

UNCLASSIFIED

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

12

REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER SAM-TR-81-293	2. GOVT ACCESSION NO. AD-A127532	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) MEDICAL STANDARDS FOR EXPERIMENTAL HUMAN USE IN ACCELERATION STRESS RESEARCH	5. TYPE OF REPORT & PERIOD COVERED Final Report 1 June 1977 - 1 March 1981	
	6. PERFORMING ORG. REPORT NUMBER	
7. AUTHOR(s) James E. Whinnery Kent K. Gillingham	8. CONTRACT OR GRANT NUMBER(s)	
9. PERFORMING ORGANIZATION NAME AND ADDRESS USAF School of Aerospace Medicine (VNB) Aerospace Medical Division (AFSC) Brooks Air Force Base, Texas 78235	10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS	
11. CONTROLLING OFFICE NAME AND ADDRESS USAF School of Aerospace Medicine (VNB) Aerospace Medical Division (AFSC) Brooks Air Force Base, Texas 78235	12. REPORT DATE	
	13. NUMBER OF PAGES	
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office)	15. SECURITY CLASS. (of this report)	
15a. DECLASSIFICATION/DOWNGRADING SCHEDULE		
16. DISTRIBUTION STATEMENT (of this Report) Approved for public release; distribution unlimited.		
17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)		
18. SUPPLEMENTARY NOTES		
19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Acceleration Human Use Medical Standards		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Acceleration research is necessary to ensure optimum protection for individuals flying high performance fighter aircraft. Volunteers exposed to high sustained +Gz stress must be carefully screened to assure that no one is at increased risk for G-induced trauma. Rigorous medical standards for qualifying research subjects must be established and followed. Careful documentation of G-related symptoms and physiologic disturbances enhances the safety aspects of human experimentation. The current medical standards and clinical diagnostic testing		

AD A127532

DTIC FILE COPY

DTIC
ELECTE
MAY 03 1983
S E D

DD FORM 1473 1 JAN 73

EDITION OF 1 NOV 68 IS OBSOLETE

UNCLASSIFIED

83 05 02 094

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

UNCLASSIFIED

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

20. ABSTRACT (Continued)

used to screen volunteer subjects at the USAF School of Aerospace Medicine are reviewed along with the symptoms which have resulted over a 3-year period of high sustained +G_z stress exposures.

Accession For	
NTIS GRA&I	<input checked="" type="checkbox"/>
DTIC TAB	<input type="checkbox"/>
Unannounced	<input type="checkbox"/>
Justification	
By _____	
Distribution/	
Availability Codes	
Dist	Avail and/or Special
A	20



UNCLASSIFIED

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

Medical Standards for Experimental Human Use in Acceleration Stress Research

JAMES E. WHINNERY, PH.D., M.D. and KENT K. GILLINGHAM, M.D., PH.D.

*Clinical Sciences Division, and Crew Technology Division,
USAF School of Aerospace Medicine, Brooks AFB,
Texas 78235*

WHINNERY, J. E., and K. K. GILLINGHAM. *Medical standards for experimental human use in acceleration stress research.* *Aviat. Space Environ. Med.* 54(3):241-245, 1983.

Acceleration research is necessary to ensure optimum protection for individuals flying high performance fighter aircraft. Human volunteers exposed to high sustained +Gz stress must be carefully screened to assure that no one is at increased risk for G-induced trauma. Rigorous medical standards for qualifying research subjects must be established and followed. Careful documentation of G-related symptoms and physiologic disturbances enhances the safety aspects of human experimentation. No severe or life-threatening incidents have occurred. A number of symptoms resulting from +Gz exposure have been documented with loss of consciousness being the most frequently documented symptom. The most frequent medical reason for disqualifying an individual volunteer from participation in the acceleration program was because of irregularities noted on spinal x-rays. The current medical standards and clinical diagnostic testing used to screen volunteer subjects at the USAF School of Aerospace Medicine are reviewed along with the symptoms which have resulted over a three year period of high sustained +Gz stress exposures.

THE USAF SCHOOL of Aerospace Medicine (USAFSAM) has had a man rated human centrifuge since 1963. Technologic advancements in aeronautics and engineering have continually made aircraft capable of attaining higher and higher acceleration levels. These technical advancements put severe demands on the individuals piloting these high performance aircraft; therefore, the USAFSAM centrifuge has been utilized to investigate human G-tolerance limits and the physiologic response to G stress. Investigation in these areas has continually required the use of volunteer human

subjects since animal models have absolute limits when being used to extrapolate to in-flight human performance. Additional benefits of the human centrifuge are G training and orientation to the high G environment. Trainees include aircrewmembers who fly in high performance fighter aircraft, not only pilots and navigators, but also flight surgeons who want to know their G tolerance and to gain confidence in their ability to perform appropriate protective straining maneuvers. Orientation to the high +Gz environment is important to flight surgeons who must care for those aircrewmembers exposed to G stress and investigate aircraft accidents and incidents which involve questions of acceleration stress. Physiological training officers also require a detailed knowledge of acceleration physiology and the various methods and equipment used to enhance G tolerance. Finally, aeromedical researchers working in hypergravitation frequently consider that a first-hand appreciation of the problem can be achieved only by experiencing G stress. The USAFSAM centrifuge has also been used in the medical evaluation of aircrewmembers with medical irregularities that might be exacerbated during +Gz stress. Since these reasons all necessitate human exposure to acceleration stress, strict medical precautions must be taken to ensure minimal risk to the individuals exposed to G stress, especially the volunteers used in experimental research.

Although the basic concern for absolute well-being is the same, fundamental differences exist between human exposure to G stress for reasons of training, medical evaluation, orientation, and exposure as a research subject. Use of human volunteer subjects for research generally requires long-term intermittent exposure to G stress. Much of the time the G levels are very high and sustained until the individual is completely exhausted. Training, orientation, and medical evaluation, on the

The research reported in this paper was conducted by personnel of the Clinical Sciences and Crew Technology Divisions, USAF School of Aerospace Medicine, Aerospace Medical Division, AFSC, United States Air Force, Brooks AFB, Texas. The voluntary informed consent of the subjects used in this research was obtained in accordance with AFR 169-3.

HUMAN ACCELERATION STANDARDS—WHINNERY & GILLINGHAM

other hand, generally require only one or two exposures. Physiologic monitoring of the experimental subject frequently puts an additional burden of stress on the research subject that is not required of the other individuals exposed to G stress. For these reasons, a rigorous medical evaluation has been required for individuals volunteering to be exposed to G stress as experimental subjects. It is the purpose of this report to describe the current medical requirements and standards used at USAFSAM to select individuals who are at minimum risk for membership on the acceleration stress panel.

Requirements for All Acceleration Exposures

Anyone who is to be exposed to levels of increased acceleration must have completed a USAF Flying Class II physical examination (Air Force Manual 160-43, Chapter Four, Medical Standards) within the preceding 12 months. All actively flying USAF aircrewmembers will have successfully passed this examination or have received an appropriate waiver. The Flying Class II examination includes a complete medical history and physical examination in addition to the routine clinical laboratory tests (blood and urine), 12-lead electrocardiogram, and chest X-rays (PA and lateral). Prospective panel members are not required to actually pass all the USAF Flying Class II standards. The examination does serve to document the individual's medical condition, such that the medical consultant and medical monitors responsible for the health and safety of all of these subjects-to-be, can determine their suitability for exposure to G stress. Certain medical conditions will disqualify an individual for USAF Flying Class II duties but not for duties on the USAF acceleration stress panel. Among these are conditions of the eye, such as a moderate degree of myopia and defective color vision. This ensures that many motivated subjects with benign visual disorders will not be excluded from participation.

High +Gz Acceleration Stress Panel Members

Subjects being considered for membership on the USAFSAM high +Gz acceleration stress panel will have an exercise tolerance test using the USAFSAM treadmill protocol (speed 3.3 mph with 5% grade increased for each 3 min of successive exercise) in addition to anteroposterior and lateral X-rays of the cervical, thoracic, and lumbar spine. These are performed after it has been determined that: 1) the individual has an acceptable G

tolerance as measured by the standard USAFSAM medical evaluation protocol (12) including medical test profiles of rapid onset rate (1 G/s) up to +7 Gz for 15 s with anti-G suit; and 2) the patient remains motivated for further exposure to G stress.

We have recently required the addition of an echocardiogram to be completed prior to final acceptance on the USAFSAM acceleration panel. The entire mandatory medical evaluation and the order of completion are shown in Table I.

Rationale for Requirements

The object for any and all requirements for medical testing is to assure the continued good health of subjects exposed to acceleration stress. The welfare of the subject cannot be overemphasized. The acceleration research performed at USAFSAM is in support of those who fly, specifically, aircrew of fighter-type aircraft. Our subject population, therefore, should be selected to simulate as closely as possible this aircrew population. Current use of qualified aircrew is not possible on a routine basis. Since continued performance of flying duties requires successfully passing a Flying Class II physical yearly, our subjects are required to meet the same standards with few exceptions. Even though color vision and visual acuity standards are not required to be rigorously met, myopia requiring more than 5.00 diopters of correction in any meridian is disqualifying, since individuals with high myopia may have a tendency to develop retinal detachments (1).

The individuals on the acceleration stress panel generally are all USAF active duty personnel stationed at Brooks AFB. Although we are not required to have an age limitation, we have not used individuals age 40 yr or above. Most of the subjects are young airmen in the early to mid-twenties. The mean age of the panel members over the past 3 yr was 28 yr. With this young age group, the use of the treadmill exercise test becomes an unreliable screening test for the presence of coronary artery disease (4,10). We recognize that any change in the S-T segment or T-wave during exercise is associated with a high probability of being a false positive test. Since we are dealing with an untrained individual in whom we have not invested considerable time or resources, we consider a positive treadmill test to be disqualifying. If a very unique individual with specific talents for enhancing a research project were to have a

TABLE I. MANDATORY MEDICAL EVALUATION FOR USAFSAM ACCELERATION PANEL MEMBERS.

1. USAF Flying Class II Physical Examination
 - a. History and Physical
 - b. 12-lead EKG
 - c. Clinical laboratory test (blood/urine)
 - d. Chest X-rays (PA and lateral)
2. Centrifuge Orientation*
 - a. Medical Evaluation Protocol (GOR, ROR and GOR with M-1/L-1)
 - b. Minimum G tolerance (ROR to +7 Gz X 15 s)
3. Maximal Treadmill Exercise Test
4. Echocardiogram (M-mode with 2-D echocardiogram if M-mode abnormal)
5. Complete Spine X-ray Series

*GOR - Gradual Onset Run (1G/15 s)
ROR - Rapid Onset Run (1G/s)

HUMAN ACCELERATION STANDARDS—WHINNERY & GILLINGHAM

positive exercise test, in light of the very high probability of false positivity, we would consider accepting him on the panel if the individual had a normal gated Thallium-201 myocardial perfusion study performed (11). False positive exercise tests may also not be "false" positive and, as described in a recent report on strenuous exercise and sudden death, certain abnormalities which can lead to sudden death can be identified using myocardial scintigraphy (2,9). The primary purpose of the treadmill exercise stress test is not for detection of individuals with S-T segment or T-wave changes, it is to assure a normal level of fitness, a normal heart rate response to exercise stress, and the absence of significant stress induced dysrhythmias. From previous work we know that, in normal acceleration panel members, centrifuge stress testing is more dysrhythmogenic than treadmill exercise testing (13); therefore, if a significant dysrhythmia is seen during treadmill testing, then its probability of recurring or worsening is high if the subject is exposed to high sustained +Gz stress.

The requirement for a complete cervical, thoracic and lumbar spine X-ray series (anteroposterior and lateral) is related to the severe head to foot spinal stress that occurs during +Gz stress. Evidence of degenerative disk disease, including Schmorl's nodes, is disqualifying. Also disqualifying are congenital or acquired anomalies of the vertebrae themselves, including transitional vertebrae, although minor degrees of spina bifida occulta (1 mm or less) may not be disqualifying. Each questionable case is reviewed with a radiologist, and disqualification for spinal abnormalities is generally based on the recommendations set forth by Kazarian (6).

A normal echocardiogram is now considered essential. The test is simple and without risk to the individual. A recent review of sudden and unexpected death in young athletes which occurred during or just after severe exertion revealed the most common cause of death to be hypertrophic cardiomyopathy (8). The structural cardiovascular disease seen in these athletes with sudden death was rarely associated with coronary artery disease and could only have been noninvasively found by means of echocardiography. No significant anatomic or pathologic findings were found in any other organ system in the athletes with sudden death, again emphasizing the importance of the heart in exertion-related sudden death in young, apparently healthy, individuals. Emphasis should also be placed on obtaining a detailed family history in light of these findings to assure no predisposition to familial cardiovascular disease.

Disqualification Experience

The past 2 yr of disqualifications (Table II) exemplify use of the described medical standards (with the exception of the echocardiogram, which was only recently required). This table does not include those individuals with gross disqualifications found during the Flying Class II physical. As can be seen from Table II, the major medical conditions resulting in disqualification were abnormalities found on spine series (eight subjects) and electrocardiographic abnormalities (four subjects). The electrocardiographic abnormalities consisted of one individual with an abnormal response (S-T segment depression) to treadmill exercise testing and three in-

TABLE II. REASONS FOR DISQUALIFICATION OF INDIVIDUALS VOLUNTEERING FOR ACCELERATION RESEARCH AFTER COMPLETING FLYING CLASS II PHYSICAL EXAMINATION (2-YR HISTORY).*

Reasons for Disqualification	Number of Occurrences
Medically Related:	(13)
Spinal X-rays	8
EKG/Arrhythmias	4
Excessive Myopia	1
Centrifuge Related:	(11)
Motion Sickness	5
Low G Tolerance	3
Loss of Consciousness	3
Subject Related:	
Lack of Motivation	(8)
Total	32

*Total number of individuals completing the Flying Class II physical examination was 81, resulting in 40% disqualification after the completion of the physical examination.

dividuals who developed significant stress dysrhythmias during +Gz stress after they had been accepted as members of the acceleration stress panel. Of the volunteers, five could not overcome motion sickness and declined to continue, and three others who suffered an uncomplicated loss of consciousness episode during +Gz stress also declined to continue. Three individuals were not allowed to be panel members because of their very low tolerance to G stress (they could not tolerate +7 Gz for 15 s after repeated training and multiple attempts to do so). Although motion sickness, low G tolerance, and loss of consciousness in these 11 cases could be classified as lack of motivation, they could be further identified as to a more specific reason for disqualification. There were eight other individuals who clearly were not completely motivated to participate in frequent strenuous +Gz exposure and declined continued participation. The 32 disqualifications represented 28% of the individuals who aspired to be on the acceleration panel during the 2-yr period (114 total applicants).

Acceleration Induced Symptoms

Over the past 3 yr of using these medical standards we have had no medical problems of consequence. We consider the lack of problems to be due to the cautious screening described above. In addition, caution during continued monitoring of human subjects being exposed to high sustained +Gz also prevents serious symptoms from evolving. Table III lists the established reasons for aborting a G-stress run on the centrifuge. Table IV lists

TABLE III. CRITERIA FOR ABORTING ACCELERATION RUN.

1. Loss of 100% peripheral lights or 50% central light
2. Heart rate >200 bpm
3. Significant cardiac dysrhythmia
a. Frequent PVCs (>5/min)
b. Multiform PVCs
c. Paired PVCs
d. Ventricular bigeminy/trigeminy
e. Ventricular tachycardia
f. Supraventricular tachycardia
g. Stress-induced bradycardia
4. Any unusual pain or other symptoms

HUMAN ACCELERATION STANDARDS—WHINNERY & GILLINGHAM

TABLE IV. TYPE AND NUMBER OF OCCURRENCES OF Gz-INDUCED SYMPTOMS OVER THREE YEAR PERIOD.*

Number of Occurrences	Symptom Description
16	Abdominal pain
16	Arm pain
1	Clonic movements
5	Disorientation, vertigo
3	Hyperventilation
67	Loss of consciousness
2	Loss of consciousness with severe convulsion
15	Neck pain
16	Petechial hemorrhages
2	Scrotal hematoma/discomfort

*This 3-yr period included exposure of 544 subjects on 2,066 separate +Gz stress exposures composed of 9,831 +Gz stress runs.

the type and frequency of all symptoms which have occurred over the past 3 yr during acceleration stress. These are the results from the exposure of 544 different individuals to 9,831 runs on the USAFSAM centrifuge.

Discussion

It is important to provide prospective panel members with accurate information regarding the potential hazards associated with high sustained G, and further to describe to them the actual symptoms and problems that have been experienced during past human experimentation. Table V shows the potential hazards that all subjects are currently briefed before being allowed to undergo any acceleration stress. Careful documentation of all symptoms associated with acceleration stress provides important information for clinicians in the field who see pilots exposed daily to G stress and also to researchers who are trying to optimize G-protective equipment and techniques (14). A comparison of the current potential hazards briefed to volunteer subjects (Table V) and the actual symptoms experienced (Table IV) reveals that adequate information is being conveyed to the volunteers. Review of the reasons for medical disqualifications reveals that a significant number of in-

dividuals were disqualified for asymptomatic spinal irregularities and for cardiac dysrhythmias. Considering the recent reports in the medical literature on sudden death related to structural cardiovascular disease (8), we have made an additional requirement for having a normal echocardiogram. Mitral valve prolapse found by echocardiography would also be disqualifying because there is an as yet uncharacterized subset of individuals with this condition who are at risk for malignant dysrhythmias and sudden death (3). Although the additional requirement for a normal echocardiogram will undoubtedly result in additional expense and possibly more disqualifications, we consider its noninvasive nature and the additional assurance of cardiovascular normality to be essential for hazardous duty qualification in a high sustained G environment. To date we have not had any serious G-related problems. Actual harm to subjects has been reported to occur in 3-4% of other research projects (5), but most of these occurrences were trivial or only temporarily disabling; however, fatal incidents have occurred (7). Even when we have observed significant dysrhythmias such as ventricular tachycardia in subjects exposed to high sustained G stress, retrospective evaluation including echocardiograms has failed to show

TABLE V. POTENTIAL ACCELERATION HAZARDS DESCRIBED TO EACH SUBJECT PRIOR TO ANY EXPOSURE TO +Gz STRESS.

- I. Symptoms:
 - a. Blackout
 - b. Loss of consciousness
 - c. Seizures, convulsions, amnesia, confusion
 - d. Vertigo
 - e. Motion sickness, vomiting
 - f. Dyspnea
 - g. Pain, fatigue
- II. Trauma:
 - a. Pneumothorax
 - b. Muscle soreness
 - c. Vertebral body compression fractures
 - d. Herniated nucleus pulposus
 - e. Petechial hemorrhages
 - f. Swelling, lower extremities
 - g. Scrotal hematoma
 - h. Hernia
- III. Cardiac Stress:
 - a. Dysrhythmias (Tachyarrhythmias and Bradyarrhythmias)
 - b. Heart blocks
 - c. Stress cardiomyopathy

HUMAN ACCELERATION STANDARDS—WHINNERY & GILLINGHAM

any cardiovascular disease or other causative etiology. We consider that high sustained G is extremely stressful, and every precaution should be taken in an experimental setting to protect human volunteers.

Conclusion

Since current and future fighter aircraft will continue to easily exceed human tolerance, acceleration research will continue to be high-sustained-G-oriented. To carry out high-sustained-G research a panel of trained human volunteer subjects is essential. It is difficult to find and keep a sufficient number of individuals who are motivated to participate repeatedly in high-sustained-G research. Rigorous medical standards are absolutely necessary to assure maximum safety in a research setting. Medical standards must also be realistic and not disqualify without sound reasons. The needs of principal investigators eager to qualify panel members for their research projects must be considered and weighed in light of established medical standards.

REFERENCES

1. Adler, F. H. Optical defects of the eye. *Gifford's Textbook of Ophthalmology*. Philadelphia: W. B. Saunders, Co.; 1957:116.
2. Chung, E. K. Exercise ECG Testing: Is it indicated for asymptomatic individuals before engaging in any exercise program? *Arch. Intern. Med.* 140:895-896, 1980.
3. Engle, P. J., and J. R. Hickman. Mitral value prolapse, a review. *Aviat. Space Environ. Med.* 51:273-286, 1980.
4. Epstein, S. E. Value and limitations of the electrocardiographic response to exercise in the assessment of patients with coronary artery disease. *Am J. Cardiol.* 42:667-674, 1978.
5. Gray, B. H., R. A. Cooke, and A. S. Tannenbaum. Research involving human subjects. *Science.* 201:1094-1101, 1978.
6. Kazarian, L. E., and W. F. Belk. Spinal column considerations. *Proceedings of the USAF Multidisciplinary Workshop on Pilot Selection and Flying Physical Standards for the 1980s*. Office of the Surgeon General, Brooks AFB, Texas; 265-283, 1979.
7. Kolata, G. B. NIH shaken by death of research volunteer. *Science.* 209:475-479, 1980.
8. Maron, B. J., W. C. Roberts, H. A. McAllister, D. R. Rosing, and S. E. Epstein. Sudden death in young athletes. *Circulation.* 62:218-229, 1980.
9. Morales, A. R., R. Romanelli, and R. J. Boucek. The mural left anterior descending coronary artery, strenuous exercise and sudden death. *Circulation.* 62:230-237, 1980.
10. Redwood, D. R., J. S. Borer, and S. E. Epstein. Whither the ST segment during exercise? *Circulation.* 54:703-706, 1976.
11. Uhl, G. S., T. N. Kay, J. R. Hickman, M. A. Montgomery, and G. M. McGranahan. Detection of coronary artery disease in asymptomatic aircrew members with Thallium-201 scintigraphy. *Aviat. Space Environ. Med.* 51:1250-1255, 1980.
12. Whinnery, J. E., and M. R. Gondek. Medical evaluation of G-sensitive aircrewmembers. *Aviat. Space Environ. Med.* 49:1009-1013, 1978.
13. Whinnery, J. E., M. H. Laughlin, and G. S. Uhl. Coincident loss of consciousness and ventricular tachycardia during +Gz stress. *Aviat. Space Environ. Med.* 51:827-831, 1980.
14. Whinnery, J. E., and J. S. Slaughter. A computerized repository for collection, storage and retrieval of acceleration stress data. *Meth. Info. Med.* 20:10-15, 1981.