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Advancing Safety in Pediatric Cardiology—Approaches Developed in Aviation

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Pediatric cardiology is an enterprise associated with wide range of risk, including relatively great risk, to patient safety (Figure 1) (1-7). The natural history of many of the disorders that afflict pediatric cardiology patients predicts significant morbidity and mortality. Although great progress has been made in modifying the natural history of these disorders, there remains ample room for improvement. Somewhat paradoxically, innovative patient management strategies and procedures impose risks of their own. Human error, which is ubiquitous in the provision of health care, represents an additional threat to the safety of pediatric cardiology patients.

The most frequently cited report describing deficiencies in patient safety is "To Err is Human," the 1999 report of the Institute of Medicine Quality of Healthcare in America Committee (8). The report extrapolated that there is an alarming incidence of preventable patient injuries and deaths occurring in American hospitals—44,000 to 98,000 preventable deaths per year, and it projected an extraordinary national cost associated with these adverse events—17 to 29 billion dollars per year! Certainly, pediatric cardiology patients were among those affected by the deficiencies described in the report. The report recommended that health care organizations establish "interdisciplinary team training programs—including the use of simulation" and that they incorporate "proven methods of managing work in teams as exemplified in aviation (where it is known as crew resource management)."

> ***"...the application of safety measures developed in aviation to the practice of pediatric cardiology might quite promptly advance patient safety and quality of care and thus lead to at least modest improvement in outcomes."***

There is an expanding body of literature discussing adaptation by health care providers and organizations of approaches to safety developed in aviation (9-14). In this paper, we describe a few of these approaches and explore how they may be helpful by reducing risk and mitigating error in the provision of care to pediatric cardiology patients.

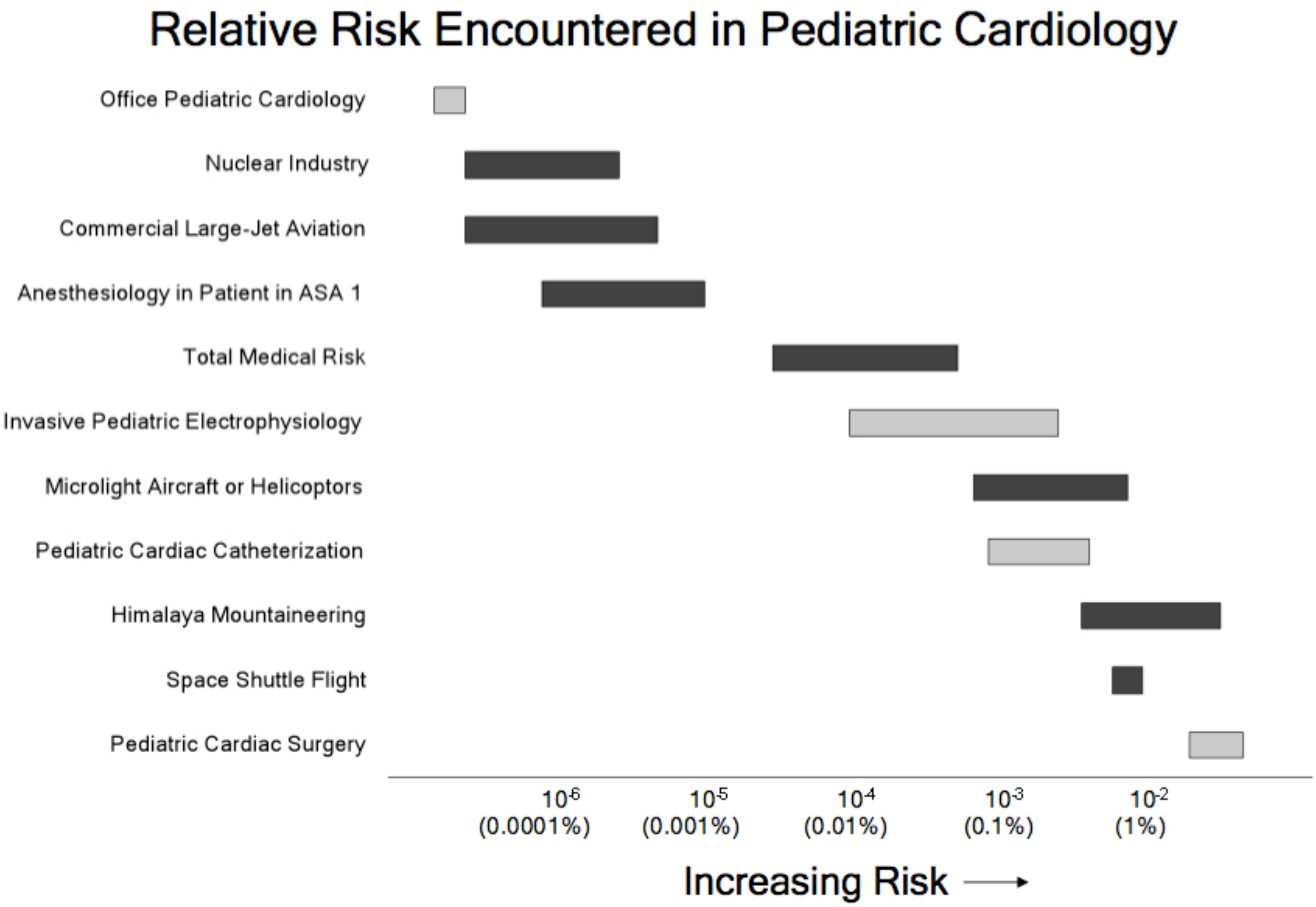


Figure 1. Approximate mortality risk in selected areas of pediatric cardiology (shaded bars) in relation to mortality risk or risk of catastrophic failure in other areas of medicine and other endeavors (solid bars). For purposes of illustration, minimal risk of office pediatric cardiology arbitrarily set between 2 and 3.3 x 10-7. Lower limit of risk of invasive pediatric electrophysiology arbitrarily set at 10-4 (1), and (dated) upper limit set at 2.2 x 10-3 (2). Risk of pediatric cardiac catheterization conservatively set between 8 x 10-4 and 1.4 x 10-3 (3,4). Risk of pediatric cardiac surgery (for neonates, infants, and children) set between anecdotal lower limit of 1.8 x 10-2 and upper limit of 3.8 x 10-2 (5). Risk of space shuttle flight set between anecdotal lower limit of 5 x 10-3 and upper limit of 8 x 10-3 (6). Risk in other areas of medicine and other endeavors (remaining solid bars) derived from Amalberti (7).

Table I. Crew Resource Management Teamwork and Communication Behaviors	
Rapid, effective team building	Recognition and mitigation of fatigue/stress
Precise, effective communication without regard to rank	Team-oriented problem solving and decision making
Recognition and communication of adverse situations	Specific, non-threatening performance feedback

Table II. Crew Resource Management Safety Tools	
Briefings	Standard operating procedures (SOP)
Read files	Standardized communications
Checklists	Debriefings
Note: Read files are policy and procedure updates and changes specific to a unit’s operation that must be read and initialed or otherwise acknowledged by team members at regular intervals.	

Crew Resource Management

The impetus in aviation for development of crew resource management (CRM) programs stemmed from the unacceptably high number of civilian and military aircraft accidents occurring in the 1970s. During the five-year period, 1975-79, American heavy commercial airliners were involved in 8 accidents that claimed 1,223 lives (15). Safety in military aviation was similarly deficient. For example, in the late 1970s, a single naval carrier air wing, comprising approximately 75 aircraft and 5,000 personnel aboard one ship, experienced, over the course of 2-1/2 years, 9 aircraft accidents with loss of 16 aircraft and 6 lives. Analysis by NASA and industry led to the conclusion that 70 to 80% of all aviation accidents resulted from human error in a team setting (16).

What is CRM? It can be defined as the systematic development and application of teamwork and communication behaviors (Table I) and the use of safety tools that support those behaviors (Table II) in order to enhance safety in high-risk industries such as aviation and health care (17).

Why is CRM pertinent to pediatric cardiology? When associated with CRM programs, high-risk systems, like those in aviation, provide error rates better than health care (Figure 1). Components of CRM have progressively been mandated by The Joint Commission, e.g. procedure timeouts (analogous to pre-flight or pre-approach briefings), readback of verbal orders, standardized handoffs of patient care (11) (analogous to aviation standard communication procedures), and medication reconciliation forms (analogous to cockpit checklists). Many health care organizations contract with consultants in CRM, and training in CRM is now obligatory at some health care institutions. CRM training need not just contribute to institutional safety and quality, it can also enhance an organization's standing with the public, regulatory agencies, and contracting industry, thus enhancing profitability.

Vanderbilt Medical Center

Operating Room Checklist

Charge Nurse

CO2 Gas Tank (2) . . . . Check
Sterilizer . . . . Verify QC check

Circulator

Room . . . . Damp Dust
Defibrillators . . . . Run Self Test
Perfusion booms . . . . Positioned
Big monitor . . . . Positioned
Lights . . . . Positioned
. . . . ON
Mini-Siemens Monitor . . . . Positioned
Camera (C-Arm) . . . . Controls Active
. . . . Park Position
Table . . . . Controls active
Chargeable cart . . . . Check for Implants
Room Camera (Siemens). . . . . Pt Loaded
VPIMS. . . . . Pt Loaded
Witt . . . . ON
. . . . Pt Loaded
STORZ (displays) . . . . Selected & Displayed
Warmer. . . . . ON
. . . . Blankets Warm
. . . . .Saline Warm
Bair Hugger. . . . . ON
Witt Leads. . . . . Place with Anesthesia

Figure 2. Preoperative checklist for preparation of hybrid suite. Reproduced by permission of Vanderbilt University Medical Center.

An example of a CRM safety tool that can be used in pediatric cardiology is the checklist used by charge and circulating nurses in the hybrid suite at Vanderbilt University (Figure 2). The hybrid suite combines both cardiac operating room and catheterization laboratory, and proper preparation of the suite's extensive array of equipment is critical to safety. Use of checklists like this one promotes teamwork, fosters mutual understanding of intended goals, and ensures completion of essential tasks.

Use of CRM is believed to have contributed to a dramatic decline in aviation accidents. As early as 1991, in both civil and military aviation, a 28-81% decline in accidents was associated with introduction of CRM training (18). Since 2001, there has been a dramatic reduction in fatalities associated with operation of heavy air liners by American air transportation companies. In fact, there has been just one such death (19). In health care, similarly positive results have been reported to be associated with CRM training, e.g., elimination of wrong surgeries, 40% decrease in surgical wound infections, 43-57% improvement in observed to expected mortality ratios, 51% improvement in operating room turnaround times, 50% decrease in open malpractice claims (20).

Although CRM training is widely held to be effective, it is only in its infancy in health care with wide variation in the content of training programs. Moreover, whether it actually works to enhance safety remains to be rigorously demonstrated. A recent review of CRM training applied in several industries including aviation and health care concluded that:

1. CRM training generally produces positive reactions from trainees,
2. the impact of CRM training on learning and behavior is mixed across and within domains, and
3. it is not yet possible to rigorously ascertain the impact of CRM training on organizational safety (21).

Nonetheless, common sense suggests that CRM training has considerable potential for reducing risk and improving quality of care in those areas of pediatric cardiology where teams of individuals work together to provide care.

Simulation

In 1929, Edwin Link of Binghamton, New York produced a sophisticated flight simulator that would revolutionize flight training. Military organizations quickly recognized the value of the Link Trainers. In 1934, the United States Army Air Corps became Link's first customer followed closely by the Japanese Imperial Navy and the Soviet Union! Approximately 10,000 Link Trainers were manufactured for use by Allied forces during the Second World War. In 2001, the 9/11 attacks were flown by inexperienced pilots whose success was partly attributed to training using flight simulators for heavy commercial air liners (22).

Figure 3. Catheterization laboratory simulator demonstrating coronary angiography. Reproduced by permission of Immersion Medical, Inc., Copyright © 2007 Immersion Medical, Inc. All rights reserved.

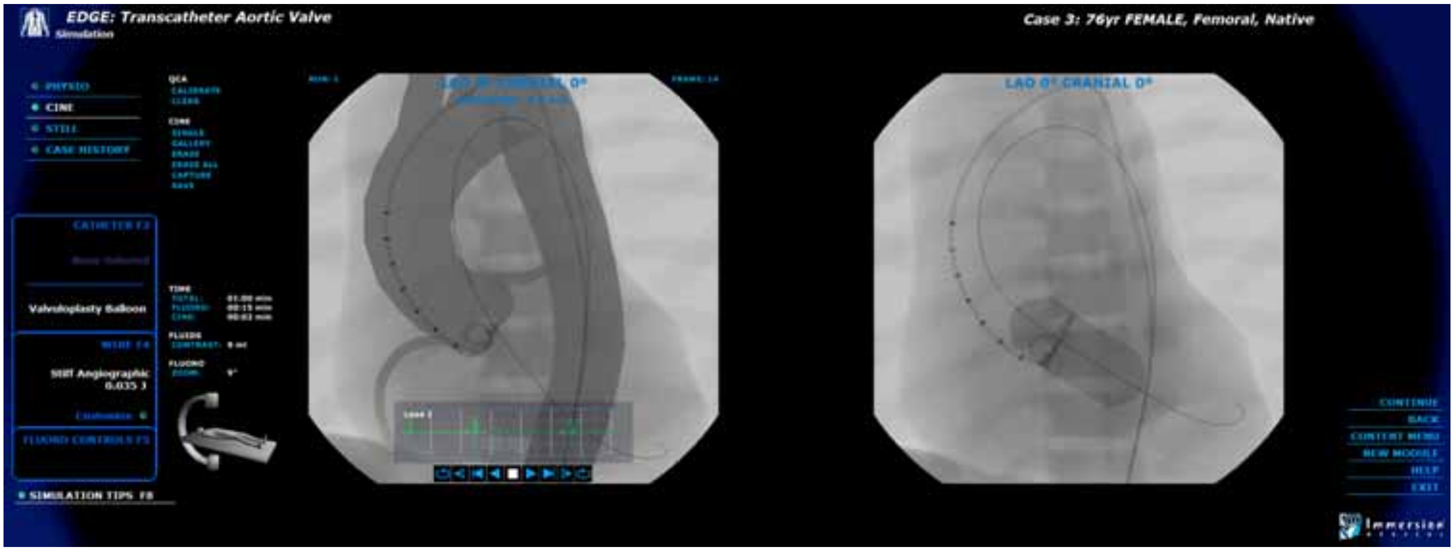


Figure 4. Catheterization laboratory simulator demonstrating percutaneous implantation of prosthetic aortic valve. Reproduced by permission of Immersion Medical, Inc., Copyright © 2007 Immersion Medical, Inc. All rights reserved.

Flight simulators are now commonly used across the spectrum of aviation, from general aviation to space flight. Even the most rudimentary of these simulators, which run on personal computers, are extraordinarily sophisticated and useful. Air line pilots transitioning to new aircraft types receive the entirety of their training in advanced simulators, which duplicate the actual aircraft cockpit and crew composition and realistically simulate aircraft motion, performance, and operating environments in normal and emergency situations. These transitioning pilots receive their type ratings for their new aircraft before ever flying the actual aircraft. A transitioning pilot's first crew responsibility in the actual aircraft is to serve as pilot on regularly-scheduled, passenger-carrying flights while his or her performance is monitored for a short interval by a check pilot dedicated to ensuring safe completion of the type training.

Crew resource management is an important component of initial and recurrent training using flight simulators. Pilots and co-pilots develop and rehearse teamwork and communication skills, and they practice use of safety tools such as checklists, read files, and standard operating and communication procedures for both normal and emergency situations. Every simulator session, like every actual flight, is briefed and debriefed.

Medical simulators introduced in the 1960s included the Resusci-Annie and Harvey cardiology simulators. By the 1980s, mannequin-based anesthesia simulators were in use. Medical simulators have become progressively more sophisticated. Complete operating room simulators have been constructed to enable simulation of various anesthetic and surgical procedures. Simulation centers have been opened at many medical centers. Training in laparoscopic cholecystectomy that combines simulation with conventional training has been demonstrated to be superior to conventional training alone (23). In general, high-fidelity simulation has been validated as a legitimate training approach in health care (24).

Providers in pediatric cardiology are familiar with the mannequins and related devices used for training in Pediatric Advanced Life Support, Advanced Cardiac Life Support, and deep sedation. These devices are becoming increasingly sophisticated. For example, sensors and displays are now used in conjunction with mannequins to not only assess chest compression frequency and amplitude during simulated closed chest cardiac massage but also compression waveform in order to teach the optimal quality of compressions. Simulators are available to teach introduction of peripheral and central intravenous, systemic arterial, and pulmonary arterial catheters. Thus, invasive as well as noninvasive hemodynamic monitoring can be simulated. Sophisticated mannequins can simulate corneal reflexes and speech and various respiratory and cardiovascular states that improve or deteriorate in conjunction with simulated interventions including use of medications. Simulation has been validated as an effective training approach for teaching bedside cardiology skills and Advanced Cardiac Life Support skills (24).

Simulators are now being used for training in cardiac catheterization (Figure 3). Catheterization simulators can be used without exposing patients, trainees, instructors, or ancillary personnel to ionizing radiation or biohazardous materials. These devices employ "haptics" to mimic the tactile sensation of catheter manipulation within the cardiovascular system, much like fly-by-wire control systems mimic "normal" control pressures in advanced aircraft. Catheterization simulators allow a broad variety of catheters and devices to be used during training. Although these simulators have largely been developed for training in coronary, peripheral, and neurovascular interventions and in cardiac rhythm management, one manufacturer is now using simulation to introduce cardiologists to devices that close atrial septal openings, and another manufacturer is using simulation to introduce cardiologists to percutaneous implantation of pulmonary and aortic valves (Figure 4). Software will presumably be developed to facilitate training in more fundamental aspects of cardiac catheterization. Although currently available systems simulate single plane fluoroscopy equipment, biplane simulators are readily conceivable.

Simulation provides learners opportunity to deliberately acquire and repetitively practice cognitive and psychomotor skills in a focused domain and a controlled environment. Simulators can rigorously assess skills and provide learners with specific feedback that can result in progressive enhancement of skills. Simulation provides opportunities for groups of trainees to learn coherent team behavioral skills and use of safety tools and to rehearse these organizational skills in simulated normal and emergent situations. Simulation offers the obvious advantage of separating patients from training in painful, potentially hazardous, or expensive procedures. Simulation offers potential financial advantages by providing trainees with skills and experience that can result in shortened actual procedure times, more efficient utilization of materiel, and reduced occurrence of adverse events (23). Finally, simulators offer the opportunity to model procedures before applying them to patients. For example, angiographic, CT, or MR images can be loaded into a simulator to enable a cardiologist to simulate a procedure within a specific patient's anatomy before that patient's actual catheterization is performed (Figure 4).

There does not appear to have been any rigorous evaluation of the impact of simulation on safety in pediatric cardiology (25). Again however, common sense suggests that simulation has considerable potential for reducing risk and improving quality of care in pediatric cardiology.

Personal Minimums

In aviation, the term, minimums, is generally used to describe distances extending downward and forward that a pilot or flight crew must be able to see when transitioning from reference to cockpit instruments to visual reference to the runway environment during the final phase of an instrument approach to landing. If the runway environment is not in sight at the minimum distances, a climbing procedure, or missed approach, must immediately be initiated. Although descent below minimums without the prescribed visual contact with the runway environment is prohibited, there is no requirement to descend to the prescribed minimums, and a pilot has the option of executing a missed approach above minimums in order to allow for a wider margin of safety. Such optional higher minimums can be called personal minimums, and they are typically used by general aviation pilots.

Safety in general aviation is inferior to that in other sectors of aviation. General aviation pilots may be less well-trained, less experienced, and less current than commercial air line and military pilots. They often fly as individual pilots rather than as members of flight crews, and they typically operate their sometimes less sophisticated and less weather-capable aircraft without the same structured and supportive milieu that surrounds their commercial air line and military pilot counterparts.

In order to enhance safety, industry and the Federal Aviation Administration have developed so-called personal minimums checklists to be used by pilots to manage risk. These checklists do include consideration of the aforementioned minimum visibility requirements during instrument approaches, but they have been greatly expanded to include many other considerations pertinent to safe pilot behavior (Figure 5).

Similar checklists have been developed for use in other aviation activities. For example, one naval aviation squadron with a superb safety record (more than 40 years and 77,000 flight hours—many of them during aircraft carrier operations—without a major accident) has developed personal minimums checklists for personnel performing maintenance on squadron aircraft (Table III) (26).

Whether the use of the personal minimums approach to safety in aviation has actually served to enhance safety does not appear to have been rigorously evaluated. Although checklists are increasingly being used as safety tools in health care (11,27-30), the use of personal minimums checklists has not yet been extensively applied. A structured approach to minimizing adverse effects upon patients of learning curves for new procedures has been advocated (31). Cultivation of "error wisdom" among junior providers has been suggested as a way to enhance patient safety (32). The IM SAFE (Illness, Medication, Stress, Alcohol, Fatigue/Food, Emotion) checklist developed for aviation personnel has received mention (29).

Pediatric cardiologists and pediatric cardiac surgeons are granted great autonomy and wide latitude in choosing how they provide care for their patients. However, they or their team members may not always have the requisite knowledge, skill, or experience to provide specific types or levels of care. Individual physicians or team members may not always be mentally or physically prepared to provide optimal care. Thus, disciplined use of the personal minimums approach by individual providers in order to enhance safety in pediatric cardiology appears to be worthy of evaluation and considered application.

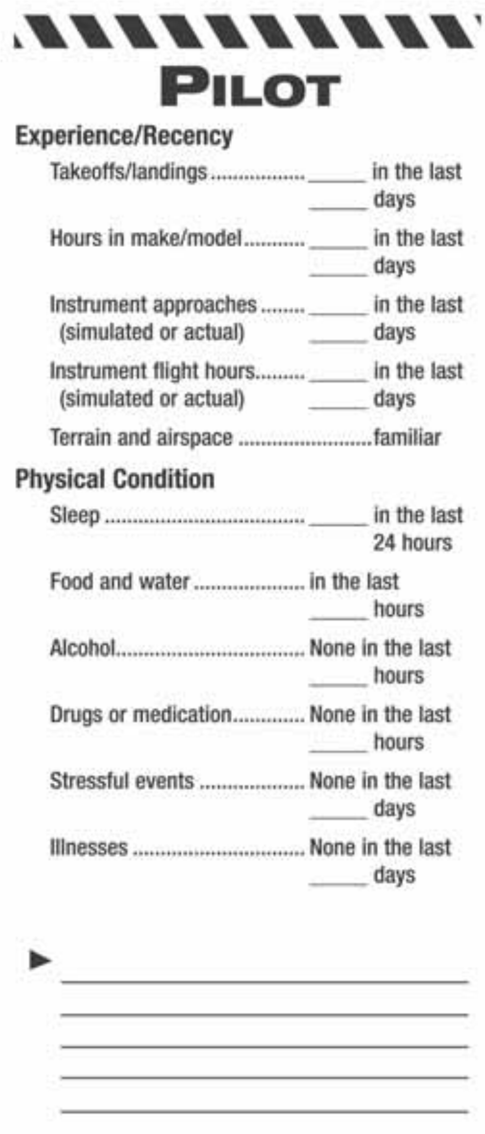
Pushing the Outside of the Envelope

This phrase came into common use following its appearance in the 1979 novel about test pilots and the space program, The Right Stuff (33). Now the phrase is frequently applied when attempts are made to expand the capabilities of technological systems, such as systems in health care, to perform.

In aviation, the envelope is defined as the area lying within boundaries that describe the limits of safe aircraft operation under various conditions such as weight, velocity, and acceleration (Figure 6). The boundaries of an envelope are typically developed using engineering estimates, validated in wind tunnels, and finally confirmed by experimental test flights. The outside or "edge" of an envelope is "pushed" when a test vehicle is deliberately flown to approach, meet, or exceed the predicted limits in order to establish the exact capabilities of the vehicle or to determine where failure is likely to occur.

Safe pilots normally strive to fly within the established safe center of the aircraft operating envelope. For certified aircraft, flight near the outside of the envelope is restricted, and flight outside of the envelope is prohibited (Figure 6). In contrast, although pediatric cardiologists and pediatric cardiac surgeons may strive to operate within the accepted safe center of the specialty's envelope, doing so is not always consistent with the best interests of their patients. Situations frequently arise in which varying degrees of calculated risk must be assumed in order to achieve acceptable outcomes (34).

Pushing the outside of the envelope in pediatric cardiology, that is, expanding the capabilities of the specialty to apply new patient management strategies or perform novel procedures, is ideally accomplished by conducting well-designed, carefully-executed, prospective, randomized, controlled clinical trials. This approach is made difficult by a number of factors including small patient numbers, wide variation in individual patient characteristics and clinical needs, limited financial incentives, issues surrounding informed consent, and, in some cases, restrictive regulatory oversight. Indeed, the pediatric cardiology community has recently learned the hazard of pushing the envelope without strict compliance with regulatory requirements (35). Despite such impediments, however, pediatric cardiologists and pediatric cardiac surgeons have


PILOT

Experience/Recency

Takeoffs/landings .... _____ in the last _____ days

Hours in make/model .... _____ in the last _____ days

Instrument approaches .... _____ in the last (simulated or actual) _____ days

Instrument flight hours......... _____ in the last (simulated or actual) _____ days

Terrain and airspace ....familiar

Physical Condition

Sleep .... _____ in the last 24 hours

Food and water .... in the last _____ hours

Alcohol................................. None in the last _____ hours

Drugs or medication............. None in the last _____ hours

Stressful events .... None in the last _____ days

Illnesses .... None in the last _____ days

Figure 5. General aviation personal minimums checklist. The checklist consists of four sections: Pilot, Aircraft, Environment, and External Pressures. Due to space limitations, only the Pilot section is shown. Reproduced by permission of King Schools, Inc., San Diego, CA.

Table III. VAW-121 Bluetail's Personal Minimums Checklist. Check BEFORE the task (26)	
Do I have the knowledge to perform the task?	Am I mentally prepared to perform the job task?
Do I have the technical data to perform the task?	Am I physically prepared to perform the task?
Have I performed the task previously?	Have I taken the proper safety precautions to perform the task?
Do I have the proper tools and equipment to perform the task?	Do I have the resources available to perform the task?
Have I had the proper training to support the job task?	Have I researched the MIMS to ensure compliance?
Note: MIMS = Maintenance Instruction Manuals. With permission, Commanding Officer, Carrier Airborne Early Warning Squadron 121.	

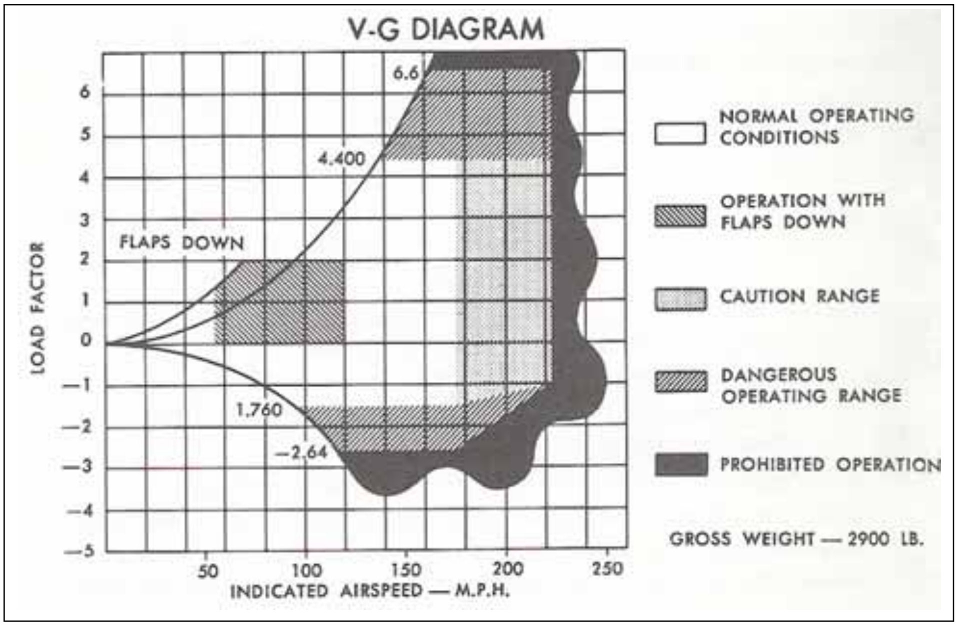


Figure 6. Operating envelope for J-35 Bonanza aircraft manufactured by Beech Aircraft Corporation, revision dated March 30, 1958. Load Factor is expressed in units of apparent gravity, g, (in common usage, "g-force" or "g-load") caused by acceleration of the airframe in the direction of its vertical axis during flight. Courtesy of American Bonanza Society and with permission of Hawker Beechcraft Corporation, Wichita, KS.

amply demonstrated that the capabilities of the specialty can be safely expanded. It cannot be emphasized too strongly, however, that the operative terms applicable to the expansion of the envelope in pediatric cardiology, as in aviation, must always remain: considered, cautious, deliberate, rigorous, compliant, and self-critical (36).

Conclusions

The health care industry is a relative latecomer to awareness of deficiencies in safety. Now, however, such awareness is acute (37,38). The industry is beginning to understand that safety will not be greatly enhanced by individual providers "just being more careful" (39) and that systems must be developed, implemented, evaluated, and relentlessly optimized so that individual providers, teams of providers, and health care organizations as a whole achieve the highest possible level of safety.

As yet, there is little hard evidence that adaptation by the health care industry of approaches to safety developed in aviation has actually advanced patient safety. Furthermore, it seems likely that rigorous validation of the use of these approaches will prove as difficult in pediatric cardiology as it has elsewhere (12,21). Absent such validation, application of these safety practices should be viewed with a measure of skepticism. As Helmreich wrote in 2000, "This [the operating theater] is a milieu more complex than the cockpit, with differing specialties interacting to treat a patient whose condition and response may have unknown characteristics. Aircraft tend to be more predictable than patients." (40)

On the other hand, as Samuel Johnson wrote in 1759, "Nothing will ever be attempted, if all possible objections must be first overcome."(41) More specifically, Leape and colleagues have proposed that lack of rigorous validation of the adaptation by the health care industry of safety strategies developed in other industries should not preclude their application when both common sense and some evidence of efficacy are supportive (42). In fact, it now appears inevitable that approaches previously developed to enhance safety in other high-risk industries such as aviation, approaches like those described in this article, will increasingly be applied, if not mandated, by health care organizations in an effort to improve safety, with or without their rigorous validation.

It seems possible that, in comparison with the evolutionary nature of the development of new patient management strategies and procedures, which typically only gradually lead to improved outcomes, the application of safety measures developed in aviation to the practice of pediatric cardiology might quite promptly advance patient safety and quality of care and thus lead to at least modest improvement in outcomes. Individual providers in pediatric cardiology, teams of providers, and the organizations that support them would do well to proactively investigate these approaches to safety and apply them wherever that seems to be appropriate.

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