Blending the Disciplines (Part II)

Medical and Engineering

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APPLICATIONS AND EXAMPLES

Clinical teams are continuously on the lookout for knowledgeable engineering partners who could enhance data collection in their complex studies. Many engineering groups have been formed to provide a forum for engineers at the cutting edges of biomedical engineering. The German Association for Biomedical Engineering (Deutsche Gesellschaft fuer Biomedizinische Technik) is representative of the type of international interest and professional encouragement provided to engineers working in the clinical sector. Products from these groups emphasize improved measurement techniques within clinical situations. Substantial contributions to improved biological replacement products are also presented.

In these associations the engineer may find his or her main support among fellow professional colleagues, since he or she frequently finds himself or herself among clinical personnel who just want a better result, with little understanding of the technical complexity of many of their requests. Without a doubt, the day-to-day work for the engineer is more stimulating if the lead clinician has an engineering orientation and can bring out the best capabilities of the engineering members of a particular team.

Unfortunately, the research set-up is typically an ad hoc compilation of specialists focused on the clinical problems of interest and specifically on those that have received funding, or show the prospect for funding, within an operational site like a hospital or medical school.

Remember also that large employers such as hospitals and medical clinics may make additional specific clinical demands of potential hires or participants. They are trying to add to the process of ensuring standardized medical care. But these specialized credentials (e.g., years of training and numbers and types of specific medical procedures under the belt) interact unpredictably with the conduct of research within such institutions. In their attempt to standardize medical care, administrators may inadvertently put nooses around the participants in research projects.

Here the lack of experience with research may lead to demands that may be both insufficient and excessive. The engineering member of a multi-disciplinary research team should keep these driving forces for specialization and certification in mind as he or she tries to find the best niche on a research team.

AN APPROACH TO MULTIDISCIPLINARY RESEARCH

To continue the exposure to multidisciplinary research settings, the author will share the formats used within the Federal Aviation Administration. These were observed for numerous years, largely in the author’s capacity as manager of one of the lead research divisions within the FAA, the aeromedical research division. We will describe the teams in this professional setting and avoid making claims that these are the dominant patterns available. The basic structures were nonetheless matched in many other government entities.

After the completion of our formal review of the FAA approaches, we will present a hypothetical hybrid team and apply some of the lessons learned from watching clinical-research teams in action. Though a light-hearted approach will be introduced, we will still emphasize realistic backgrounds and skills that make such teams work. Presumably, you can best decide for yourself where you might fit into such clinical-engineering teams, using data gleaned from either the realistic example or the slightly tongue-in-cheek hypothetical example.

The FAA’s aeromedical research division was responsible for the biomedical, bioengineering, and biochemical issues relevant to civil aviation flight. The focus was both on the maintenance of safe flight conditions and on the maximization of human functioning during emergency conditions within flight or after landing.

The U.S.A. funded necessary activity within this broad chunk of research to the sum of approximately $4 million per year, the bulk of which went to personnel costs. The formal teams were defined according to funded mission elements and not the desires of the scientists and engineers. People frequently stopped by to explore the option of working in our laboratories, and these were people with varied and high-level training across many different clini-
eral and engineering disciplines. Entry was typically restricted to bidding on the job of an incumbent who was retiring, since the system was not designed as a growth industry. Those who made it into this team structure included physicians, chemists, engineers, physiologists, and various biomedical technicians.

Understandably, the work that did not involve human test subjects would be headed by the engineering, physiological, or psychological discipline most suited to the problem at hand. For instance, a major program of research into seat-and-restraint systems was effectively run by a small team of engineers and support persons. On the other hand, a specialized program to improve post-aircraft crash evacuations did not match one of the classical academic disciplines, and heads of this activity included persons with engineering and psychological experience. Because these evacuation studies typically involved direct physical risk to test subjects, there had to be close integration between the core test team and resident medical personnel. All responsibilities would fall under the general safety guidelines and oversight of the human-subject research-review process. The more cross-training any individual member had, the better the chance for an effective research series.

Research teams requiring altitude chambers and human subjects invariably fell under medical or physiologist team oversight. Much of the productive research in this area addressed the efficacy of protective breathing gear.

However, many other environmental issues related to aircraft cabin exposure were not properly highlighted, because lack of biomedical-engineering expertise prevented formulation of the test bed and assessment methods. A project that used aircraft-cargo compartments under commercial conditions of flight and transport of animals was incompletely developed because of inexperience with atmospheric measurement recordings and interpretations. These types of studies about current practices in animal transport, using prevalent aircraft, posed more questions than they resolved.

The paucity of studies to evaluate interference of medical devices used in aircraft was another consequence of inadequate project support that required high levels of biomedical engineering expertise.

Research into the work conditions of the aircraft-cabin environment was resisted by the FAA as not falling within its charter. The administration also made the generic claim that no problems of any note were being detected in the general work environment of the flight attendants. This aspect of research had to be left to outside specialists, because the lack of internal priority led to concomitant lack of hiring priority for addressing and solving problems in this sector. Additional medical and engineering expertise would have been necessary for proper progress to be made.

Research into human performance under simulated laboratory settings relied on standard measurement tools; computer-simulated models of performance demands of piloting an aircraft or managing air-traffic control for flight situations were mainstays of this activity. Team leads ranged from psychology to medical specialists, and these teams could frequently have profited from additional biomedical engineering expertise onsite to sharpen both the simulations and the measurement techniques. An historical quirk had two FAA divisions addressing the activity described in this paragraph: The aero-medical research division and the human resources research division had overlapping responsibilities in this area, and this separation arguably sharpened or diluted the required research effort.

Human-performance assessment in the context of actual aircraft accidents was more complex and needed utmost attention to detail, since physicians, engineers, and psychologists were blended under a program of operational research. Data would help allocate the human responsibility for accident causation. Primary responsibility was assigned to an aircraft-accident research team headed by a physician. This team was closely integrated with the aviation-forensic-toxicology assessments that were carried out by the division on behalf of both the FAA and the National Transportation Safety Board.

The FAA teams worked with numerous university and industrial research teams in collaborative assessments, and proper mixes of medical and bioengineering expertise were keys for success in these outside groups. If the outside teams did not acknowledge proper staffing, they would go spinning off toward some irrational medical or engineering tangent, and their proposals for joint work were rela-
tively useless to the government. As a related point, we noted that university and governmental groups entering some new field of aviation health and safety research were most successful if they accommodated both engineering and clinical thinking and expertise early in the process. As a corollary, it would seem logical for a job seeker in biomedical engineering to search for such accommodative multidisciplinary thinking by any future employer. As a point of additional observation, when the author resigned from the FAA in 1999, he had urged management to consider either a physician or engineer with appropriate clinical exposure as his successor in the aeromedical research division, but management still preferred a traditional physician recruit.

A HYPOTHETICAL MULTIDISCIPLINARY TEAM

The above paragraphs may have sounded a bit formal and may have left some readers wondering how to narrow their assessment sights, when contemplating research or work that blends clinical and engineering skills.

We’ll try to convey the ideas by presenting a combined hypothetical team staffed intelligently and geared for output success. We’ll pick an arena wherein clinical and engineering skills are absolutely necessary, and we will describe the different work and thought environments of the members who were lucky enough to join this mixed-discipline team.

The skilled management of cardiovascular problems within the human had brought together the surgeon (Dr. SeeAndDo–S&D), the internist (Dr. SeeAndThink–S&T), the oncologist (Dr. Chemical Bath–CB), the physiologist (Dr. KnowsHowItWorks–KHIW), the electrical engineer and concurrent computer systems specialist (Dr. Connection–C+), the biomedical technicians (Drs. Device–D), the radiation specialist (Dr. Scatter&Count–S&C), the biomedical materials engineering guru (Dr. WhatIsItMadeOf–WIIMO), and a statistician (Dr. ChallengeTheResult–CTR). Please note that all participants have been raised to Dr. status, although that would not usually be the norm. Be aware that all clinical members are more than fully trained and are board certified, often in dual sub-specialties.

Be aware that the other specialists belong to their separate professional societies and are considered leaders within their respective fields. The team appears for work. Their mechanisms of interaction and their internal participation styles right through the publication of the scientific report are available for review. How did all this get started? How were people invited to the team?

Dr. S&D had a distinguished career as a surgeon for 10 years after becoming board certified in vascular surgery. Patients love him for his bedside manner, as well as for his technical acumen, stories about which spread rapidly without any additional advertising. But anyone this successful looks for new horizons, and Dr. S&D asked the hospital director if he could work with a particular oncologist and internist (Dr. S&T and Dr. CB) to develop a new surgical technique for strategically placing toxic doses of chemicals near the cancer sites. Dr. S&D knew that he would not want to stop his regular practice style, but he did want to add a new facet of work.

The hospital director, who had a good friend at the medical school, thought this would be an excellent opportunity for the hospital to bring in additional money. He gave the lead responsibility for developing a research plan to Dr. S&D. Dr. S&D originally recommended a team incorporating the disciplines of internal medicine, oncology, electrical engineering, computer software analysis, biomedical-equipment maintenance, biomedical materials engineering, fluid dynamics, radiation dosimetry, physiology, and statistics. The clinicians were to be medical-board certified, and the other persons were to possess the highest degrees in their fields. Recruitment interest was high, and positions were rapidly filled by word of mouth. A couple of the disciplines were collapsed because recruits were cross-trained in more than one field.

The hospital had a limited amount of seed money and would focus it per Dr. S&D's requests. But Dr. S&D found that he could quickly spend all his seed money just developing one version of the new cancer agent, much less developing new surgical techniques for distributing the dose within the body. Dr. S&D knew he had better obtain new research money if he wanted to test his pet theories. The protocol would be written to appeal to two specific pharmaceutical and medical-device manufacturing companies.

The compromise protocol was targeted to develop a site-specific dosing approach to the introduction of cancer antibodies in up to two-dozen colon-cancer patients. The basic hypotheses included:

1) that antibodies against Stage 3 colon cancer could be developed (Dr. S&T and Dr. CB);
2) that the cancer sites could be microscopically and macroscopically targeted (Dr. S&D, Dr. CB, Dr. C+, Drs. D, Dr. S&C, Dr. WIIMO, Dr. KHIW);
3) that a profile of implanted release devices and associated dosing levels for the antibodies could be developed (Dr. S&D, Dr. CB, Dr. S&T, Drs. D, Dr. S&C, Dr. WIIMO, Dr. KHIW);
4) that a software program could be written to “define and work up” a typical colon-cancer patient for a treatment protocol (Dr. C+); and
5) that an improvement in survivability and quality of life would result from this protocol (all the above, plus Dr. CTR).

The surgeon thought that the trial procedures would begin within a month. He was reminded by the statistician that a formal protocol would need to be written and reviewed by the human-research review committee of the neighboring medical school, which had agreed to provide this service because several of its part-time employees were also on the research team.

The oncologists wanted to start collecting patient volunteers, but they disagreed as to whether they should target patients who had exhausted the usual modes of therapy or try to obtain clearance to access patients before other treatment. Some said they could not recruit patients until they received review-board approval. Another whispered that this research should be done overseas. The statistician reminded the group that it would need to agree on the patient selection criteria as part of the formal protocol being sent to the research review board.
The oncologist and the internist had different methods for eliciting antibody formation, and they argued about whose antibody-generation approach should first be included in the protocol. The team leader, Dr. S&D, was called away for an emergency just as discussions proceeded.

The biomedical technicians, the physiologist, the materials engineer, and the radiation specialist all went away, either to drink coffee or to read more about various topics within the upcoming project. They wanted to be sure that none of the lead guys was chasing some impossible scientific dream. They did want to contribute their ideas to make the study the best possible. Some really enterprising team members talked about setting up a company that would build devices that inject controlled amounts of chemicals and/or antibodies into select portions of the body. They would sell these devices to all who were searching for targeted delivery techniques. They would ensure that the devices won FDA approval, and then clinicians would feel more comfortable about buying these tools.

The statistician went back to the business office, muttering that these scientists never know what they are doing, that they do not use enough subjects, and that they just “don’t understand statistics.”

Nearly all of the non-physicians stated that they were glad not to have formally studied medicine. It may have seemed nice to be in charge of the research ship, but you weren’t allowed to do anything anyway because of the FDA, the human-subject review boards, and other oversight bodies. All those clinical certificates and credentials just allowed you to put your name on a door and offer to heal more complex patient problems.

The physicians returned and found that their team had scattered. They wondered if they had had enough management training to be able to conduct a complex research protocol like those they had envisioned. Just then, letters arrived from three small companies, which promised turn-key research project completion and offered quick development of the protocol and its approval by all necessary authorities. They would recruit patient subjects. Their overhead was low for all these services because their staff members were all former researchers with tremendous amounts of experience and who had left their original employers in search of greener pastures. The firms offered access to all clinical and engineering disciplines that might be needed for the execution of the studies of one’s choice.

The story will stop here, long before the first draft publication is available. The rest is left to the reader’s imagination.

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Dr. Hordinsky’s career in occupational and aerospace medicine was abruptly ended by a diagnosis of cancer, and the author retired from the FAA in 1999. Because of the special support of his wife, Martha R. Hordinsky, the author was able to offer professional contributions to the community until he died on October 20, 2000. This article is possible because of her devotion and cooperation.

Jerry R. Hordinsky worked as a flight surgeon with NASA in 1972-81 after a tour of duty as an Army flight surgeon. From 1982 until he took medical retirement in 1999, he was manager of aero-medical research within the FAA and adjunct associate professor in the department of environmental health at the University of Oklahoma. Although his career path emphasized aerospace medicine, he was active in the broader field of occupational medicine and had a long-term commitment to practice applications that integrate medical care around the occupational health team.

Graduating from the University of Minnesota from a pre-medicine and engineering curriculum with a B.S. in applied mathematics, he attended Northwestern University in Chicago and earned a doctor of medicine in 1967. He continued his studies in occupational medicine and earned a master’s degree in industrial health from Harvard University in 1972. Board certified in both occupational and aerospace medicine, Dr. Hordinsky published more than 50 papers, ranging in topics from space flight to formal assessments of FAA issues, such as toxicological findings in general aviation fatalities, neuropsychological screening of fliers after head injury or disease, emergency medical kits within the civil aviation sector, and optimization of aircraft cabin environmental and work conditions.