve the abstract and more general guidelines for the ways in which social research is conducted in sensitive settings with potentially vulnerable participants. Still, the situational sensitivity that inductive studies call for may be diminished if you make the guidelines more explicit with regard to when and how to carry out research in specific settings. Moreover, it is not always possible to predetermine who is vulnerable. Researchers’ conceptions of vulnerability have a significant impact on roles and relationships in field research between researchers and participants and the negotiation of informed consent. If the researcher has a dual identity as both a nurse and researcher, such as Nordentoft and Kappel have, the issue of vulnerability poses an even greater challenge in maintaining ethical research standards. To quote Lawton:

A particular responsibility is thus placed on a researcher to use the data collected during such a study in a very careful and selective manner. Ultimately, it is his or her discretion and integrity that are at stake.

(Lawton, 2001, p. 703)

The vulnerable researcher

De Raeve (1994) raises the issue of the seductiveness of this type of research, in which it can be difficult to pinpoint the role of the researcher, and that role confusion has profound implications for consent. Is the researcher a nurse, friend or visitor? Allen (2004) asserts that this dissonance between the responsibilities of a nurse and a researcher to particularly vulnerable groups reflects the ‘thorny issue of intervention’, as Gerrish illustrates below:

Throughout fieldwork I was acutely aware of the dissonance between my responsibilities as a nurse towards patients should I observe nursing practice that I considered detrimental to their well being, and the effect I would have on the research should I challenge a particular nurse’s practice.

(Gerrish, 1995, p. 90)

Gerrish’s comment reflects researchers’ moral responsibilities, which may be in conflict with the norms of the staff or social groups they are observing. This moral responsibility, and the nature of research into vulnerable groups, makes researchers potentially vulnerable. So when we talk about ‘vulnerable participants’, we not only mean research participants – (people who are subject and object of research) – we also conceive researchers to be potentially vulnerable themselves. Nonetheless, we want to emphasize that there are different degrees of participation and, therefore, vulnerability. In this respect, researchers have an advantage in that they are called to make decisions about inclusion or exclusion of data in their analyses and publications. This point, however, makes it important to support potentially vulnerable researchers in making sound judgements, as it pertains to treating data in an appropriate manner.
Like Cannon (1989) and Johnson and Clarke (2003), we find ethnographic research in stressful settings to be emotionally demanding. In the progression of our studies, our personal vulnerability seemed to increase for several reasons. First, our relationships with both staff and patients made it more imperative to act ethically and ‘do the right thing’ — that is, ensure that our research was not merely a ‘means to an end’. Second, the emotional nature of our research initiated intimate conversations with both staff and patients. Initially it was Nordentoft’s ambition to illuminate both the staff’s and patients’ perspectives in her study. She chose to wear a uniform and not her own clothes when she was in the ward, which was a choice based on methodological as well as practical factors. The medical staff outnumbered the other members of the interdisciplinary team, so wearing a white uniform downplayed her ‘difference’ when she observed interactions with patients. As such, the uniform indicated that she was a nurse — and not a researcher — and made it a challenge to maintain her distance to the nurses and stick to her researcher identity. This distance became increasingly difficult to maintain because she got along very well with the other nurses. As mentioned above, she also became close to Iben, who was one of the patients. It appeared to be impossible to remain on intimate terms with both parties without losing the trust of one of them. Nordentoft — so to speak — got ‘caught’ between the staff and patients. Because of this, she became vulnerable and unsure of her position in the field of study, until the situation was resolved as described above.

Being an insider (a nurse) and an outsider (a researcher) (Allen, 2004) at the same time, Kappel chose not to wear a white uniform to protect her neutrality. For patients and healthcare professionals, the white uniform symbolizes membership of the nursing profession, and it was important for Kappel to make a clear distinction between herself and this profession. Vulnerable groups such as drug users often distrust the system, and Kappel emphasized that she was neither a member of staff nor a part of the hospital system, she informed patients and staff members about her nursing background and her present position as a researcher. Perhaps for this reason, several patients shared details of their lives. Kappel’s vulnerability became increasingly evident during interviews and observations, in which she was often struck with a feeling of hopelessness and powerlessness, which possibly affected her judgement of her own and the participants’ mental state in the negotiations of informed consent.

To summarize, field research can be a lonely affair with no fellow researchers to discuss the moment by moment observations and decisions that constantly need to be made. We argue that the research process contributes to researchers’ vulnerability and judgements in the research setting by enforcing intimate relationships with both staff and patients.

Second thoughts in the analytic phase

When we looked at our data in the analytic phase, many interesting things appeared. Several times, we were unsure and had second thoughts as to whether to use the data or not. During the data collection process we had renegotiated informed consent with our participants; however, it was impossible to foresee some of the themes that arose in the analytic phase. Both studies illuminate how different roles and relationships in research affect data production and the process of negotiating informed consent. In addition, patients who are ill may die or, in the case of drug users, become impossible to reach.
after leaving the hospital because they live on the streets and there is no way to renegotiate the informed consent. These situations then leave the researcher with a particular ethical responsibility.

Concluding discussion

In this article we discuss some of the ethical concerns or quandaries experienced in our research. These situations help to illuminate the challenges in applying normative universal guidelines in health research. The purpose of the article has been to highlight ethical challenges and negotiations in obtaining informed consent from vulnerable participants, as is suggested by the Helsinki Declaration of 1964. According to Burgess (2007):

Abstract ethical reasoning in bioethics attempts to justify normative claims by referring to moral theory and arguments in an effort to defend conclusions with which all reasonable people must agree.

(Burgess, 2007, p. 2285)

However, as we have illustrated, ethical guidelines and notions of informed consent are normative claims that may be challenged in social and health research. The guidelines from medical research are based on the idea that the implications, including the psycho-social risks participants may experience in social research, can be predicted (Parker, 2007). The process of obtaining informed consent has to be handled differently in inductive studies based on participant observation. In this methodological approach, research questions and analyses are developed ‘in the context of emergent relationships of trust’ between researchers and participants in the study (Parker, 2007, p. 2252). Therefore, it ‘must involve developmental and creative processes incompatible with the concept of anticipatory consent’ (Parker, 2007, p. 2252).

Like Miller and Bell (2002), we suggest that informed consent should be considered as an ongoing process that is renegotiated during the research process. In this context, ethnographic consent is seen as a relational and sequential process, as opposed to a contractual agreement, and it lasts until the research is completed. Sometimes, consent could even be received retrospectively in order to catch the ‘lived order’ and not disturb the particular situation in which the data collection takes place. Moreover, we believe that the negotiable and developmental nature of informed consent should also apply where there is vulnerability. In this process it can be problematic and even paternalistic to exclude patients who may be particularly vulnerable without giving them a chance to speak for themselves.

In this article, we have proposed that it is not always possible to determine who is vulnerable prior to the study since this often emerges in the research process. The article has illuminated the interactional construction of roles and relationships and how they affect the contextual construction of vulnerability. In this respect, we have also demonstrated that not only patients, but also researchers are at risk of being vulnerable and that this vulnerability potentially affects their ethical judgements. So an awareness of the researcher’s vulnerability is important, although this awareness should be
balanced with a primary focus on the vulnerable people who are subjects and objects of research.

The question then is how will researchers know if someone, including themselves, is vulnerable? In the context of our studies we have found that patients such as Iben and Bente, who have made it difficult for staff members and researchers to live up to their professional ideals, have become vulnerable. The staff categorizes these patients as being ‘troubled’ and difficult (Li & Arber, 2006) and in the research process Bente and Iben potentially become exposed and perhaps compromised for research purposes. The cases we have presented in this paper illustrate our ethical considerations with regard to obtaining informed consent and of using the data in our projects. To qualify these considerations, we argue that researchers must constantly work with and improve their individual relational and reflective competencies. These competencies can be developed in both individual and group supervisory sessions. In fact, we suggest that research communities could organize a peer network in which researchers could seek advice and discuss ethical challenges in, for example, supervisory groups. If research was conceived as more of a collective activity, networks could support researchers in their studies and qualify not only the research, but also protect researchers and research participants to assist in making them less vulnerable (Dickson-Swift et al., 2008).

De Raeve raises an important issue when she criticizes the ‘undeniable good’ of research into a vulnerable group such as that of dying patients. The question is how is it possible to balance research interests and human considerations? In our opinion, there is no simple answer to this question, and there is no specific way to know if these interests have been balanced. Yet, one way to rephrase De Raeve’s question is to ask whether the research benefits the vulnerable group of patients who have been researched, and, if so, how and why? After our dissertation work, we have both revisited the wards where we collected our data, and there has been a number of changes which have altered the situation of these vulnerable patients in different ways for the better – i.e. organizationally, professionally and physically. The most significant change, however, is the way in which the illumination of the needs and frustrations of this group of patients has initiated a better understanding of their perspective and hopefully a more balanced, inclusive and respectful communication. Additionally, we hope that this article and other publications on the issue of vulnerability will improve both future care for and research into vulnerable participants.

In conclusion, there are no simple answers to the complex dilemma of wanting to catch ‘real’ reality on the one hand, while protecting the integrity of the participants on the other. The point we wish to make here is that healthcare research will never be able to catch the ‘lived order’ of people’s lives if informed consent must be obtained according to the Helsinki Declaration before including data in a study.

Note
1 In the paper we use first person plural when we describe common themes and arguments deriving from our research projects. When we specifically refer to our individual projects we use our names, Nordentoft or Kappel, and the third person singular.
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**Helle Merete Nordentoft**, RN, MA, PhD, is Associate Professor within the guidance research unit at the School of Education, University of Aarhus, Denmark. She researches interactions in healthcare settings from interactional theoretical approaches inspired by action research. **Address**: Institute for Education and pedagogy Aarhus University, Tuborgvej 164 2400 Copenhagen NV/DK. [email: HNJ@dpu.dk]

**Nanna Kappel**, PhD, is Senior Lecturer in Nursing within the School of Nursing and Midwifery at the Metropolitan University College in Copenhagen. She primarily teaches undergraduate students. She has developed a curriculum on drug abuse at the School of Nursing and more recently, a multidisciplinary curriculum on urban health for students from health professions. [email: naka@phmetropol.dk]