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Criteria for Flight Crew Participation in Medical Procedures

This question is older than the space program, and has hitherto been solved empirically. The crew position tends to be: do only what's necessary to keep us alive and well. The medical position tends to be: do any procedure which results in more data.

The nature of the Shuttle program, and the pending selection of new astronauts, make it timely to set down the criteria whereby questions of this kind can be resolved.

Crew objections to proliferating medical procedures are of three kinds. First is that they occasionally interfere with the training for, and conduct of, space flight. The second is the basic disinclination to overexpose oneself to procedures that might result in disqualification - especially if the basis is a poorly understood research procedure whose results are controversial in significance. The third is the risk of bodily harm, temporary or permanent.

The medical rejoinder is that the crewman, when he accepted the job, implicitly agreed to be a medical subject, and was aware that it was a requirement to obtain medical data on space crews.

That is a true statement. Another true statement is that crewmen, like any other human beings, are required to give their informed consent as to the nature of, reasons for, and risks of an experiment in which they volunteer as subjects on a case-by-case basis. Our job is to ~~rewrite~~ reconcile the two statements. The question is: which medical procedures must crewmen undergo as a condition of employment, and which are voluntary?

There are four pertinent categories of medical procedures involved.

1. Medical procedures required to determine and maintain the crewman's fitness for duty. This includes diagnostic and treatment procedures for illness if the illness is disqualifying, and includes inflight measurements required to evaluate crew health. These are clearly mandatory. The corresponding responsibility of the

physician is to limit the tests used to those which have a documented screening or diagnostic value.

2. Medical monitoring for safety purposes, such as is done in altitude chambers, and in some cases, spacecraft. The purpose here is really to use the crewman as an indicator of a system problem (e.g. loss of pressure). Provided the data are really needed for that purpose, this category is also mandatory.

3. The collection of medical data to document and understand changes in body function which result from space flight. This category represents the meat of the medical research program. It includes flight experiments and ground data collection in direct support of flight experiments. The distinction from 1. and 2. is that you don't need the data to conduct the ongoing mission; you only need it for the experiment. The crewmember's obligation to submit to the experiment is a condition, not of his employment, but of his assignment to the relevant flight, and has to be reconciled to the principle of informed consent. This can be done in the following way.

There are two principal characteristics of inflight medical experiments to which a value can be assigned: relevance and risk.

Relevance means the degree to which the results of the experiment affect subsequent space flight operations, or its importance to ongoing programs. An example of relevant experimentation is the elucidation of motion sickness mechanisms. Historical examples include the measurement of exercise capacity on Skylab (for determining the feasibility of EVA) and lower body negative pressure testing (for predicting reentry tolerance.) The Project Mercury flights per se were relevant medical experiments. Calcium balance determination on shuttle is of considerably less urgency because even the most conservative extrapolations from Skylab data predict to operational limitations short of approximately 9 months. Some proposed experiments have no known operational value. Thus, relevance can be categorized as high, low or unknown.

Risk means the likelihood of bodily harm to the subject as a result of the experiment. In space flight it has the additional shade of meaning of impairing the individual's fitness for his job. Semantics make the degree of risk difficult to define, except by comparison. I propose that "high risk" means a chance of harmful consequences in excess of the normal diagnostic or treatment procedures

carried out by physicians without informed consent. Whether a procedure is worth the risk depends on what is gained by it, and cannot be computed by formula. But it is fair to say that any high-risk procedure requires that the subjects be volunteers; and that implies that they may refuse to volunteer without compromising their employment status.

4. Collection of medical baseline data not in association with a space flight experiment. These studies are aimed at exploring the one-G physiology of humans in areas relevant to space flight, or to evaluating surrogates of space flight such as bed rest. Originally, such studies were undertaken to anticipate the as-yet unknown effects of weightlessness. Now they are more likely to be used to validate the surrogate, e.g. to answer the question, "Is bed rest really similar to weightlessness?" Such questions are of practical importance only if the surrogate is to be substituted for weightlessness in new or extensive ways.

The only logical argument that can be made for using flight crews as subjects in ground-based "background" studies is a statistical one. A major problem in flight experiments to date has been the small sample size. Statistics say that the smaller the sample, the larger must be the deviation in the measured characteristic before a statistically significant change can be inferred. A mathematically valid way of getting around this problem is the use of paired samples; i.e., using the experimental subject as his own control. Thus, instead of having to compare the subject's inflight calcium excretion (for example) with the national average you compare it with his own preflight value. This makes it easier to tell whether space flight changed his calcium excretion. But it doesn't tell you whether the average American's excretion would have changed, because you didn't treat the crew statistically as a sample of that population. So, what you gain in sensitivity you lose in the ability to generalize your results.

Similarly, using the astronaut population as a sample for ground-based research will teach you no more about the population's response to the test than will any other sample -- less of the present astronaut population is not representative of the general population or of the future makeup of crews. All it's good for is to state with greater sensitivity whether that particular sample responded differently to the ground test than they did in flight. This is attractive because we don't, at the moment, have inflight data on a broader sample. But the test won't tell you whether girls, old folks, etc. will respond the way your astronaut sample did, either to flight or to the test. The information simply isn't in the data, because the sample is not representative of the population of interest.

A final category of baseline testing is the long-term follow-up testing of individuals who have flown, in the hope that long-term changes as a result of flight will be elicited. The value of such studies is apt to be in what they don't discover.

The implication of the above discussion is that the use of crew personnel as subjects for baseline studies is largely a matter of convenience. Such studies should be voluntary.

I would summarize my recommendations as follows: The following categories of medical procedures involving flight crew personnel exist:

1. Medical procedures required to determine and maintain the crewman's fitness for duty. These are mandatory for all crewmen.

2. Valid medical safety monitoring procedures. These are mandatory for all crewmen.

3. Space flight experiments, including the necessary ground data collection. These fall into three groups.

   a. High risk. These are voluntary.

   b. Low risk, high relevance. These are mandatory upon crewmen assigned to the flight(s) for which the experiments are approved.

   c. Low risk, low or unknown relevance. These experiments should be assigned to dedicated life sciences missions only, and are mandatory upon the crew of such flights. Voluntary on other flights.

4. Ground based baseline studies not part of an approved flight experiment. These are voluntary.