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Perspectives in quality: designing the WHO Surgical Safety Checklist

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Abstract

The World Health Organization's Patient Safety Programme created an initiative to improve the safety of surgery around the world. In order to accomplish this goal the programme team developed a checklist with items that could and, if at all possible, should be practised in all settings where surgery takes place. There is little guidance in the literature regarding methods for creating a medical checklist. The airline industry, however, has more than 70 years of experience in developing and using checklists. The authors of the WHO Surgical Safety Checklist drew lessons from the aviation experience to create a safety tool that supports essential clinical practice. In order to inform the methodology for development of future checklists in health care, we review how we applied lessons learned from the aviation experience in checklist development to the development of the Surgical Safety Checklist and also discuss the differences that exist between aviation and medicine that impact the use of checklists in health care.

Keywords: quality improvement, quality management, consensus methods, general methodology, surgery, teamwork, human resources

Introduction

A checklist is 'a formal list used to identify, schedule, compare or verify a group of elements or . . . used as a visual or oral aid that enables the user to overcome the limitations of short-term human memory' [1]. The use of checklists in health care is increasingly common. One of the first widely publicized checklists was for the insertion of central venous catheters. This checklist, in addition to other team-building exercises, helped significantly decrease the central line infection rate per 1000 catheter days from 2.7 at baseline to zero [2]. Building on this early success, the World Health Organization's Patient Safety Programme 'Safe Surgery Saves Lives' developed a Surgical Safety Checklist as a means of improving the safety of surgical care around the world. In a multinational study involving eight hospitals from diverse economic settings, its use improved compliance with standards of care by 65% and reduced the death rate following surgery by nearly 50% [3].

In order to develop the WHO Surgical Safety Checklist, the WHO Patient Safety Programme turned to the wealth of experience in the aviation industry [4]. The goal was to create a tool that supported clinical practice without attempting to substitute a rigid algorithm for professional judgement. We therefore reviewed the aviation experience and literature on checklists to construct a development strategy for the Surgical Safety Checklist. In his recent book The Checklist Manifesto [4], one of the authors (A.A.G.) provides a perspective for a lay audience on the role of checklists in multiple industries, but does not provide a detailed description to guide systems researchers wishing to develop their own checklists. Here, we describe more specifically how lessons from the aviation industry were applied to the development of the WHO Surgical Safety Checklist to inform the development of future medical checklists.

This checklist development process can be broken down into five steps: content and format, timing, trial and feedback, formal testing and evaluation, and local modification. We believe that these five steps adapted from the aviation industry and applied to the development of the WHO Surgical Safety Checklist can help inform the development of future medical checklists.

Content and format

In aviation, checklist developers seek to construct a checklist as a series of succinct items ideally comprising no more than a single page [5]. Sentences are intended to be simple and clear, yet maintain the professional language of the field [6]. Type font is legible and uses upper and lower case text. Clutter and colouring is limited and non-glossy lamination used when reflective glare is anticipated. Most importantly, the checklist items are associated with actions that allow corrections or modifications to ensure safety [7]. We tried to keep all of these lessons in mind as we developed the draft WHO Surgical Safety Checklist.

The WHO Safe Surgery Saves Lives team began by compiling a background document of safety practices with known benefits to surgical patients. This document was critical for not only establishing targets for improvement but also the specific practices necessary to achieve these targets. The WHO Patient Safety Programme then convened an international consultation of experts to review this background document and suggest additional topics to be considered for the checklist. These and other steps in the development of the WHO Surgical Safety Checklist are outlined in Fig. 1. To ensure that the checklist would be applicable in a wide range of settings, the international consultation was attended by participants from low, middle and high income countries from around the globe.

The topics considered relevant in all operating rooms around the world by this group of experts were then converted into potential checklist items that were amenable to verbal confirmation by an operating team and that allowed corrective action if they were noted to have been overlooked. Some items were relatively straightforward problems, for example confirmation of prophylactic antibiotic administration. Some required more complicated decision-making, such as preparation for high blood loss or a difficult airway. Other checklist items identified complex problems whose nature and response could not be fully anticipated. These items were less concrete but left to the discretion of the clinicians to determine, such as a discussion of critical events that the operating team might anticipate. The overarching goal was to focus the checklist only on ‘killer items’, those steps that are most critical, known to often be overlooked, and that put the patient at the highest risk of harm when omitted. In this manner the checklist would not and should not supplant the decision-making of trained professionals, but would rather remind clinicians of tasks that if forgotten lead to serious consequences. There is a tendency when making a checklist to specify every step in care; but to be efficient and effective, the aviation lesson is to focus on items that are recognized to either be outright deadly if missed or, if not deadly, then high risk and known to be recurrently overlooked or missed.

As we learned from the airline industry, each item considered for inclusion was created as a simple check rather than an algorithm. It needed to be associated with a corrective action that would bring the team using the checklist into procedural compliance with expected standards without dictating how that action should be performed. Each potential safety step was carefully considered by an international group of surgeons, anaesthetists, nurses, biomedical engineers and other patient safety experts. Because errors of omission and commission are usually not well-recognized or publicized and because medical simulation is not nearly as advanced as simulation in the aviation industry [4], these practitioners provided expert consensus estimates of where errors occur.

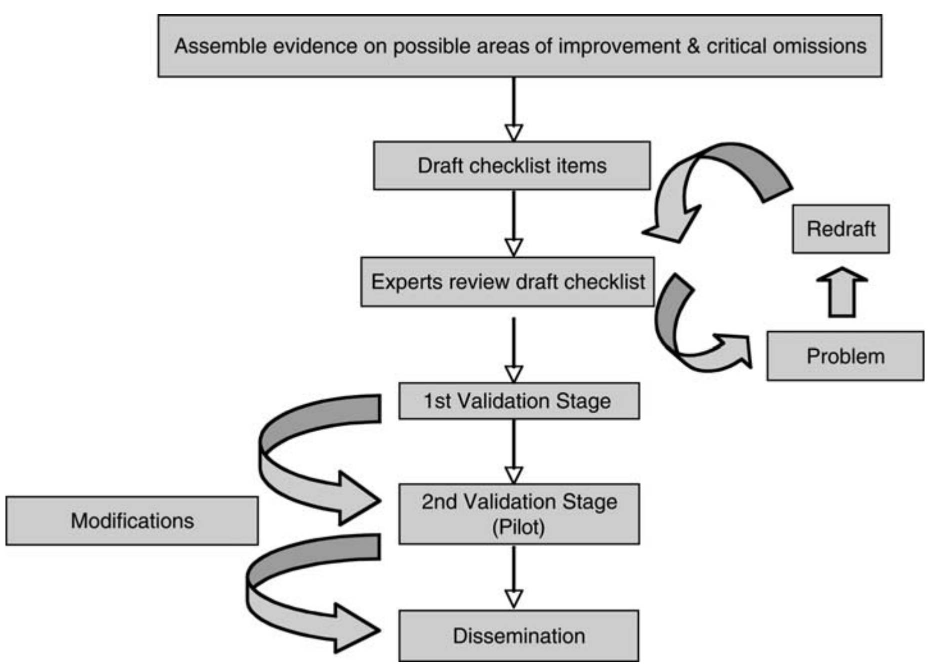

Figure 1 Development process of WHO Surgical Safety Checklist.

The tension between comprehensiveness and practicability was carefully evaluated with a goal of creating a checklist that prompted team communication and interaction, was widely applicable, would save lives and could be completed in 60–90 s in most situations.

Timing

In aviation, checklists are designed around operational workflow patterns, such as before takeoff or landing, when the flight crew can confirm that critical steps have been completed while detection of their omission is still remediable. They are explicitly designed to promote adherence to basic standards through a process known as 'error trapping' [8, 9]. The theory long understood by the airline industry is that humans make errors and checklists allow these to be identified and remedied before they cause harm [4].

For the timing of the WHO Surgical Safety Checklist, the team identified three phases in the workflow pattern that had natural 'pause points' in the typical workflow—one prior to induction of anaesthesia, one prior to skin incision and one prior to the patient leaving the operating room—when simple yet important actions could be confirmed and performed if needed. The checklist did not dictate how these actions were to be done, or in what sequence, just that they were verbally confirmed to have been done prior to commencing with the next stage of operative care, or if they had been overlooked, that corrective action was taken.

Trial and feedback

Once an aviation checklist is created, the developers trial it and solicit feedback [10]. This strategy is based on the Plan-Do-Study-Act (PDSA) model of quality control familiar to industry and manufacturing [11, 12]. Since engineers, pilots, human factors experts and flight mechanics all contribute to the crafting of a checklist, simulators are used to evaluate functionality. The balance between brevity and comprehensiveness is carefully scrutinized and refinements are made based on experience. This is done rapidly and without great formality, allowing improvements in content and format before the checklist is widely disseminated.

The Safe Surgery Saves Lives initiative tried to emulate this step by subjecting each draft checklist to a trial with one team. Some steps that had seemed self-evident were found to be unclear and problems with logistics, timing and team interactions inevitably arose. During each trial of a checklist, clinical teams clarified actions and language that were confusing. Once it was refined and in use in one setting, it was trialled in a variety of other settings. After a sufficient number of trials, the checklist was put into wider practice. Identifying and correcting problems early in the process minimized resistance and reduced barriers to implementation.

Formal testing and evaluation

Formal evaluation of aviation checklists demonstrates efficacy and functionality [13]. Their use must improve compliance with the processes described, engage the team in a meaningful way and be an integral part of the workflow [9, 14]. This is most often done through observation and measurement of the processes that are addressed in the checklist [15].

The use of a surgical checklist faced significant resistance and scepticism, so evaluating its effect on patient care and outcome was considered essential for success. In addition to process measures typical of aviation, the programme built into its study a formal evaluation of surgical outcomes. This added a substantial burden to data collection and the cost of formal testing and evaluation. The results, however, were a critical demonstration of the importance of such a safety tool and its potential impact on clinical care [3].

Local modification

Aviation checklists are not overly rigid or proscriptive. Airline companies often modify checklists provided to them by aircraft manufacturers to identify and formalize procedures specific to company policy [16]. These modifications usually reflect airline culture and local procedures while attempting to maintain the focus, brevity and action-oriented steps that make a checklist workable [8]. Deletion of items from the manufacturer's recommended checklist is rare. The FAA typically will require the company to submit its revised checklist to the manufacturer to ensure that it is not omitting an essential safety element [13]. Both during the evaluation and after dissemination of the WHO Surgical Safety Checklist, we encouraged health-care workers and hospital administrators to modify the checklist so that it best fits their local practice and work flow. Globally, surgical settings are vastly more diverse than aviation. Therefore, the Safe Surgery Programme encourages modification to fit local context and circumstance. However, it discourages elimination of any safety step unless that step was incorporated into another process that ensures its completion. During evaluation, modifications were done with a critical eye and in a collaborative context with members from the different disciplines involved in the process to ensure balance and functionality. The programme encouraged a rapid-cycle trial and feedback of the modified checklist before widespread local dissemination to help ensure its workability in clinical practice.

Similarities and differences between aviation and medicine

There are several similarities between aviation and medicine summarized in Table 1. These similarities include the complex nature of the tasks coupled with time-critical events and actions. In both medicine and aviation these complex tasks are managed by highly trained individuals with a

Table 1 Summary of similarities between the airline industry and medicine

Similarities	
Complexity	Complex procedures and processes with a series of critical steps that must occur to ensure the safe outcome for the patient/passengers
Time-critical events	Time-critical event flows and actions
Unpredictability	Element of unpredictability (for aviation, unexpected weather events and other external operating conditions; for medical, patient response to treatment)
Rare deviations	Most days have normal procedure and process flows, but a variety of deviations may occur requiring urgent response; some of these deviations are extremely rare
Lengthy training	Highly trained professionals involving many years of training
Hierarchy	A team of professionals, with a gradient of authority present in the team. Often a single person is designated as the final authority for the safe outcome of the flight/procedure/process
Highly visible implications	As an industry, the practices result in highly visible public safety implications

Table 2 Summary of differences between the airline industry and medicine

Differences	
Personal risk	The pilot's fate is tied to the fate of passengers; in the doctor/patient relationship, only the patient's safety is at risk
Public perception	Passengers are not often aware of the errors that pilots make. Medical errors are more frequently visible to the patient or their family
Litigation	Doctors are more often the principle target of litigation when errors occur in medicine. This impacts how voluntary reporting systems are used: NASA's Aviation Safety Reporting System (ASRS) effectively results in immunity for the reporter in most cases, and is very widely used by pilots. Doctors are often reluctant to report errors in their systems because of the potential for litigation
Level of training and roles	Most surgical procedures are performed by one surgeon (with resident, etc. assisting) resulting in a single high-authority figure. Air carriers are two-crew, the captain and first officer trade the 'pilot flying' role on alternate flights. The other pilot role is 'pilot monitoring' and their job is to catch and report errors. This yields a high probability of catching errors
Authority structure within team	Flight crew authority gradient is improving over time with Crew Resource Management adoption. Medical teams are generally autocratic, with even more extreme authority gradient in some developing countries, so there is little opportunity for error catching due to cross-check
Culture of standardization	Pilot culture generally accepts Standard Operating Procedures (SOP), with disciplined use of procedures and checklists; medical culture values extreme level of knowledge, judgment and expertise, but is resistant to imposed SOPs, rigor or discipline
Oversight	Pilots' performance is subject to random checks by Line Check Airmen, regulatory observation, recurrent training and checking, and Flight Operations Quality Assurance performance data gathering. Doctors are subject to less formal oversight and less frequent mandatory ongoing training
Labour Unions	Pilots are represented by labour unions in many parts of the world, so feedback or discipline due to errors is often done with the union as intermediary. Health-care workers are sometimes members of unions, but these unions do not usually act as intermediaries in incidents involving patient harm
Litigation	If a pilot violates the Federal Aviation Regulations (FARs), they are subject to the provisions of the FARs, which are federal laws. Litigation is a potential consequence of medical error, but very few errors committed by health-care workers are a direct violation of the law
Outside authority	Pilot procedures have an original authoritative source with the aircraft manufacturer (OEM, or Original Equipment Manufacturer). The medical community is a group of peers, generally without a single authoritative source of procedures and standards

hierarchy in the team structure that supports rapid responses and decision-making when deviations from normal protocol occur.

Although the aviation model was useful for informing the process of checklist creation, surgical checklist development and implementation involves additional challenges and differences outlined in Table 2. In general, the operating room environment and patient's condition are markedly more variable than an aeroplane cockpit, which is relatively constant and engineered for safety. Surgical care occurs in a highly complex and often poorly structured environment, as patients present to diverse practice settings with an astounding variety of conditions that must be simultaneously recognized and managed. In addition, aviation briefings are a normal and expected component of pre-flight planning and culture; the Surgical Safety Checklist had to engender communication and information exchange through a briefing process built into the checklist itself. Finally, after more than 70 years of use in aviation checklists are nearly universally accepted and valued. The traditional culture of surgery is rigid and resists changes to convention, including the introduction of checklists, which are not part of its traditional practice pattern.

Conclusion and future applications

Over the past 70 years the airline industry has learned a great deal about the science of developing checklists. The use of medical checklists to improve the safety and reliability of clinical practice has gained increased attention and there are emerging discussions in the literature on strategies to develop checklists for health care [17, 18]. Checklists have been shown to help improve clinical outcomes in obstetrics, anaesthesia care, emergency departments and in intensive care units to prevent ventilator-associated pneumonia and central line-associated bloodstream infections [2, 19–22]. In addition, the WHO Patient Safety Programme has now shown that a checklist can be of benefit in both wealthy and resource-poor environments. There are numerous clinical settings in developed and developing countries where team checklists are likely to be beneficial. From childbirth to trauma care to the work-up of fever or diarrhoeal illness, checklists can help teams improve adherence to important, life-saving steps in the process of care.

Checklists alone cannot solve the complex clinical issues that need to be addressed to improve adherence to best practices at the bedside and it is critical that each checklist be carefully designed and evaluated to ensure that it supports rather than interferes with clinical care. There also needs to be a strategy for translating the component elements of the checklist into clinical practice [23]. Simply providing clinicians with a checklist will not provide them with the resources to complete the checklist nor will it create a culture of safety that we see in the airline industry, which encourages the use of the checklist. Incorporating checklists into practice requires a concerted, energy-intensive mechanism to promote teamwork and communication and reinforce training and knowledge. This allows clinical teams to focus on the complex issues while ensuring that simple ones are addressed for every patient, every time. Feedback and continued monitoring are also essential to ensure that care is comprehensive, efficient, effective and safe. This is truly the height of professionalism, and it is hoped that the experience of the WHO Patient Safety Programme will be instructive as the science of developing team checklists for medicine evolves.

Authors' roles

T.G.W., A.B.H., G.D., W.B. and A.A.G. were responsible for the original quality improvement study conception; T.G.W., A.B.H., A.L., D.J.B., W.B. and A.A.G. were responsible for the background work evaluating the aviation model; T.G.W. drafted the manuscript, which was critically revised by all the authors.

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