

## BACKGROUND

The Federal Aviation Agency is responsible for prescribing standards, rules, and regulations to promote the flight safety of civil aircraft in air commerce. In meeting this responsibility, FAA conducts medical research aimed at (1) eliminating, insofar as possible, the human factors that are causes of accidents in civil aviation and (2) developing means by which persons involved in accidents can survive. The current annual cost of FAA's medical research program is about \$2.8 million.

The Public Health Service is responsible for promoting protection of and improvement in the health of the people of the Nation. In meeting this responsibility, PHS conducts and supports research and training in medical and related sciences and in public health methods and administration.

The objective of FAA's research project on the aging of aviation personnel is to develop methods for measuring a person's physiologic age (age in functional capacity) as distinguished from his chronologic age (age in years). FAA believes that this project, being conducted at GCRI, will enable the Agency to establish standards based on functional age, instead of chronologic age, for the retirement or reassignment of aviation personnel.

In the FAA aging study, a group of approximately 550 persons is subjected to periodic examinations. FAA records show that the group includes pilots and air traffic controllers—many of whom are pilots. These persons are given a battery of tests in six general laboratories: Cardiovascular, pulmonary, neurological, pharmacology and biochemistry, behavioral sciences, and visual and auditory.

At June 30, 1965, FAA had spent about \$1 million, or about \$200,000 annually, for its aging study. FAA plans to continue this research for a total of 25 years. On the basis of the average yearly cost to date, FAA will expend approximately \$5 million on its aging research project.

PHS also is supporting a research project on the aging of aviation personnel. This study, being performed by the Foundation, is aimed at developing a practical and scientifically acceptable measure for the quantitative evaluation of functional deterioration of individual pilots. In the Foundation's study, examinations are given once every 3 to 5 years. The Foundation informed us that the group being examined consists of 225 commercial, military, and test pilots. The pilots are given a series of tests in four general laboratories: Cardiovascular, pulmonary, anthropometric and physical competence, and psychological, including the visual and auditory senses.

PHS has approved grants of \$1 million to the Foundation over an 8-year period extending through September 30, 1969. Moreover, the Foundation expects its aging research to continue for a total of 30 years. If PHS renews the grant for the additional 22 years at the present annual rate of about \$165,000, the Foundation's aging project will cost the Government about \$4.7 million.

#### NEED FOR BETTER COORDINATION BEFORE STARTING LONG-TERM MEDICAL RESEARCH PROJECTS

The Federal Aviation Agency is financing a long-term project for medical research on the aging of aviation personnel. In addition, the Public Health Service is supporting a long-term project on aging of pilots. These projects, currently funded at annual rates totaling about \$365,000, will cost the Government \$9.7 million if they are financed to completion. In our opinion, the need for FAA to undertake a separate long-term project on the aging of pilots and other aviation personnel is questionable because (1) the general objectives of each project are similar and each project is based on the same planning study and (2) the information being developed under the PHS-supported research project could, it seems, have been adapted to meet the objectives of the project which FAA had recently initiated.

FAA originally awarded a contract to the Foundation for a research planning study of aging criteria. The Foundation stated that this study was necessary before any long-term project on aging could be effectively initiated. In a progress report on the planning study, issued to FAA before the Agency had made the first examinations in its long-term project, the Foundation indicated that it intended to apply to PHS for a grant to support a long-term project on the aging of pilots. Subsequently, FAA began making examinations in its long-term project on the aging of aviation personnel and PHS approved the grant application submitted by the Foundation.

unnecessary duplication of efforts are either non-existent or inadequate. In our opinion, this recommendation by the GAO staff further indicates a lack of understanding of the PHS processes for reviewing research grant proposals and the controls built into such processes which not only serve to avoid unnecessary duplication of effort but also to disseminate research findings to the scientific community.

#### DIFFERENCES IN PURPOSE

As stated above, PHS disagrees with the report's assertion that both PHS and FAA are conducting or supporting these studies for the same purpose.

The FAA medical research program is an in-house research program conducted for the purpose of meeting specifically defined program needs associated with FAA missions. The Public Health Service extramural medical research program, which is supporting the Lovelace Foundation grant, is a nationwide program of basic medical research conducted by thousands of independent researchers whose projects must survive a highly competitive process of dual scientific review in order to be funded. The purpose of the Public Health Service extramural research program is to increase the store of scientific knowledge bearing on problems of human health.

Thus, there is a basic difference between the medical research missions of FAA and PHS, and therefore there is substantial difference between what each agency is trying to accomplish in the conduct of these research projects.

One major concern of FAA is flying safety. As the number of aging civilian pilots grows, FAA naturally becomes concerned with the question of when does a person, because of aging, become functionally incapable of safely operating an airplane. The FAA also has a serious interest in reassessing its retirement policy in regard to FAA air traffic controllers. At present, controllers are under the regular Civil Service retirement system, but FAA has reasons to believe that a more flexible retirement policy is needed. The FAA-CCRI project is specifically aimed at this problem. It will result in the development and maintenance of standards which can be widely used in evaluating the capability of older aviation personnel to carry out their duties properly and safely.

On the other hand, the Public Health Service is interested in aging as a health problem. It is a stage of life devolving from a series of processes and body changes of which comparatively little is known. The PHS, through the Aging Program of NICHD, is attempting to increase the store of scientific knowledge concerning the aging process in humans, and to apply this knowledge to improve health services and resources for all Americans. The aim of the PHS-supported Lovelace project is to learn more about the process of physiological aging, and its progress in relation to chronological age.

On page 2, the report states "PHS is also supporting a research project on the aging of pilots. This study is being performed by the Foundation and is interested also in developing methods of measuring differences between a pilot's functional age and his chronological age." Actually the PHS study is not concerned with the aging of pilots as such but with human aging in general. The grant applications submitted on HD-00518 do not refer to the study as one dealing exclusively with the aging of pilots.

In 1964, the Foundation's application stated "It might at first sight be thought that the best approach to the investigation of the effects of aging in this professional group would be to study their actual performance as pilots. However, since our primary interest is not to assess pilot performance, the study of physiologic aging of this professional group in the laboratory is more apparently advantageous."

In the "conclusion" of the report, it is implied that NIH and FAA are "interested in a solution to the same medical problems." This conclusion is incorrect. The program on Aging of NICHD-NIH is interested in supporting any and all research which will further the understanding of the basic processes of aging in normal humans. Both the Lovelace and the FAA effort may, however, contribute to two general goals; first, the discovery of fundamental scientific information about the course of aging in humans; and second, the development of a "physiological age rating" system which would permit improvements in retirement policies for pilots and other aviation personnel. The Public Health Service is interested in the second objective only as it may contribute to the first objective. This is evident from the Study Section's comments on Lovelace's 1964 application for a grant;

"The potential contribution of this program is great, primarily because it promises to provide a large mass of well-collected data changes in functions with age—data of a kind which are presently either spotty or non-existent.

FAA projects are, in fact, quite different. The most salient differences apparent in the two projects include these:

1. FAA conducts a rather elaborate neurological examination of each patient, including electroencephalograms, whereas Lovelace does not.
2. FAA conducts rheocephalographic measurements (measurements of electrical impedances of the head which reflect aspects of blood flow in the brain), whereas Lovelace does not.
3. FAA conducts far more elaborate studies of vision and visual function and perception than does Lovelace.
4. FAA makes a more elaborate study of the retinal fundi than does Lovelace, and Lovelace does not take microphotographs of the retinal fundus, while FAA does this biennially.
5. FAA takes a number of biochemical and metabolic measures, while Lovelace does no work in this area.
6. FAA studies autonomic nervous system and dynamics, using the pupillary response and highly sophisticated techniques. Lovelace does not take autonomic nervous system measures.
7. Lovelace studies a variety of behavioral performance capacities rather elaborately. The FAA measures of behavioral capacities is far less elaborate, and the measurements of the two organizations are founded on rather different theoretical assumptions. The magnitude of the Lovelace effort in the behavioral capacities areas is unusual in medical research and represents a major point of interest in the Lovelace work.
8. The two organizations utilize different measures of personality structure.
9. Both organizations emphasize pulmonary and physical work studies, although their methods differ considerably.
10. Both organizations emphasize cardiovascular measures, although the two sets of measures differ considerably. For example, both organizations are working with ballistocardiography, but their approaches, equipment and methods differ considerably, and the FAA system is more elaborate. Lovelace is taking plethysmographic measures of non-cerebral peripheral blood flow, and is using radioisotopes in tracing blood flow, whereas FAA is not doing either of these things.
11. Lovelace measures lean body mass of its subject and takes a battery of anthropometric measures. These things are not done at FAA.
12. The subject-populations studied by the two organizations appear similar but actually differ considerably. Lovelace has limited its pilot sample to civil air-transport and some military pilots, who are a superselect group. FAA-GCRI studies all classes of civil aviation medical certificates, most of whom are not pilots, but are air traffic controllers. FAA also studies some older, former aviation personnel.
13. FAA subjects are examined more frequently (each year or each second year) than the Lovelace subjects, who are to be examined once each five years. Lovelace intends to examine 500 men periodically. FAA has examined about 1,500 subjects at least once, although it appears that a somewhat smaller number will be examined on a periodic basis.

There are several other differences of this nature which could be added to this list, but these are the major ones.

#### DUPLICATION OF RESEARCH EFFORT

In general, the report demonstrates that the GAO investigators did not understand what is and what is not duplication in medical research. GAO staff was assured by NIH staff that the possibility of unnecessary duplication of effort was considered as the grant was reviewed, and that it was the determination of the reviewers and NIH staff that the Lovelace effort did not duplicate research conducted by FAA, or NIH's Gerontology Branch or other research being conducted in Europe. Rather, it was the determination of these reviewers that the Lovelace project was quite unique.

Further, the report indicates a lack of understanding of NIH's processes for reviewing research grant proposals which have built-in controls to prevent unnecessary duplication of effort.

One control is found in the heavy reliance upon peer judgment. All grant applications are reviewed by a competent group of researchers who are working or are familiar with the discreet field or discipline in which the proposed research will be conducted. These experts are aware of the state of the art in the field as well as ongoing work. They generally are quite critical of unnecessary duplication. Dr. John Sherman, NIH Associate Director for Extramural Programs,