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Administrators' Perspectives on Ethical Issues in Long-Term Care Research

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ABSTRACT: ethical issues are a significant potential barrier to much-needed research in long-term care settings. LTC stakeholder perspectives are largely absent from the development of regulation and guidelines. Fifteen long-term care administrators were interviewed as part of a study of ethical issues in community-based, long-term care research. Established qualitative procedures for conducting content analysis were used to organize the data. Findings suggest that existing mechanisms to protect human subjects do not take into account important differences between academic and long-term care settings. The full potential of LTC research will not be realized until supportive processes to enhance human subjects protections are developed in a way that is reflective of the LTC environment.

KEY WORDS: Long-term care, informed consent

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There is a pressing need for research on how to best serve the growing number of older adults living in long-term care (LTC) settings such as assisted living and nursing facilities. However, the ethical issues raised by research in LTC settings are challenging and complicate efforts to conduct studies (Annas & Glantz, 1986; Boult et al., 2003; Cassel, 1985; Franzi & Weiler, 1992; Sachs, Rhymes, & Cassel, 1993). Ethical concerns stem from characteristics shared by most long-term care facilities, regardless of level of care. These include institutional or semi-institutional settings in which residents have varying degrees of dependency on paid caregivers to meet physical, social and emotional needs. Residents in these settings often have diminished decision-making capacity, rendering them particularly vulnerable to coercion and raising concerns about appropriate levels of research risk. This combination of characteristics contributes to challenges in evaluating whether proposed research is ethical. This paper describes the perspectives of LTC administrators regarding the value of research and the ethics of human subjects protections. Their views are important to understand because administrators provide oversight for all activities within their facilities including permitting researchers entrée to the setting.

Regulations and Guidelines for the Ethical Conduct of Research in LTC

Regulatory efforts to enhance human subjects protections in community-based research adds an additional layer of complexity. The Federalwide Assurance (FWA) process requires an institutional contract that must be signed by any organization "engaged" in research. LTC facilities that collaborate with researchers on federally funded research may be required to obtain an FWA. This involves designating a human subjects protection officer who will oversee the ethical conduct of the research, identifying a signatory official to legally agree to uphold federal regulations, and registration with the Office of Human Research Protections (Maloney, 2001; OHRP, 2003). Although facilities must agree to adhere to either the Belmont Report principles or Common Rule, no education in research ethics is required. FWAs can represent a barrier to the participation of community-based partners in much-needed research (Cartwright, Hickman, Bevan, & Shupert, 2004; Newgard & Lewis, 2002). In 2005, the Office for Human Research Protections issued guidance enabling the extension of an FWA to collaborating individual investigators or institutions through the Individual Investigator Agreement (IIA). This establishes an alternative to the FWA for institutions that do not routinely conduct human subjects research. While this mechanism lessens the logistical barriers for community-based research, the agreement is still contingent upon a collaborating individual who is willing to comply with the Common Rule or equivalent and "all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protections for human subjects" (OHRP, 2005, p. 4). Similar to the FWA, the IIA guidance makes no recommendations regarding research ethics education to facilitate adherence to the terms and spirit of the agreement.

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TABLE 1. Overview of Published Ethical Guidelines Specific to LTC Research.

Respect for Persons	Cassel[1]	Sachs[2]	AMDA[3]
Informed Consent			
Obtain informed consent in advance from residents or surrogates			X
Adapt consent process for LTC setting		X	
Assess decisional capacity of potential participants	X	X	X
Capacity assessment by qualified health care professionals who know person over time, includes functional abilities beyond mental status, involves family and MD	X		
Determination of lack of capacity balanced by evaluation of relative risks/potential benefits	X		
Periodic re-evaluation of decisional capacity			X
Identify proxy or surrogate for residents who lack capacity through resident or facility	X	X	X
For incapacitated residents in studies with greater than minimal risk but potential direct benefits, surrogate should seek court-appointed guardianship for consent to research	X		
Do not permit research with incapacitated residents with significant risk and no benefit	X		
Respect resident dissent/refusal to participate even if enrolled by proxy		X	X
Instruct proxy in criteria for decision to enroll (substituted judgment/best interest standards)		X	
Right to consent or revoke consent at any time (participant or proxy)			X
Encourage use of research advance directives		X	
Ask resident how clinically important information should be handled in advance or as arises	X	X	
Provide instruction for staff, residents, and family regarding confidentiality	X		
Record Keeping and Management			
Data collection, storage, and retrieval designed to ensure confidentiality of participant		X	
Follow normal standards for handling of/access to data		X	
Informing participants of data handling/access policies		X	
Beneficence	**Cassel[1]**	**Sachs[2]**	**AMDA[3]**
Study Design			
Importance of well designed research; methodological rigor; worthwhile question		X	X
Reasonable risk to benefit ratio; minimizing risks/burdens and maximizing benefits		X	X
Research Review			
IRB with knowledge of LTC setting to review proposal	X		X
Initial approval by IRB before research begins	X	X	X
Initial review and approval by medical director, facility, or patient physician	X		X
On-going review by facility and IRB	X		X
Review by nursing home committee that can include resident, family member, staff	X	X	X
Higher standards for protection than for individuals without dementia/in community			X
Review committee should include broad representation of professionals and organizations	X		
Conflict of Interest			
Researcher vs. clinician role (e.g., methods to diminish conflict, dealing with clinical information disclosed to researcher, consent obtained by neutral individual)	X		
General caution to be aware of conflicts of interest (for staff, proxies, and investigators)		X	
Justice	**Cassel[1]**	**Sachs[2]**	**AMDA[3]**
Participant Selection and Recruitment			
Select participants with methodological rigor in mind	X		
Avoid exploitation of participants and use LTC residents only when directly relevant to their care (e.g., using residents as convenience sample; unreasonable payments/inducements)	X	X	
Avoid unnecessary exclusion of participants (e.g., with sensory impairments, dementia, etc)	X	X	X
Modify research methods to accommodate impaired participants		X	
Provide description of selection and recruitment procedures in proposals and reports		X	
Recognize participation in research provides benefits, not just burdens	X		
Payment or compensation must be modest to avoid coercion	X		
Quality of Care			
Quality of care supercedes research interests	X		
Careful selection of research contexts; ensure basic standards of good care are met at facility	X	X	

Note: Guideline categories derived from Sachs et al., 1993. [1]Cassel, 1988; [2]Sachs et al., 1993; [3]Boult et al., 2003.

Under the Common Rule, LTC residents are not specifically identified as a class of participants who warrant additional human subjects protections. Instead, federal law defers important decisions about human subjects protections to state laws and individual IRBs, often without clear guidance about how to apply regulations (Kapp, 2002). Data suggest that IRBs' lack of familiarity with LTC research can result in both inadequate and overly restrictive requirements (Cassell, 1988). Non-governmental strategies such as improved education and consensus guidelines have been recommended over further regulation to address ethical concerns in LTC research (Kapp, 2002). Three sets of guidelines have been proposed to address the challenging ethical issues that arise in the conduct of LTC research using input from investigators (Cassel, 1988), medical directors (Boult et al., 2003), and the literature (Sachs et al., 1993). Table 1 contains a summary of these guidelines organized by the principles of autonomy, beneficence, and justice articulated in the Belmont Report (National Commission, 1979). However, a review of these guidelines suggests they may not be sufficient. Many of the guidelines are vaguely written without specific strategies identified for their implementation and the feasibility of some of the specific recommendations is not clear. Others are reflective of existing federal regulations.

A key problem with existing regulatory mechanisms and proposed guidelines is that both were developed with no apparent involvement by LTC facility staff who are directly responsible for research in their facility. It is unclear whether it is realistic to expect LTC facilities to share in the responsibility for the ethical conduct of research in their facilities as is required by the FWA and IIA mechanisms. These expectations presume a certain level of knowledge on the part of facility staff regarding research and research ethics. Similarly, the utility of guidelines may be diminished if the implicit assumptions underlying guidelines are not shared by LTC partners.

This qualitative exploratory study was undertaken to examine the perspectives of LTC administrators with a range of research experiences to determine their ideas about the ethical conduct of research. This information is intended to inform the evaluation of guidelines and regulations regarding the participation of LTC facilities in research and enhance researchers' understanding of human subjects protections in the LTC setting.

Method

SETTING

This study was conducted in Oregon with administrators from nursing, assisted living, and residential care facilities. These settings vary in the level of care they provide, but share several key features, including the provision of assistance with instrumental activities of daily living such as medication management and housekeeping, as well as self-care (Wunderlich & Kohler, 2001).

SAMPLE

The sample consisted of 15 administrators of Oregon LTC facilities. Administrators were selected over other potential professionals because they can be found in all types of LTC settings, regardless of the level of care offered, and are responsible for overseeing all aspects of facility management. Administrators were identified using purposive sampling to identify participants with a range of prior experiences with research in their settings. To obtain data about their perspectives and experiences, the administrators were interviewed by telephone.

PROCEDURES

The OHSU Institutional Review Board reviewed and approved the study protocol prior to data collection. Personalized advance letters were sent to potential administrators to alert them to the upcoming call and provide basic information about the study (Dillman, 1978; Lavrakas, 1993). Administrators who did not return an opt-out postcard were contacted by telephone and invited to participate. A brief description of the study was provided and an interview appointment was scheduled with those who interested in further participation (Dillman, 1978; Lavrakas, 1993). Verbal consent was obtained prior to the start of the interview. Interviews lasted approximately 45 to 60 minutes. Audio recordings were transcribed verbatim and all personally identifying data were removed. The transcripts were reviewed and corrected by the interviewer.

DATA COLLECTION

A semi-structured interview guide was developed to obtain the following information from participating administrators: prior research experience, attitudes towards research, the potential risks and benefits of research, beliefs about resident consent to participate, and familiarity with internal and external research regulations. Descriptive data were requested from participants including their educational background, professional role, experiences with LTC research, and characteristics of their facility.

DATA ANALYSIS

Demographic and categorical data were entered into SPSS 13.0 for analysis using descriptive statistics. Transcribed interview data were entered into the QSR

NUD*IST Version 6.0 software program that facilitates processing and analyzing data. Established procedures (Sandelowski, 2000) for conducting qualitative content analysis were used to organize the data to make sense of the variety of perceptions and experiences. These included open coding, or descriptive labeling of words or phrases that inductively suggest key concepts, and constant comparative analysis as additional text data were examined to locate patterns of similar experiences or perceptions. Theoretical memos provided records of team members' thinking about the analysis.

A number of strategies maximized the reliability and validity of the analysis process (Brink, 1991; Guba & Lincoln, 1989). The investigators separately read and coded transcripts. Regular meetings provided a forum to discuss the coding, clarify inductive thinking about the data, debate differences in interpretations, and reach consensus. Minutes documented discussions and decisions related to the analysis, and supplemented coding notes and theoretical memos about the data. Throughout the analysis a Qualitative Research Advisor (H.M.Y.) reviewed and discussed samples of raw data and findings with the team. The qualitative findings are organized by the major themes reflective of attitudes towards research, ethical concerns, and the impact of regulations and guidelines on research decisions. Administrators are referred to using the letter "A" for administrator and an unlinked participant identification number.

Results

ADMINISTRATOR CHARACTERISTICS

A majority of the 15 administrators (80%) had a 4-year college degree or higher with a professional background in health care administration (73%). Most were women (73%) and all were Caucasian (100%). Just over half (53%) reported experience with research in their facilities, though these experiences varied from having one resident enrolled in an off-site study to intervention research involving staff and modifications to the physical environment.

The qualitative findings are presented to summarize major themes regarding attitudes towards research, ethical concerns, and impact of regulations and guidelines on research decisions.

ATTITUDES TOWARDS RESEARCH

Administrators' views regarding the value of research were mixed. A few expressed the belief that long-term care research is needed and beneficial. One administrator suggested that research is a way to confirm the success of industry changes. "We're finally getting some recognition for all the good work that's been done and good care that has occurred . . . long-term care environments can be positive experiences for people" (A55). Several commented that research is useful as a mental and social activity for residents: "It is something the resident would enjoy doing . . . they would get some bang out of their buck for it. Either one-on-one activity or . . . sharing their history" (A43). In contrast, others described research as "pretty boring most of the time" or did not feel findings could be used in their settings. One participant initially suggested that research on residents' eating habits might be helpful, but went on to discount this notion. "I mean, their meal times are . . . are pretty set, and they [residents] are pretty set. . . . I'm not sure change would help" (A41). Overall, research in the abstract was perceived as separate from and not necessarily relevant to practice.

ETHICAL CONCERNS

Potential Risks and Benefits of Research Participation for Residents. Two categories of risks were identified for residents: physical and psychological. *Physical* risks such as pain or death were typically mentioned in relation to clinical trials such as drug studies. Administrators were concerned about risks that have "something to do with treatments or medications, or a negative physical reaction" (A46). Others were concerned that residents would be physically harmed because of an inability to appropriately judge their own limitations or the situation. For example, both A46 and A52 were concerned that residents might go overboard or take on more than they could handle, over-exerting themselves during study participation.

Potential *psychological* risks to residents included emotional distress or discomfort, or a negative experience. As A43 stated, "I would want a positive outcome for everyone." This goal seemed to encompass both participating and nonparticipating residents, as a few administrators were worried that residents who were not involved in the study would feel left out: "that might really hurt their feelings or, you know . . . it may trigger depression" (A44). Administrators were less certain that a positive outcome was possible for residents with dementia who participate in research, expressing concern that these residents may become upset by research activities or researchers. A51 expressed concerns that residents with Alzheimer's "pick up on . . . so much on body language and so forth that sometimes it's the actions, not the words, that cause concerns." Many of the concerns about psychological risks were related to the belief that disruptions to residents' routines would

be harmful. Other risks identified were harm through the revelation of sensitive personal information: "My biggest area of concern would be if any emotional issues were stirred up. The older ones, 80 plus [years], you're going to find some emotional factors. They're a very, very guarded population . . . they have fears" (A43). Two administrators could not identify any potential risks to residents involved in research: "I guess I'm not sure what kind of studies you would do that would cause them risk" (A41).

Administrators identified an enhanced quality of life as a primary benefit from research participation for residents. Sometimes, these benefits were conceptualized as direct. A55 expressed a hope that residents would benefit by improved mobility or "an easier way to deal with their current chronic conditions." Similarly, A44 hoped that "they would be much more knowledgeable about their health conditions" after participating in a research study. Other, more indirect benefits included emotional gains from the altruism involved in participating in a study. "I would hope that they would gain a sense that they may still be able to benefit from any research that was done . . . and that they would feel good about being able to participate" (A51). A52 noted, "their whole lives and careers they've given to society . . . and a lot of times you reach a certain age where you feel like 'What am I contributing any more?'"

Potential Risks and Benefits for Facilities. Potential risks and benefits for the facility were specifically solicited and, overall, were more frequently identified in comparison to the potential risks and benefits to residents. The most frequently identified risk to facilities related to the use of staff time and energy to support the conduct of research at the expense of fulfilling their primary mission—resident care. Those with research experience were particularly sensitive to this issue. "I understand the reality of the pressure that research places upon my staff on an ongoing basis" (A63). She went on to share:

> The greatest lesson that we have learned is don't take on too many [studies] at one time. . . . There have been times that we will be participating in a research project or grant project and we have said, you know, the cup runneth over, the plate is too full, and we had to learn that the hard way. People [staff] were stressed out. People contracted migraine headaches. I think that tempers became shorter.

A65 expressed a common concern about the time pressures that arise from involving the facility in research: "It takes time to have research going on in your facility and to have someone who's going to oversee the scheduling and getting everything ready."

Other potential facility risks identified by administrators were legal liability and concerns about the facility's image. A55 reported concerns that "maybe researchers wouldn't reflect a true picture of your facility." Similarly, participants were worried about negative media exposure related to either study participation or unfavorable findings with the potential to damage the facilities reputation. A67 reported going to great lengths to ensure the community was aware of the research, for fear study-related renovations would be misunderstood. "So somebody didn't call [Adult Protective Services] and say 'You know, they're tearing down the building and they've got residents in it!'" Agreeing to participate in a research study was viewed as opening oneself to scrutiny by the outside world with the risk of being found deficient.

Research participation was also viewed as having numerous benefits for facilities. One direct benefit mentioned by most administrators was the acquisition of practical information to improve resident care. As A46 stated, "I would hope that we would learn new information . . . and help us meet the needs of our residents in a more complete fashion." A65 expressed the hope that "whatever the object of the research, we would be able to use those outcomes in a positive way for our residents and our staff to make us a better organization." Several administrators conceptualized this practical benefit as potentially improving staff training and the work environment. "[Participation] is helping us move forward because we have access to a variety of different resources for training, education, and ideas about how we can improve our facility . . ." (A65). Research was also viewed as beneficial to staff on a more personal level. "Many of the people who enter our field have pretty low self-esteem. They loved being listened to, having their opinion sought" (A50). Another potential benefit was public exposure for the facility. Administrators described involvement in research as a marketing asset because of what participation suggests about their organization. "From a business perspective, it's helpful for people to know that we do participate in these projects because we do care about the future and want to assist in making a better future for elders" (A63). Interestingly, an administrator who complained about their IRB experience indicated that this benefit caused a great deal of difficulty for the facility and study, as the IRB did not view this it as legitimate and questioned the facility's motivations for wanting their name on the study brochure (A67). Indirect benefits were more altruistic expressions reflecting a desire to improve the lives of older adults. "You want it to affect your campus, but ultimately, you want it to affect the general population of seniors that we work with" (A52).

Consent to Participate in Research. Most administrators believed that residents who lack capacity should be allowed to participate in research if consent is provided by a family member who is a legally authorized decision-maker such as a health care power of attorney. Legal guardians were mentioned by a few, though as A63 pointed out, guardians often do not have a long-standing relationship with residents on which to base such decisions. "Would this legal guardian know whether or not she would want to participate in research? No, she does not. So is that person ethically the right person to make that decision? . . . I have an ethical problem with that." This administrator went on to share that in a prior study, consent was provided by family members with no specific legal authorization. For residents with capacity, approximately a third of administrators thought that family members should be consulted regarding a residents' participation in a research study. "That's probably a good idea just, um, to ensure that even if the resident could make their own decision . . . it could be a sensitive subject . . . for the family member . . . and so if they are informed and also consent it probably does help protect everybody from any potential issue arising later" (A57). Concern was expressed that the content of a study (e.g., sexuality) might upset family members, whose opinions were perceived as equally important if not more important than the opinions of residents.

REGULATIONS

LTC Regulations. Multiple administrators described LTC as the most regulated industry, with requirements above and beyond regulations for "the disposal of nuclear waste" (A63). However, participants were generally not familiar with the specifics of how these regulations would impact the conduct of research in their facility. "We have state guidelines that say our residents can't be part of a research study unless we have to jump through a thousand hoops" reported one administrator (A68). Another tried in vain during the interview to locate specific state regulations online. HIPAA was the most frequently mentioned regulatory issue of relevance to the conduct of research.

> I think the only thing that we really have to be careful about is HIPAA because you're getting someone's specific record. But if you have permission from the resident, from the family, I think that's key . . . if you're following HIPAA and you've done all the right things, asked all the right people and got permission, there's probably no other person to go to (A52).

Research Regulations and Guidelines. When asked, the majority of administrators were completely unaware of the existence of federal regulations, IRBs, or guidelines regarding the conduct of research. "I really don't know anything about it . . . ," said A48, "That's your responsibility [laughs]." Generally, prior experience with research did not seem to correspond with a greater level of awareness of federal regulations. Only one administrator seemed quite knowledgeable about the IRB process, and this person had a frustrating experience with the local IRB that seemed driven by misunderstandings and assumptions about the LTC setting, concluding that "if research is going to be conducted in a setting that the Institutional Review Board is not familiar with, that maybe they need to make a site visit" (A67). Although published guidelines suggest review of research by a nursing home committee (Boult et al., 2003; Cassel, 1988; Sachs et al., 1993) none of the administrators interviewed reported the existence of such a group in their facility.

Discussion

Researchers, IRBs, and LTC facilities may all have the best interests of participants in mind, but their culture and context has a distinctly different focus and purpose which shapes their perspectives on how to achieve this goal during the conduct of a study. Findings suggest that LTC administrators are focused on resident care, employee relations, and meeting industry regulatory requirements with the goal of financial viability. LTC administrators do not necessarily value research or see it as a helpful tool for change, and this perspective may impact their willingness to participate with studies. This is a poor fit with researchers and academic institutions that are focused on the enhancing lives through the pursuit of knowledge while being mindful of regulatory requirements for research. Understanding the differences between the academic and LTC culture is critical in collaborative research in this setting (Decker & Adamek, 2004; Sachs et al., 1993). Participation in research is not a frequent experience for most long-term care facilities, so opinions are formed based on limited direct experience as well as general beliefs about research.

Administrators' views about risks and potential benefits are reflective of these differences. Two primary potential benefits of research were identified. Several administrators expressed the belief that research participation will be immediately and directly beneficial to residents, despite the reality that research is designed to test the efficacy of interventions of unknown value.

This belief appears to be driven by the *therapeutic misconception*. Research was also perceived as a resident activity, as has been previously reported (Decker & Adamek, 2004), which raises concerns about the potential for intentional or unintentional coercion (Cassel, 1988). Interestingly, LTC administrators tend to focus more on the potential risks and benefit to the facility over the residents. The perception of risk to the facility has been mentioned previously in the literature (Franzi & Weiler, 1992) and includes concerns about accusations of coercion or complicity on the part of facilities that allow researchers entrée into their organization, as well as concerns about the implications of a negative outcome. These perceived risks may influence the types of facilities that agree to participate in research, which in turn may impact the generalizability of findings (Cassel, 1988). Conversely, LTC facilities may view participation as an opportunity to enhance their image and/or increase occupancy, goals that are at odds with academic ideals and may be viewed as problematic by IRBs.

Another area of potential conflict is around resident autonomy. Although traditional notions of autonomy underscore the individual's right to make independent decisions about research participation, some administrators were equally concerned about ensuring family members were in agreement. In some instances, administrators reported they would allow families the right to overrule a resident's decision to participate in a study regardless of a resident's decisional capacity. While facilities might be motivated to avoid family concerns about participation, this stance might also exclude residents with full capacity who would elect to participate without the consent of family members. This perspective is in conflict with traditional notions of autonomy (National Commission, 1979) and may impact resident autonomy around research participation.

IMPLICATIONS FOR FEDERAL REGULATORY REQUIREMENTS AND GUIDELINES

LTC facilities are governed by a different set of regulations than academic research settings. Although researchers are advised to become familiar with the LTC setting, they should not assume administrators understand the academic setting. Most administrators in this study were completely unfamiliar with research regulations and were unaware that researchers have external oversight, regardless of the administrator's prior research experience. Although this lack of familiarity is not altogether unexpected, it does raise questions about requirements in both the FWA and IIA that collaborating partners sign a statement agreeing to uphold The Common Rule. The protection that these agreements presumably afford research institutions is built on the unsupported assumption that facilities have the same values and knowledge as researchers and likely provides a false sense of security to all involved. This approach seems to provide protection to the research institution at the expense of LTC partners by holding facilities accountable for the behavior of researchers in their facility. The findings raise questions about whether such mechanisms do anything to enhance human subjects protections in LTC research. Administrators did consistently identify HIPAA as important, one of the only regulations that intersects LTC institutions and academic health centers. However, research suggests that HIPAA forms are often confusing and may discourage participation, so caution should be used in assuming this commonality translates into less confusion (Breese, Rietmeijer, & Burman, 2007; Ness, 2007). Moreover, the intense focus on HIPAA may result in an overemphasis on confidentiality at the expense of other ethical issues.

Existing guidelines for LTC research (Boult et al., 2003; Cassel, 1988; Sachs et al., 1993) appear to have been designed without input from LTC administrators and staff. A review of Table 1 suggests only minimal relevance to the issues raised by administrators in this study. Findings suggest that some of the ideals outlined in existing guidelines are not uniformly followed, such as review by a nursing home committee or LTC expertise on IRBs, and highlight the need for evidence-based guidelines that identify information relevant to the LTC community (Cartwright & Hickman, 2007).

LIMITATIONS

Findings are limited by the small size of this sample. While the sampling strategy purposively included those with and without research experience, individuals without experience were understandably limited in their ability to give examples. The interview's focus on research in general rather than on a specific research protocol may have affected participants' responses. It is possible that interviewing around a specific protocol would have enabled participants to speak more conversantly about ethical issues in research. Additionally, most participants had health care administration backgrounds. Their views may not be representative of LTC providers (such as nurses) in general. Typically, though, it is the administrator who would be approving research participation and signing related paperwork such as an FWA or IIA based on their organizational role, so their perspectives are directly relevant to this topic. Finally, findings represent the views of administrators who agreed to participate in a

research study and thus may not be reflective of the views of all administrators.

CONCLUSION

IRBs are driven by existing federal regulatory requirements that community research partners conform to the norms of academia without any appreciation of the enormous culture gap between academic and "real world" environments. The findings of this study suggest that the current regulatory approach of mandating FWAs or IIAs is a one-sided solution that does not reflect the reality of LTC administrators' knowledge or primary regulatory and operational concerns. Optional guidelines are of unclear utility. Unfortunately, the full potential of LTC research will not be realized until supportive processes to enhance human subjects protections are developed in a way that is reflective of the LTC environment. It is clear that the growing population of residents in LTC settings will drive the need for knowledge to inform care. Therefore, it is in the interest of all parties that research opportunities are optimized.

Best Practices

Collaborative research between academic researchers and LTC facilities should include a thoughtful discussion with the administrator and possibly other staff about the research. This discussion should include who is conducting the research, the purpose of the study, what is expected of the community partner, what is expected of the research team, potential drawbacks to collaboration, and potential benefits to collaboration (Cartwright & Hickman, 2007). Both parties need to carefully monitor the conduct of research and avoid assuming that collaborative partners share the same understanding of the research and regulatory issues relevant to their respective settings. As has been recommended elsewhere, IRBs should seek consultation when reviewing research conducted in community-based settings such as LTC facilities.

Research Agenda

Additional inquiry is needed into the relationships, expectations, and responsibilities of researchers and partnering LTC facilities in order to enhance the ethical conduct of research in these community-based settings. Research should focus on key stakeholders including researchers, IRBs, and LTC residents in addition to LTC facility staff. Studies focused on specific types of research designs and methods rather than general concepts are advised, and these could be achieved by adding supplemental studies to existing projects in the LTC setting. Findings also suggest the need for additional investigation into the pros and cons of the FWA and IIA processes both in LTC and other community-based settings.

Educational Implications

Findings suggest that investigators working in LTC settings should provide personalized education for facility staff about the potential ethical issues that might arise in collaborative research (Cartwright & Hickman, 2007; Decker & Adamek, 2004) and the implications of both the FWA and IIA process.

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Authors' Biographical Sketches

Susan E. Hickman, Ph.D., is Associate Professor and Research Scientist in the School of Nursing, a Senior Scholar with the Center for Ethics in Health Care, and Co-Chair on the Institutional Review Board at Oregon Health & Science University. Her program of research is focused on ethical issues in end-of-life care and research with the goal of improving the care of older adults. Through her research experiences and service on the Institutional Review Board, Dr. Hickman has been sensitized to the complex ethical issues that arise in conducting research with vulnerable populations. As a result, she is pursuing a line of research focused on ethical issues in long-term care research as well as end-of-life research.

Juliana C. Cartwright, Ph.D., R.N., is Associate Professor in the School of Nursing at Oregon Health & Science University. Her research focus is on end-of-life care in assisted living facilities, with emphasis on how nurses and caregiving staffs can work together to support

'good deaths' in these settings. Dr. Cartwright is also interested in ethical challenges related to conducting research in community residential care settings. Dr. Cartwright also serves on a community IRB that is responsible for reviewing all research conducted in a two-county region of southern Oregon.

Heather M. Young, Ph.D., G.N.P., F.A.A.N., is the Grace Phelps Distinguished Professor, the Director of the John A. Hartford Center for Geriatric Nursing Excellence, and the Director of Rural Health Research Development at Oregon Health & Science University School of Nursing. Dr. Young's research and clinical interests focus on environments that promote healthy aging, with a particular focus on the interface between family and formal health care systems for older adults in transition. For over a decade, she held a joint appointment on faculty at the University of Washington School of Nursing and as the Chief Operations Officer for a retirement community company and was responsible for an academic-corporate partnership managing and designing programs in independent living, assisted living, and skilled nursing. Dr. Young's current research focuses on the medication management in rural assisted living settings, technological approaches to promoting medication safety in rural hospitals, and community-based strategies to promote health for rural older adults.

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