Apr 1st, 8:00 AM

Medical Technology Transfer

James N. Brown
Director, Center for Technology Applications, Research Triangle Institute

William A. Fischer
Assistant Professor, School of Business Administration, University of North Carolina

F. T. Wooten
Executive Assistant to the President, Research Triangle Institute

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ABSTRACT

The Biomedical Applications Team program sponsored by the National Aeronautics and Space Administration is an effective means for transferring aerospace technology to applications in medicine. A conceptual framework for medical technology transfer is presented to describe the transfer process in medicine and to supply a rationale for the Biomedical Applications Team methodology. Examples illustrate medical technology transfer at the material, design, and capacity levels. The roles of donor, recipient, and transfer agent are illustrated and factors essential to the success of medical technology transfer are summarized.

INTRODUCTION

Human cells, frozen, stored, and thawed without damage, may be made available for therapeutic use; people may benefit from the application of stimulating and monitoring electrodes that require replacement only once each week; and clinical information systems are demonstrating the potential for improved medical care without increased costs. While none of these medical advances are direct results of National Aeronautics and Space Administration (NASA) research, they have all benefited from NASA technology. The way NASA’s Biomedical Applications Teams stimulate such technology transfers not only illustrate the value of second applications of aerospace technology but can serve as a model for successful technology transfer in other areas.

The Space Act of 1958 required NASA to "provide for the widest practical and appropriate dissemination of information concerning its activity and the results thereof." The NASA Technology Utilization Program was initiated in 1962 to assist in satisfying this requirement.

In 1966, NASA established Biomedical Applications Teams to stimulate and facilitate the transfer of aerospace technology to applications in medicine. These teams identified medical problems, identified potentially applicable technology, and took necessary and appropriate steps to effect actual utilization of NASA technology in medicine. In the intervening years, the successful transfer of NASA technology to applications in the medical field via the Biomedical Applications Team program has been demonstrated. NASA technology has been successfully applied to applications in both clinical medicine and in medical research. Results include advances in medical research, improved clinical diagnosis and treatment, and the introduction of new or improved medical products.

At present, Biomedical Applications Teams are sponsored by NASA at the following institutions:

- Research Triangle Institute
  Post Office Box 12194
  Research Triangle Park, NC 27709
- Stanford University School of Medicine
  701 Welch Road
  Palo Alto, CA 94304
- University of Wisconsin
  1500 Johnson Drive
  Madison, Wisconsin 54706

PROGRAM OBJECTIVES AND APPROACH

The specific objective of the Biomedical Applications Team program is to assist NASA in obtaining widespread utilization of aerospace technology in the medical field. Widespread utilization implies that a significant sector of the medical community and the recipients of medical services should be benefitted. Implicit in this program objective is that utilization must be obtained in a relatively rapid manner.

The largest potential for rapid and widespread utilization of NASA technology in medicine is in clinical medicine. Although advances in medical research definitely have a beneficial impact on the delivery of medical services, this is, in general, a long term and expensive process. As a result, benefits from the transfer of technology to medical research are realized later than in the case in clinical medicine.

Applications of technology in clinical medicine usually involve the introduction of a new or improved, commercially available, medical product. Thus, the approach of the Biomedical Applications Team at Research Triangle Institute (RTI) in obtaining widespread utilization of NASA technology is to direct its efforts primarily to solving problems that involve the introduction of such products.
This emphasis on achieving widespread utilization by commercializing NASA technology is reflected in the methodology of the Biomedical Applications Team program. The RTI team methodology is built around the following four activities: (1) the identification of medical problems and needs and potentially applicable NASA technologies that together constitute a new medical product opportunity; (2) screening of opportunities to identify those that represent potentially successful commercial products; (3) the development of commercialization strategies that take into account any necessary adaptation of NASA technology, evaluations and clinical trials, FDA regulations, manufacturing, marketing systems, and required funding; and, (4) implementation and monitoring of commercialization strategies.

The RTI Biomedical Applications Team is a multidisciplinary team of engineers and scientists. Their educational backgrounds are physiology, biophysics, engineering, biochemistry, and biomedical engineering; their experience includes basic and applied research, development, and marketing.

CONCEPTUAL FRAMEWORK

A conceptual framework for medical technology transfer is presented diagrammatically in Figure 1. The framework is basically a bipolar, donor-recipient model for technology transfer. The role of the donor, in this case NASA, is to reveal, disseminate, and promote technology. The role of the recipient, the medical community, is to seek out, evaluate, and utilize technology.

As explained in the Introduction, the primary thrust of the Biomedical Applications Team program is to transfer technology by the introduction of new and improved medical products. Thus, a manufacturer of those products is included in Figure 1. Medical technology transfer normally involves the identification of a medical problem or need within the medical community. In response, NASA recognizes the relevance of specific aerospace technology and makes that technology available. The manufacturer designs, develops, evaluates, and markets a new or improved medical product that incorporates the aerospace technology and that represents a solution to the medical problem or need.

The purpose of the transfer agent* is to plan, stimulate, and facilitate such technology transfer. This is the role of the Biomedical Applications Team.

Research into the process of medical technology transfer at the Syracuse University Research Center has concluded that the donor, recipient, and manufacturer are frequently at cross purposes. The recipient is primarily and appropriately concerned only with solving a problem. The manufacturer by necessity is concerned with introducing a commercially viable product. And, the donor frequently obtains only satisfaction as reward for involvement in the transfer process. It is the task of the transfer agent to bring the donor, recipient, and manufacturer together in such a way that each views successful technology transfer as the primary objective. Completeness of the transfer effort must be a major goal for all parties involved.

The specific role of the transfer agent depends upon the motivation, competence, and organization of the donor, recipient, and manufacturer. NASA is highly motivated to transfer aerospace technology to applications in non-space-related fields. Further, its organization is structured to facilitate the development of sophisticated and advanced technology. NASA's understanding of the medical industry and clinical medicine, on the other hand, is not extensive. The technological competence of the recipient is highly variable. Many medical researchers in large medical centers and teaching hospitals are technologically competent; the physician in clinical practice, in general, will not be technologically competent. The manufacturer of medical products may have a long and successful history of developing and marketing medical products or may be a small aggressive company exhibiting innovative behavior but lacking relevant experience. It is the role of the Biomedical Applications Team to recognize the strengths and weaknesses of each participant and to supply the motivation, competence, and institutional linkages to ensure success.

Technology will be interpreted as including all of the skills, techniques, and understanding as well as the materials, devices, and hardware that make up a specific technology. Technology transfer as used throughout this paper will refer specifically to "horizontal" technology transfer. That is, the transfer of technology from one situational context—the one for which the technology was originally developed—to another situational context. This transfer will normally result in either a modification of the technology or a change in the situational context to which it is transferred.

Rutten and Hayami have defined three levels at which technology transfer can occur. These levels are:

- **Level 1: Material Technology Transfer.** This involves the transfer of hardware, unmodified, from one situational context to another.
- **Level 2: Design Technology Transfer.** In this case, both hardware and software may be transferred for the purpose of imitating the original technology with some modifications for a new application.
- **Level 3: Capacity Technology Transfer.** This level involves the transfer of knowledge and ability so that the recipient can generate his own technology.

In medical technology transfer, there are only a
few instances in which level 1, material, transfers occur. The transfer of physiological electrodes developed for use in space vehicles to use in clinical medicine represents a level 1 transfer. Most medical technology transfers are level 2 and level 3 transfers. The redesign of an aerospace component or system for application in medicine constitutes a level 2 transfer. The utilization of NASA-generated knowledge, techniques, and procedures in the development and design of a new medical product constitutes a level 3 transfer.

BIOMEDICAL APPLICATIONS TEAM METHODOLOGY

As noted in the Introduction and indicated in Figure 2, the activities of the Biomedical Applications Team can be separated into four phases. Within each of these phases of the program, the specific actions and responsibilities of the team are, to a certain extent, fixed. However, team methodology incorporates flexibility that allows it to respond appropriately to the specific characteristics of particular technology transfer cases.

Identification of Opportunities

The identification of technology transfer opportunities involves: (1) the identification of a medical problem or need; and, (2) the identification of relevant aerospace technology that solves the medical problem or satisfies the medical need.

The identification of medical problems occurs through the direct interaction between a team member and a researcher or physician within a medical institution. At present, the RTI team interacts directly with medical staff at 27 medical institutions throughout the eastern United States.

A study of medical technology transfer by the National Academy of Engineering has concluded that the recipient must take the lead in defining medical problems. This is consistent with the experience of the RTI team. As a result, the Biomedical Applications Team emphasizes obtaining complete and extensive descriptions of medical problems and needs from medical researchers and clinicians.

Certain medical institutions and medical professionals are more innovative than others. Research has shown that the first hospitals to adopt innovations are generally large medical centers or teaching hospitals geographically close to the place where the technology was developed. Further, those hospitals with highly trained medical staff tend to be more innovative. The "innovative elite" in medicine generally act to improve the quality of health care rather than to achieve maximum economic efficiency. Finally, once a hospital has adopted an innovation, the widespread use of that innovation is enhanced if the innovating hospital interacts frequently with other medical institutions.

The Biomedical Applications Team takes into account these factors concerning innovative behavior of the medical community in its problem identification activities.

There are indications that medical technology introduced in the past 10 to 20 years often has tended to increase the sophistication of medical diagnosis and treatment but has not contributed to a reduction in the cost of health care nor to increasing the quality of health care for the population as a whole. This indicates that there is an opportunity for introducing aerospace technology in a manner to reduce the cost of health care or at least assist in containing health care costs.

Technology relevant to medical problems and needs is identified by a variety of techniques. Once a medical problem or need is specified, a computerized information search of the aerospace literature is performed by one of the six Industrial Applications Centers (IACs). The RTI team utilizes the services of the IAC located in Research Triangle Park, North Carolina—the North Carolina Science and Technology Research Center. These computerized information searches identify information on potentially relevant technologies.

An additional approach to identifying aerospace technology is the circulation of Problem Statements to NASA Field Centers. Individual medical problems are concisely described in Problem Statements. Each Problem Statement is sent to NASA engineers and scientists working in areas related to the medical problem. Responses to Problem Statements from these engineers and scientists can lead to the identification of technological solutions.

Finally, the Biomedical Applications Team frequently contacts NASA scientists and engineers known by the team to have a strong interest in transferring technology to medicine. This is the most direct, efficient, and rapid approach to locating technology.

A medical problem in combination with a potentially relevant aerospace technology constitutes an opportunity for technology transfer. The next phase of the program is the investigation of factors that determine which opportunities are most likely to be successful.

Screening

Effective screening of opportunities enables the RTI Biomedical Applications Team to focus on those opportunities with the most promise for successful medical solutions and commercial products. In order to continue work on a particular opportunity, the team must determine that most of the following requirements are satisfied:

• The solution improves medical treatment or diagnosis or reduces the cost of health care;
• The solution is recognized by a medical mission...
agency and the medical community as a contribution to improved health care;
• The solution incorporates NASA technology or expertise;
• The market for the new or improved product justifies the required capital investment and production cost to the manufacturer;
• A manufacturer can be offered protection either by exclusive license or sudden entry of the product into the medical market; and,
• The solution represents a discrete, well-defined transfer of technology involving limited research and development effort.
These factors are evaluated by reviewing the biomedical literature, market surveys, interviews with industry representatives, and discussions with appropriate medical staff.

Development of Strategies

The development of strategy for successful technology transfer must take into account product development and marketing, clinical trials, acceptance by the medical profession, and identification of funding sources for the various tasks involved.

The previously mentioned National Academy of Engineering study of medical technology transfer reached some important conclusions concerning strategy for technology transfer. Successful technology transfer requires intimate and significant involvement of both the donor and recipient throughout the transfer process. Further, the involvement of industry throughout the transfer process is essential. Finally, the manner in which new technology is introduced to the medical field is a critical factor in its success.

The experience of the RTI Biomedical Applications Team has confirmed these conclusions and expanded upon them. Industry must be involved throughout the transfer process and must be brought into that process as early as is possible. Further, the involvement of industry will generally require some means for giving a specific manufacturer a proprietary position. This may involve either an exclusive license or sudden entry of the new or improved product into the medical market. Industry will view new product opportunities from the outside as being in competition with its own internally generated product ideas. This means that opportunities for technology transfer generated through the Biomedical Applications Team program will have to compete for industry capital and management attention.

The acceptance of a new product by the medical community involves a fairly specific sequence of events. Following development of the product it must be subjected to clinical trials. This must be followed by publication of the results by a recognized medical expert. Generally, the product must be exhibited at medical meetings. This sequence of events normally leads to physician acceptance.

Medical marketing and distribution frequently are not an integral function of medical product manufacturing firms. Thus, in addition to selecting and obtaining the participation of a medical product manufacturer, the team must also identify and bring into the transfer process an organization having the capability to market and distribute those products.

Each specific opportunity for medical technology transfer will offer a new set of barriers and strategic options. Thus, the formation of a strategy is not a repeatable and specific activity. It is in itself a problem solving effort. The most important common feature of strategy formation is thoroughness. All contingencies must be anticipated.

Implementation and Monitoring

Experience in the implementation of strategy has shown that the chance for successful technology transfer is increased by active involvement of the Biomedical Applications Team throughout the transfer process. By monitoring and coordinating the activities of the participants, minor problems can be prevented from becoming major obstacles.

Reports and documentation are an integral part of the team methodology; they are involved throughout the technology transfer process. Implementation of strategy is no exception; periodic status reports are issued informally to keep all participants informed. Upon completion of the transfer process, the team prepares a technology transfer report documenting all important aspects of the transfer process.

MEDICAL TECHNOLOGY TRANSFER EXAMPLES

Three examples of the transfer of aerospace technology to applications in medicine are presented to illustrate the transfer process. The specific cases presented were selected: (1) to illustrate material, design, and capacity transfers; (2) to elucidate the roles played by donor, recipient, and transfer agent; and (3) to emphasize other important aspects of technology transfer in medicine. Further, each case was selected such that the transfer process was typical of medical technology transfer at the material, design, and capacity levels.

Case 1: Body Surface Electrodes
(Material Transfer)

Commercially available body surface electrodes have been adequate for obtaining high quality ECG signals for several years. These electrodes, however, did not allow the long-term ECG monitoring required in NASA's ground-based tests of human subjects.

S. A. Rositano of NASA's Ames Research Center developed a flexible electrode which allowed continuous ECG monitoring for up to eight days with excellent results. His first attempts
involved suspending silver in a silicone rubber matrix. This system exhibited long term degradation of the lead wire to elastomer contact. A subsequent attempt involved the use of a silver-coated nylon net fabric similar to support hosiery in texture and finish. This material was both inexpensive and exhibited stable resistivity. The flexible material permitted construction of large electrodes that did not restrict normal skin movement. Lead wires were attached by riveting or conductive epoxy. Using these electrodes with a gel-impregnated porous paper, long term monitoring of subjects was successful.

The Stanford University Biomedical Applications Team and Rositano recognized the potential value of the NASA electrode to the medical field. Rositano was invited to present a paper on the NASA electrode at a conference at Stanford University. Approximately 200 representatives of NASA, industry, and the medical community had been invited. As a result of that conference and subsequent communications between a manufacturer and NASA, the flexible long-term monitoring electrodes were made commercially available. The manufacturer modified the material slightly to minimize offset potentials; otherwise, the commercial electrodes were the same as the NASA electrode.

Case 2: Biological Tissue Freezing System (Design Transfer)

The need to freeze, store, and subsequently thaw healthy tissue without damage is an important requirement. For example, transfusions of white cells are frequently used in the treatment of leukemia and a method of storing white cells is needed. Commercially available tissue freezing units damage a large fraction of the cells in tissue.

Cell damage in the freezing process is thought to result from a lack of precise control over the rate of cooling. At the tissue freezing temperature, the latent heat of the tissue is released and the rate of cooling is drastically lowered.

The RTI Biomedical Applications Team discussed this medical requirement in detail with an engineer and medical researcher at the National Cancer Institute (NCI) in 1970. A Problem Statement concisely describing that requirement was written and circulated to NASA Field Centers. Engineers at NASA's Jet Propulsion Laboratory (JPL) recommended an innovative technological solution.

The concept proposed by JPL engineers is illustrated in Figure 3. This concept involves placing the biological tissue in close proximity to a sufficient quantity of liquid nitrogen to freeze the material very rapidly. Electrical resistance heating elements are placed between the container of biological tissue and the liquid nitrogen containers. By precisely monitoring the temperature at the surface of the tissue container, the amount of electrically generated thermal energy injected at the tissue-liquid nitrogen interface can be adjusted rapidly to give precise control of the tissue temperature. Two innovations are involved in this concept: (1) the approach to control of cooling rate; and, (2) precise temperature monitoring technology developed by JPL for use in space.

Initial evaluations of the concept by NASA engineers, the Biomedical Applications Team, and NCI were positive. Because it is located close to NCI, NASA's Goddard Space Flight Center was selected to design and fabricate a prototype tissue freezing unit for evaluation at NCI. Experiments in freezing and thawing human and animal tissue at NCI indicated that the NASA freezing unit could control freezing rates and that stem cells and white cells could be frozen and thawed with little cell damage.

Following validation of the freezing concept, JPL engineers discussed the freezing unit, its success, and its potential applications with a number of manufacturing firms. At present, JPL, with significant funding from industry, is conducting R & D to better understand the freezing process and to generate data for designing freezing units for specific applications.

Case 3: Clinical Information System (Capacity Transfer)

For a number of years, Duke University Medical Center staff have been developing a clinical information system with the objective of improved medical care for patients with ischemic heart disease. This medical information system contains the medical histories of over 4,000 Duke University Medical Center ischemic heart disease patients. Information on disease state, medical treatment, and patient response as well as information on the patient's lifestyle are stored. A physician at Duke University Medical Center can obtain medical histories on a specific patient profile that matches a patient presently being treated. For example, the physician can obtain medical treatments and patient responses for patients in a particular age group, with certain smoking habits, and with particular disease symptoms. The system is proving to be a significant asset to the medical center staff.

Early in the development of this information system, C. F. Starmer, Duke University Medical Center, was attempting to develop a computer-based system to identify and track the movement of nodes in the coronary arterial trees recorded in biplane cineangiograms. Discussions between Starmer and the RTI Biomedical Applications Team identified the image processing work at JPL as technology relevant to Starmer's investigations. The RTI team was able to assist Starmer in obtaining a summer fellowship at the Jet Propulsion Laboratory in 1970. As a result of his summer fellowship at JPL and his continued communications with NASA engineers, Starmer became knowledgeable of NASA image processing technology which over a period
of years was introduced into the medical center clinical information system. Specifically, NASA technology contributed to: (1) an easy-to-use mechanism for inputting and storing graphic data; and (2) a data storage system that facilitates the use of accumulated patient data to develop meaningful prognoses.

MEDICAL TRANSFER CASE ANALYSIS

Examples of material, design, and capacity technology transfers in medicine have been presented. Understanding of the technology transfer process and of the participants' roles in that process is enhanced by considering the relative involvement of the participants in these three examples as summarized in Table 1.

TABLE 1
MEDICAL TECHNOLOGY TRANSFER CASE SUMMARY

<table>
<thead>
<tr>
<th>Case Number</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of Transfer</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Transfer Agent Involvement</td>
<td>M</td>
<td>H</td>
<td>L</td>
</tr>
<tr>
<td>Donor Involvement</td>
<td>H</td>
<td>H</td>
<td>L</td>
</tr>
<tr>
<td>Recipient Involvement</td>
<td>L</td>
<td>H</td>
<td>H</td>
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Notes: H—High level of involvement
M—Moderate level of involvement
L—Low level of involvement

Transfers at the material level within the context of applying aerospace technology in the medical field are infrequent. Even in the case presented, body surface electrodes, the technology was modified before becoming a commercial product. The involvement of the recipient, the medical community, was to confirm the medical utility of the NASA electrode. On the other hand, the involvement of the donor appears to have been relatively high in that NASA was involved in developing the electrode and in transferring required data and information to the manufacturer. The involvement of the transfer agent was to identify, in collaboration with the donor organization, the potential for technology transfer and to facilitate communications between NASA, the medical community, and industry. This is estimated to have been a moderate level of involvement.

The second example, the biological tissue freezing system, is clearly a design transfer. A significant development, design, and fabrication effort was required in building the prototype units. This effort was performed by NASA and constitutes a high level of donor involvement. The recipient, NCI, identified the requirement for the system, specified functional characteristics of the freezing unit, acted as consultant to Goddard Space Flight Center during development and design of prototypes, and evaluated the system through extensive experimental work. This certainly constitutes a high level of recipient involvement. The transfer agent, the RTI Biomedical Applications Team, was involved throughout the transfer process in communicating the medical requirements to NASA, in communicating potential solutions to NCI, in coordinating the collaborative effort between NASA and NCI, in avoiding potential barriers in the transfer process, and in documenting the process and the transfer. During the prototype evaluation at NCI, the medical researcher who had worked with the team in specifying the medical requirement left NCI and the experimental evaluation was temporarily terminated. Because of the continued involvement of the RTI team and the commitment to the project by other individuals at NCI, the evaluation was continued after a relatively short delay. It is judged that the involvement of the donor, recipient, and transfer agent were high throughout the transfer process, and further, that this level of involvement was critical to the success of the transfer process.

Case No. 3, clinical information system, is an excellent example of a capacity transfer. The involvement of the transfer agent, the RTI team, was low. That involvement was assistance to Starmer in obtaining a summer fellowship at JPL. The involvement of the donor, NASA, was likewise relatively low. On the other hand, the recipient was intimately and extensively involved in NASA's image processing technology and in applying that technology in the clinical information system over a period of years.

The nature of material transfers as illustrated by the body surface electrode case can be characterized as a response by the donor to a transfer opportunity. Identifying such opportunities is highly dependent upon the presence of individuals aware of both medical requirements and technologies available in donor organizations. Marketing is the major activity in material transfers.

Design and capacity transfers are a long-term process involving years of effort. Significant commitments of resources by the donor, recipient, or industry are required.

A high level of involvement on the parts of donor, recipient, and transfer agent are critical to the success of design technology transfers. In the case of capacity transfers, the recipient bears the burden of the effort.

In each of the three cases presented, the first step in the transfer process was the identification or confirmation of a medical requirement. Thus, these transfers can be characterized by "need-pull" as opposed to "technology-push."

In both design and capacity transfers, a transfer agent is essential either within the donor organization or having a strong association with the donor organization. The NASA-sponsored Biomedical Applications Teams appear to be fulfilling this role with increasing effectiveness.
CONCLUSIONS

NASA's Biomedical Applications Team program is effectively transferring aerospace technology to applications in medicine. These transfers are occurring at the material, design, and capacity levels with most of the activity occurring at the latter two levels.

NASA's Technology Utilization Program objectives and the present state of health care delivery have guided the Biomedical Applications Teams in establishing program emphasis. That emphasis is upon transferring technology via the introduction of commercially available, medical products that incorporate NASA technology. Further, emphasis is upon applying technology to improve medical diagnosis and treatment or to contain medical costs.

Successful technology transfer in medicine requires a continuing involvement of the donor, recipient, and transfer agent in the transfer process. Additionally, industry must be involved early in the transfer process when a commercial product is involved.

Successful technology transfer is, in general, a long-term process. The commitment of significant resources is required by the donor, recipient, or industry on a long-term basis.

Continued study of horizontal technology transfer in medicine and within the context of commercialization will result in greater program productivity. Increased understanding of government-industry linkages formed in technology transfer is essential.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge the assistance of Dr. W. H. Clingman, W. H. Clingman and Co., Inc., Dallas, Texas, in clarifying industry involvement in and marketing aspects of medical technology transfer.

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ILLUSTRATIONS

Figure 1. Conceptual Framework.

Figure 2. Biomedical Applications Team Methodology.

Figure 3. NASA Tissue Freezing Unit.