GRI Researcher Uses Cognitive Theory to Address Reading Problems

By Deborah Witsken*

What if we could figure out why some deaf students read skillfully while others struggle? Dr. Leonard P. Kelly, a GRI research scientist who has been conducting research on deaf students’ literacy competence since 1987, stated in a recent interview that “we are learning more all the time about the cognitive processes of successful deaf readers, and I believe this knowledge can be translated into specific teaching strategies with the potential to help average deaf readers better develop their skills.”

In the field of deaf education, where approaches to teaching English to deaf students have been abundant, varied, and often disappointing in their overall effectiveness, Kelly’s viewpoint is worth paying attention to. Literacy development continues to be a serious concern for the majority of deaf students. Norms from the Stanford Achievement Test (ninth edition) still place seventeen- and eighteen-year-old American deaf and hard of hearing students’ reading comprehension, on average, at approximately the fourth grade level. Concerned about the effects limited reading skills may have on academic and employment success, educators are still searching for teaching methods likely to yield better results. In more and more states, parents’ and educators’ concerns have intensified as a result of statewide minimum competency requirements that are preventing many deaf students from getting high school diplomas. In

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Gallaudet Professor Takes Cognitive Strategy Instruction Abroad

By Deborah Witsken

Dr. David S. Martin, a faculty member in Gallaudet’s Department of Education, believes that although deaf students, on average, tend to lag behind hearing peers on standardized achievement tests, there is no inherent reason why deaf students cannot attain higher levels of academic achievement. He has concluded that deaf students have the mental capability to excel but are too seldom exposed to what he calls “cognitive strategy instruction.”

Cognitive strategy instruction and academics

In 1982 and 1986 Martin conducted research demonstrating the positive effects of cognitive strategy instruction on deaf students. In research that he conducted with both high school and college level deaf students at Gallaudet, Martin found that direct instruction in critical thinking skills led to significant measurable results. Other researchers at the Western Pennsylvania School for the Deaf replicated these results. In each case, following systematic thinking skills instruction, the students showed significant improvement in their reasoning skills and thinking habits.

Specifically, deaf students who participated in the training were more likely to think of more than one solution to a problem, to think before responding, and to sequentially organize their responses. These are clearly skills that will benefit a deaf student in school. Of even greater relevance to parents and educators were Martin’s findings that these deaf students also showed significant improvement in reading and math concepts as measured by the Stanford Achievement Test. After two years of experience with cognitive strategy instruction, the students—when compared to a control group that did not receive this instruction—achieved a grade-level equivalent seven-tenths

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Deaf Artist Appointed to Powrie V. Doctor Chair

Mary Thornley, a former Artist in Residence in the Art Department at Gallaudet has been appointed to the Powrie V. Doctor (PVD) Chair of Deaf Studies for academic year 2000-2001. Although the range of subject and style in her work is quite broad, for the past ten years, Thornley's work has often focused on visual metaphors for the deaf experience. She looks for motifs that represent deaf life in new ways and leans toward art that offers new perspectives on events important in deaf history, such as the 1880 Milan Conference or Deaf President Now.

Thornley received her BA at Indiana University, South Bend, and her MFA in Painting and Drawing at the University of Washington, Seattle. She is a prolific artist, has had ten single shows, and has had her work included in many exhibitions. Prior to coming to Gallaudet, she was an Artist in Residence at the Art Center in Vancouver, British Columbia; taught art classes for at-risk children and teens at Pacific Arts Center in Seattle; taught expressive drawing at Edmonds Community College in Lynwood, Washington; and taught foundation drawing at the University of Washington, Seattle.

Thornley is spending the year developing her ideas literally on larger canvasses. She explains that in the past, due to constraints on space and storage, she worked on small canvases and almost exclusively in drawing and painting. With support from the PVD Chair, she is working on larger pieces and in other mediums. The University is renovating the Gate House where Thornley will have a studio on the second floor. In addition to the small sample of recent work shown in black and white on this page, Thornley has done such works of historical interpretation as "Milan, Italy, 1880" (on display in the Gallaudet University Kellogg Conference Center) and "AGBell or Deafness as Pathology" (on display in the Office of the Dean of the College of Liberal Arts, Sciences, and Technology). There will be an exhibition of her work in the Washburn Arts Building Gallery this spring.

The Powrie V. Doctor Chair of Deaf Studies is Gallaudet's only honorary professorial chair awarded to non-Gallaudet faculty or staff and is meant to recognize individuals who have made significant contributions to deafness and deaf people. The Chair is administered by the Graduate School and Research.
Gallaudet’s Research Priorities

By Michael A. Karchmer, Director of Gallaudet Research Institute

In September, 2000, members of the GRI and the Gallaudet research community at large met to develop a list of 12 research topics to be officially adopted as areas requiring priority attention at Gallaudet. The list will be used as a basis for encouraging and supporting priority research at the University. The list is being published in this issue of Research at Gallaudet not only as a public announcement but also because we desire feedback on any aspect of the list from consumers of deafness-related research nationwide. Comments or suggestions may be sent to me via e-mail (Michael.Karchmer@gallaudet.edu) or postal mail (at the address in the masthead on this page). For your comments to receive consideration before the list is finalized, I will need to receive them by May 1, 2001. Note that the order of the listing below does not necessarily reflect ranking by importance and that some areas overlap.

Some Guiding Principles

Faculty, staff, and students at Gallaudet University are committed to the creation of knowledge through research and scholarship. Research is a key component in the University’s stated goal of identifying and providing educational services to deaf and hard of hearing people of all ages in ways that reflect best available practices. Gallaudet as an institution accepts its special obligation to encourage and support research that aims to benefit deaf and hard of hearing people both on campus and beyond. The University also recognizes that in conducting deafness-related research, it must strive to incorporate the talents of those likely to be affected. Research on issues of importance to deaf and hard of hearing people should include the meaningful involvement and leadership of deaf and hard of hearing people themselves.

In addressing the priorities below, the University understands the importance of applying a broad range of quantitative and qualitative research methodologies and encourages both basic and applied research.

Gallaudet Research Priorities

1. English literacy. Basic research into the sensory, cognitive, linguistic, and sociocultural processes involved in deaf and hard of hearing people’s acquisition of English literacy from infancy through adulthood as well as applied research concerning how to promote English literacy.

2. The classroom environment. Studies on how the classroom environment affects the education of deaf and hard of hearing learners; includes studies on classroom communication and discourse as well as on factors that affect the accessibility of information for deaf and hard of hearing learners.

3. Assessment. Development and validation of tools and techniques for assessing a wide range of characteris-tics of deaf and hard of hearing people from infancy through adulthood, including specific academic knowledge, skills, interests, and aptitudes and evaluation of social and emotional characteristics; authentic assessment approaches are also included.

4. Teaching and learning. Research on such areas as: effective strategies for teaching deaf and hard of hearing students; the impact of individual learning styles; the diverse linguistic, cultural, and educational backgrounds of students; and educational technologies.

5. ASL acquisition in new signers. Research aimed at understanding the processes by which new signers acquire ASL. This priority applies both to first-language learners acquiring ASL in childhood and to second-language learners acquiring sign language later...
in life. Basic research may examine naturalistic learning situations and applied research may seek to determine optimal strategies for ASL instruction.

6. **Transition from home-to-school and school-to-work.** Studies aimed at understanding and improving student transitions from home to school, from secondary school to employment or postsecondary education, and from postsecondary education to employment.

7. **Family involvement in the education of deaf and hard of hearing children.** Understanding the ways that parents participate in their deaf and hard of hearing children’s education. Studies might be aimed at identifying successful strategies for encouraging parents of traditionally underserved deaf and hard of hearing children to participate more fully in their children’s education. Emphasis may be on involvement in placement decisions or in specific educational activities.

8. **Studies that inform public policy development and educational planning.** Supports the collection and dissemination of national and local data that can underpin the development and evaluation of public policies on education and other services used by deaf and hard of hearing people throughout their life spans. Studies may focus on specific segments of the population or on the agencies providing services. The role of genetic discoveries and the increasing use of cochlear implants as well as other developments affecting the population are particularly timely areas of study.

9. **Language, culture, and history of deaf people.** Linguistic, sociolinguistic, anthropological, and historical studies of deaf culture, sign language, and the experiences of deaf people.

10. **Language acquisition, cognitive development, and socialization of deaf children.** Studies of the interaction of spoken/written languages (e.g., English, Spanish, etc.) and sign language development among deaf children; examination of the cognitive processes in comprehending visual as opposed to auditory information; studies of deaf children in home contexts.

11. **Evaluation of technologies that may benefit deaf and hard of hearing people.** Applies to a broad range of visual and audiological technologies, including assistive devices of all kinds, telecommunication devices, and educational media. A likely focus of such study might be on the impact of specific technologies on deaf consumers.

12. **Hearing loss and aging.** Studies of the nature and consequences of hearing loss in adulthood and within the elderly population.

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fact, as emphasis on statewide testing increases in the years ahead, schools with large numbers of deaf students receiving low reading scores face the possibility of losing accreditation.¹

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**An Interactive Cognitive Model**

Kelly describes reading as a demanding mental activity in which numerous cognitive processes must be juggled with great skill (see Figure 1). He explains that this perspective on reading, in which the overall reading process is viewed as the interplay among various mental subprocesses as well as between the reader and the text, is often called an “interactive cognitive model.” The challenge to Kelly has been to isolate the subprocesses involved and assess the relative importance of each in skillful reading.

Many of the mental activities involved in reading consist of basic linguistic processes that tend to be successfully completed by skilled readers—deaf and hearing alike—without much conscious thought. These can include recognizing the meaning of individual words, detecting the relationships among words in a sentence, and predicting the next word in a sentence from the ones read earlier. It is important that these basic processes be completed without drawing much attention, because most of our attention is needed for “higher level” reading.

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¹ An article on this subject will appear in the Spring issue of *Research at Gallaudet.*
operations that almost always do require conscious, intentional thought. These can include inferring the author’s goals and using them to guide reading, integrating the information of two separate sentences or paragraphs, retrieving and applying our own prior knowledge of a text’s topic, and occasionally asking ourselves whether we understand what we are reading. A considerable amount of research has been done by cognitive scientists examining how each of these subprocesses functions, not only in isolation, but also as a contributing member of the entire reading process. \(^2\) Kelly believes this approach may be particularly advantageous for use with deaf students because it provides a means of defining areas critical to skilled performance that can potentially lead to specific instructional interventions.

**Research on Deaf Readers**

In his research, Kelly has tried to determine which capabilities are consistently found among skilled deaf readers. In 1995, he found several differences between groups of skilled and average deaf readers in their use of basic linguistic reading processes (sometimes referred to as “bottom-up” processes). The skilled deaf readers read much more swiftly and demonstrated a smoother reading profile than the average deaf readers, whose reading was broken up by long pauses on individual words. Most likely, these readers were stopping to analyze challenging language. The two groups did not differ significantly in their use of higher level reading processes (sometimes referred to as “top-down” processes). As an example of this, skilled and average deaf readers both used their knowledge of a topic to help understand the text.

In a 1996 study aimed at finding how a weakness in one reading process obstructs another, Kelly found that deaf students’ difficulty in processing syntax had a negative impact on the students’ ability to recognize words they actually knew. Their access to reading strengths (specifically, drawing upon known vocabulary meanings) was diminished because words already recognized may have been pushed out of working memory by the prolonged focus on syntax. (“Working memory” is the limited mental space where information is both temporarily stored and processed.) In contrast, deaf readers with better syntactic competence were more adept at using their vocabulary knowledge to facilitate comprehension.

Simply stated, Kelly describes the differences between skilled and average deaf readers as follows. Skilled readers are able to perform basic reading processes with minimal mental effort. Average readers experience much more difficulty in performing these basic reading processes. These readers are said to read with low “automaticity” because they must frequently interrupt the momentum of their reading to figure out vocabulary meanings and work through challenging syntactic structures. As Figure 2 illustrates, these processing burdens divert attention from critical higher level processes and limit their contribution to an understanding of the whole passage. Not surprisingly, readers with low automaticity also have difficulty retaining the gist of what they have already read.

**Implications**

Kelly’s findings that basic linguistic processes rather than higher level reading processes differentiated skilled readers from average readers have significant educational implications. Rationally, it would not make sense to try to enhance the performance of average deaf readers by instructing them to use skills that they are already using effectively. As Kelly’s (1995) research indicates, higher level processing skills such as making use of topic

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familiarity or familiar text to facilitate comprehension were comparable for both the average and the skilled deaf readers. These are the kinds of processes emphasized in a “whole language” instructional approach to reading. The whole language approach has a lot to offer in terms of developing these higher level processes. Kelly’s findings that average deaf students fail to use bottom-up reading skills effectively indicates that whole language programs may need to incorporate teaching methods which more directly address these weaknesses. Kelly believes that practice may be a critical key to improved automaticity. He furthermore suggests that it may be possible to incorporate these instructional goals into existing programs without radical revisions in teachers’ overall philosophies.

In a recent study (Kelly, 1998) Kelly demonstrated that frequent opportunities to practice complex syntactic structures (i.e., passive voice and relative clause sentences) fostered comprehension of these structures, which have traditionally been troublesome for deaf students. This project demonstrated that practice exercises do not have to be the monotonous drills that dampen motivation and make teachers and students shudder. In fact, in this experiment, Kelly used humorous silent motion pictures as a context for practicing complex sentence structures. Kelly believes that more engaging educational interventions are needed to help students overcome weak foundational reading skills. “Practice exercises may be necessary,” says Kelly, “but they don’t have to be necessary evils.”

This research not only highlighted the positive effects of practice for improving reading competency, but also demonstrated how these exercises can be consistent with a whole language instructional approach. For example, in the study cited above, Kelly’s indirect instruction strategy that addressed skills on an “as-needed” basis parallels the whole language approach. Likewise, the study’s emphasis on meaning, use of “real literature” (in this case classic movie materials), and specific skills instruction only within the context of complete story, are characteristic of the whole language philosophy.

**Practice, practice, practice**

Even at the college level, many deaf students have difficulty reading due to low automaticity. Kelly’s main advice to teachers and deaf readers is to “practice, practice, practice.” Based on the implications of his research demonstrating the need for automaticity, Kelly hypothesizes that it may be necessary to build students’ fluency in basic reading operations by providing them with repeated successful reading experiences in texts that are challenging to students without overwhelming their reading ability. He cites the “Repeated Reading” method used by Ensor and Koller (1997) as one potentially valuable model of a systematic approach to this kind of practice. Kelly is also optimistic that educators may find guidance in developing engaging practice exercises from the work of researchers in other areas of psychology, such as Csikszentmihalyi’s research showing the characteristics of enjoyable experiences.

Most importantly, Kelly emphasizes the necessity of both the quantity and quality of practice exercises to improve students’ dexterity with basic reading operations. Unfortunately, the alternative, as described by a term called the “Matthew Effect,” is that deaf readers who get less practice improving weak basic reading skills will continue to fall farther and farther behind their peers. Kelly summarizes his views on the importance of extensive practice by stating, “Well designed practice is not guaranteed to raise the reading comprehension of most deaf readers, but failing to provide abundant practice does guarantee that reading comprehension will remain low.”

**Bibliography**


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4 (pronounced chick-simmy-high)

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of a year higher in Reading Comprehension and one and one-tenth years higher on Math Concepts. Strikingly, the students showed improvement in specific academic areas though they were never explicitly taught related academic skills.

What’s so unique about cognitive strategy instruction?

While these positive results of Martin’s research support what many probably suspected about the academic potential of deaf students, some confusion may remain about how the thinking skills taught in cognitive strategy instruction differ from how students are already taught. What is it about this specific method of instruction that leads to improved academic performance? The key to these questions is a powerful cognitive tool called “metacognition” that deaf students learned to use through cognitive strategy instruction.

The psychological term metacognition refers to the process by which we reflect on our thought processes. It may be described as occurring during several stages of the problem-solving process. The first stage takes place when we are about to attack a problem and we take a step back to consider possible solutions. The second occurs during the process when we use metacognition to monitor our progress. For example, one might internally say to oneself, “Oh, that didn’t work, what can I try now?” Finally, after the problem has been solved, we often evaluate our thinking to determine how we reached the answer. Martin stresses that these skills are extremely important. Deaf students who are taught to use them learn to take a step back and evaluate the process and tools that they used to solve a problem. The next time they face a similar problem, they will not have to “reinvent the wheel” because they have already *consciously* established effective problem solving strategies. These students become independent, productive learners. This may explain their improvement not only in thinking skills alone but also in academic subjects.

The Next Step

For Martin, the importance of training deaf students to become metacognitive thinkers was confirmed by the consistently successful results of cognitive strategy instruction on American deaf students. However, he wondered about the universality of these results. Would the same techniques have similar results in different cultural and educational contexts? This question prompted Martin’s most recent study, supported by a GRI priority grant, on the effects of cognitive strategy instruction on deaf students in England and the People’s Republic of China—countries with distinctly different educational philosophies.

The British philosophy can be described as fairly similar to the American philosophy. To varying degrees, British and American educators follow a model in which the students are viewed as constructors of knowledge. Hence, group discussions and interactions are the norm. In contrast, the Chinese educational philosophy views students as receivers of knowledge provided by teachers. Martin wondered if cognitive strategy techniques, which essentially teach students the skills to direct their own learning, could be successfully used by teachers and students who are accustomed to a more teacher-directed educational philosophy.

Taking Cognitive Strategy Instruction Abroad

Before Martin could begin using cognitive strategy
instruction in British and Chinese classrooms, a lot of groundwork had to be completed. He began by recruiting teachers from schools in both England and China. Data was collected on teacher’s beliefs about classroom interaction, their behaviors related to fostering thinking, and their ability to demonstrate creative teaching by responding to a contrived classroom scenario. These measures were also collected following the experimental period in order to note significant changes that might be attributed to the cognitive strategy training and instruction. In addition, the teachers kept weekly reflection journals and participated in a post-experiment group discussion to reflect on the program’s effects on both themselves and the children.

Information was also collected from students in control and experimental classrooms. All students were observed using a checklist for creative and critical thinking behaviors. A random set of students from the experimental and control groups was selected to take the Ravens Standard Progressive Matrices, a measure of reasoning skills (Raven, 1959). This is a non-verbal test that is therefore not only appropriate for deaf students but also controlled for other language differences between the student groups. In addition, all students were asked to write or narrate their response to two problem situations. For example, students were asked to develop solutions for problems such as how they would respond if they and a friend were the only deaf individuals eating in a restaurant and the friend suddenly became ill. At the completion of the experimental period, the students were then re-administered each of the items described above to measure cognitive strategy instruction’s effectiveness.

Martin’s previous research indicated the importance of teacher education in successful implementation of cognitive strategy instruction. Thus, extensive care was taken to train teachers before they started using cognitive strategy instruction techniques. This training included topics such as recent theories of multiple intelligences, cognitive modifiability, metacognition, and the role of the teacher as a cognitive mediator. In addition, teachers participated in activities that required them to use the critical and creative thinking strategies they would later teach their students. Critical thinking skills were demonstrated and applied to problems incorporating concepts such as categorizing, determining cause and effect, and prediction. Activities emphasizing the creative problem solving process were based on themes such as risk-taking, applying innovations, assessing multiple possibilities and solving hypothetical problem situations. By working individually and in small groups, teachers brainstormed how to solve sample problems, make use of their own creativity, and apply these activities to their own classrooms. Most importantly, teachers were trained to reflect on what they had done to solve these activities in order to understand how to model their own thinking processes for their students.

Once this training was completed and all pre-experimental measures had been collected, teachers began a six-month period of implementing cognitive strategy activities. These critical and creative thinking activities occurred three times weekly for approximately thirty minutes per session. Some of the included procedures were non-verbal pencil and paper exercises (such as comparing and contrasting matching pictures) and group discussions involving solving problems and creating ideas. Each instructional session consisted of three segments: (1) teaching of the processes used to solve the problem, (2) engaging students in a metacognitive discussion of the mental processes they used to solve the problem, and (3) discussion and demonstration of applications of the skill to specific content areas within the curriculum. Purposefully embedding the use of cognitive strategies within the framework of the regular curriculum in this way ensures that students will generalize these new thinking skills to areas other than the specific activities in which they learned the skills.

Cognitive Strategy Instruction Does it Again

Once again, Martin’s results demonstrated the positive effects of cognitive strategy instruction. Compared to students who did not receive cognitive strategy instruction, Chinese and British students in the experimental group showed significant improvement in reasoning skills on a number of measures. Indeed, teachers recognized this improvement in their classrooms. These results were consistent with Martin’s research on deaf subjects in America. Based on the success that cognitive strategy
instruction had in both China and England, it appears that though the students’ styles of problem-solving may be different, the effects of the critical and creative thinking program are similar, even when applied to students with vastly different cultural backgrounds.

The greatest testimonial to the usefulness of cognitive strategy instruction is found in qualitative findings of the intervention’s positive side effects. For example, teachers in both countries reported that students were using the cognitive vocabulary learned during the intervention in other classes. That is, students began using vocabulary words well above their previous vocabulary level to describe cognitive processes such as “comparing,” “sequencing,” and “categorization.” Students in both countries also appeared to have improved in their ability to take others’ viewpoints into consideration, to elaborate on their responses to questions, and to explain a problem in their own words. Teachers also noted that student attentiveness and motivation had increased. Most significantly, these effects were noticeable in academic areas unrelated to the time period set aside specifically for cognitive strategy instruction. In other words, students had internalized the new approach to learning and were using those strategies in other academic areas.

The positive results of cognitive strategy instruction were not limited to areas of student improvement. Teachers also noticed positive changes in their teaching habits and personal outlook. For example, teachers from both countries reported an increase in their own daily use of cognitive strategies and cognitive vocabulary across content areas, as well as more frequent use of discussion formats and higher-level questioning in these discussions. Furthermore, teachers commented that they felt less compelled to focus rigorously on a particular topic when they were teaching, that they had more of a tendency to encourage independent thinking, and that they generally had more confidence in their students’ innate capabilities.

Martin admits being slightly surprised that cognitive strategy instruction resulted in significant improvements in deaf students’ reasoning skills in the short time frame of about seven months and in spite of considerable cultural obstacles. Cultural barriers clearly could have dampened the results, particularly in the Chinese system, where the use of cognitive strategy instruction seems to have changed the role of the student from being strictly a receiver of knowledge to one in which the student was an active participant in creating knowledge.

These results, Martin says, suggest that teacher education programs should include instruction in how to teach students higher level thinking skills. Cognitive strategy instruction not only leads to measurable improvements in thinking skills, he says, but also increases student motivation and creates a positive learning environment for both students and teachers. This study confirmed Martin’s belief that deaf students have the mental capability to excel and can do so if given an academic environment that stimulates higher order thinking and creativity.

**Meeting Addresses Human Research Issues and Guidelines**

On October 2 and 3, 2000, approximately 150 people interested in issues related to the protection of human research subjects met to attend a series of presentations and discussions at the Gallaudet University Kellogg Conference Center (GUKCC). The conference was entitled “Current Human Research Issues and Solutions: Regulatory Overview and Special Population Groups.” The event was co-sponsored by Gallaudet University, Howard University, Children’s National Medical Center, the U.S. Veterans Health Administration, the U.S. Food and Drug Administration, and the new Office for Human Research Protections (OHRP), an agency within the U.S. Department of Health and Human Services. OHRP planned the meeting as the first of a series of workshops to be held nationwide in fiscal year 2001. Planning for most details of the meeting was coordinated by Dr. Carolyn Corbett, chair of the Gallaudet Institutional Review Board (IRB) and Ms. Sally Dunn, Gallaudet’s IRB administrator. Participants ranged from administrators of federal agencies whose role is to craft and enforce guidelines, research subjects who wished to describe their experiences, and researchers who often conduct research involving human subjects.

**Federal Regulations and Guidelines**

The first day of the conference focused on federal
regulatory provisions and ethical guidelines involving diverse populations. Dr. Jeffrey M. Cohen, associate director for education at the OHRP, said that the agency, which interprets and implements federal regulations and policy on human subjects research and reviews written assurances of compliance submitted for federal approval, wishes to make itself as accessible as possible for answering questions on related topics. Questions can be addressed in workshops such as this one and in responses to inquiries sent to the following e-mail address: ohrp@od.nih.gov. Cohen also said that documents on such aspects of human subject research as assurances, informed consent, guidelines, and oversight activities can be found and downloaded at the website: oahrp.osophs.dhhs.gov or can be sent via fax. One reason for this effort to increase accessibility, Cohen explained, is that OHRP wishes for the principles of human subject protection to be widely known and an ingrained part of researchers’ consciences, not merely a set of guidelines to be accounted for in proposals seeking federal funding.

Dr. John Mather, chief of the Veterans Health Administration Office of Research Compliance and Assurance (ORCA), said that ORCA oversees research on human and animal subjects in 120 VA medical centers nationwide. He said that ORCA, like OHRP, is putting increased emphasis on educating researchers and less on fixing blame for violations in the hope that greater awareness of the issues will prevent violations from occurring.

Mather emphasized that the only way oversight agencies can get reliable information about compliance is through careful documentation by researchers concerning precisely how compliance was handled in their projects. He said that although documentation is obviously burdensome, it is clearly necessary. To ensure vigilance in compliance, he said, periodic unannounced site visits may also be needed.

The next speaker, David A. Lepay, MD, PhD, acting director of the Office of Clinical Science at the U.S. Food and Drug Administration (FDA), said the FDA is responsible for regulating 25% of the U.S. economy, including all U.S.-distributed pharmaceuticals and diagnostic and therapeutic devices, plus FDA-regulated foods and cosmetics. Lepay said that the FDA monitors the quality of both U.S. and international research supporting manufacturer claims for new products and is striving to foster a stronger sense of professional ethics among researchers working for profit-based corporations. “First and foremost,” Lepay said, “we are there to protect the public health.”

Lepay emphasized that FDA approval of products inspires confidence in consumers primarily because the agency withholds approval until the “quality of data and the interpretation of that data” has been carefully assessed and deemed sound. This has proved more difficult than is often believed as the pressure for FDA approval is high and the agency must be ever vigilant in detecting fabrications and falsifications of data. Lepay also pointed out that Institutional Review Boards (IRBs) play a particularly important role in insisting on compliance in profit-oriented businesses. Equally important, Lepay said, is the dissemination of information to potential research subjects to make sure they understand the risks involved in participating in medical research.

Dealing with Violations
In the afternoon of the first day speakers addressed how the three agencies deal with complaints about the use of human subjects in particular projects. Dr. Cohen said that hundreds of calls are received daily at the OHRP with complaints from investigators, IRB members, subjects, private citizens, reporters, and media. Once OHRP jurisdiction is ascertained, every complaint is investigated and documents are requested. Ideally, a resolution can be communicated via telephone and correspondence. It may be recommended that use of human subjects be suspended until a problem has been appropriately addressed. Of particular concern are systemic problems in which a “culture of compliance” at an institution is found to be inadequate. Occasionally, entire facilities are “shut down” until adequate compliance measures are in place.

Dr. David Webber of the Veterans Health Administration said that complaints about VA research are usually dealt with by the nearest of five regional VA centers or whichever center specializes in the type of research in question. Whenever there are serious complaints, Webber said, the project’s data and data gathering procedures are

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given serious scrutiny, and in most cases, recommendations for new procedures are made with the understanding that compliance is critical for the project’s continuation.

Joseph Salewski, chief of the bioresearch monitoring branch of the Center for Biologics Evaluation and Research at the FDA, said that his office investigates the research and review procedures cited by manufacturers or producers as the basis for their claim that a new drug or other FDA-monitored product should be marketed. The primary means of checking is to correspond with and inspect the procedures of 250 to 300 IRBs annually. If an institution fails to correct erroneous procedures after warning letters have been issued, official action may follow, in the form of stopping a researcher from using subjects or stopping a study completely. Also, if an IRB fails to correct faulty monitoring procedures, it may be disqualified. Salewski said that in many cases, IRBs were overextended and unable to review projects adequately due to lack of institutional support.

The Importance of Caring

The second day of the meeting began with an address by Greg Koski, MD, PhD, director of the OHRP. Koski said that although human subjects have technically been protected by IRBs, that protection has all too often been primarily aimed at ensuring that compliance with guidelines is written into research proposals and that care is taken to ensure that research audits later on will not reveal lack of compliance. “We have lost sight of the fact that the true goal is the actual protection of subjects in research,” Koski said, adding that “responsibility for the protection of human subjects is shared by every participant in the research process.”

Koski said that researchers, keen on advancing knowledge, “need to build a sense of caring into the system” following the lead of medical professions which have worked harder in recent years to incorporate caring into their practices. The OHRP, Koski said, is well-positioned to take the lead in providing a road map to help researchers “move in the right direction.”

Koski also pointed out that steps need to be taken to educate the public at large about the nature of research with human subjects. One reason, he said, is that many people volunteer for medical experiments on the false assumption that such experiments do not entail risks.

Subjects Tell Their Stories

In light of this theme of caring, a subsequent panel discussion by research subjects could be considered a centerpiece of the conference. Some panelists had been HIV–positive for many years and were motivated to participate in experiments both by the hope of getting beneficial drug treatments prior to FDA approval and by the altruistic aim of helping researchers identify drugs helpful to HIV-positive people in general. The subjects indicated awareness of the risks associated with as-of-yet unapproved drugs. They also indicated that the hope to help others—a genuine motivator—could be fulfilled even in “blind” experiments in which a subject may receive a placebo. One subject added, however, that respect needs to be given to subjects’ wishes not to be given placebos in study after study, thus removing an understandable personal reason for participating. The subjects emphasized the importance of good communication with medical staff administering drugs so that treatments that are having harmful effects can be discontinued.

Of particular interest to readers of this newsletter, the final subject panelist was a deaf woman who—with her husband and children—had been videotaped in studies of child-rearing and literacy-development practices in all-deaf families. This subject said that videotaping sessions in her home had been pleasurable and the family’s rapport with the researchers had been friendly, but family members had found it disconcerting, years after the conclusion of a project, to learn that portions of the videos were sometimes shown in classes or at conferences without the subjects’ knowledge or permission.

Researchers on Human Subject Issues

In the next session, researchers discussed ways they had found to address various human subject issues. What constitutes a fair, reasonable compensation of subjects was discussed extensively. One researcher who had worked with aphasics spoke of allowing subjects to keep computers that had facilitated communication during a project as a way of minimizing the sadness experienced once researchers stopped visiting. The importance of screening out high risk subjects in drug experiments was emphasized, with particular concern for women who might be in the early stages of pregnancy. The complexity of acquiring informed consent was discussed from many angles, as were problems related to coercion and undue inducement in the recruitment of subjects.

Concerning deaf subjects, Drs. Irene Leigh and
Carolyn Corbett of Gallaudet’s clinical psychology program emphasized that in addition to concern for individual deaf subjects, the Gallaudet IRB must keep the values of the Deaf community in mind, taking care to ensure that researchers wishing to study deaf students at Gallaudet are truly capable of communicating with the subjects and do not have an agenda likely to harm the Deaf community.

Dr. Irene Leigh, a researcher from Gallaudet’s Clinical Psychology Program, discusses issues related to the protection of deaf subjects. Other panelists shown are Dr. Carolyn Corbett (left), Gallaudet Clinical Psychology Program, Ms. Donalia Keene Clay, IRB Administrative Assistant at Howard University, and Dr. Richard Levine, Chief of Staff for Research and Development, Veterans Affairs Medical Center.

Mental Health Services Directory Available
Available for $12.95 per copy plus postage and handling, Mental Health Services for Deaf People: A Resource Directory --2000 Edition, developed by Dr. Diane Morton of Gallaudet’s counseling department, contains a descriptive listing of over 300 programs in the United States and Canada. To order, photocopy this page, fill out the order form, and mail with check or money order payable to Gallaudet University to: Mental Health Services for Deaf People: A Resource Directory, Gallaudet Research Institute, Gallaudet University, Washington, DC 20002. For orders of ten or more copies, inquire about discounts and postage.

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