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Protocols: help for improvement but beware of regression to the mean and mediocrity

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It is now well recognized that organizational factors in the ICU are of great importance in improving the outcome of critically ill and injured patients [1]. These factors include “closed ICUs” staffed by intensivists who possess the knowledge, skills, and expertise to manage critically ill and injured patients on the basis of the best current scientific evidence while at the same time respecting the goals and values of the patients, ensuring adequate staffing by well-trained dedicated ICU nurses, pharmacists, and ancillary support staff, excellent teamwork, cooperation of all medical specialities involved in the management of the patient and administrators who place

the interests of the patients’ as the overarching priority. Every ICU patient deserves to receive high-quality, compassionate, and time-sensitive care. All of these mentioned elements can be jeopardized by many factors, including poor human and financial resources, poor leadership, inadequate training, poor teamwork, and inconsistent, inappropriate, and conflicting treatments. The objective of clinical protocols is to enact the best up-to-date knowledge and ensure consistency in the treatment of patients. Indeed, several publications have reported on an improvement of outcomes in groups of patients in association with the introduction and implementation of clinical protocols [2–4]. Whether a protocol actually improves outcome depends to a large extent on the baseline outcome of interest, i.e., before the introduction of the protocol. Checklists and protocols are therefore expected to be useful in the hands of inexperienced healthcare providers or those working in suboptimal environments. The findings from an “emerging country” as reported by Soares et al. in a recent article in *Intensive Care Medicine* [5], together with data that surgical checklists are associated with improved perioperative outcomes in developing nations, support the concept that protocols and checklists per se improve outcome. The concept of checklists was popularized following the Keystone Quality ICU project where the risk of catheter-associated bloodstream infection was reduced using a checklist consisting of five items, namely handwashing, full barrier precautions during the insertion of central venous catheters, cleaning the skin with chlorhexidine, and avoiding the femoral site, although some of these checklist factors are either self-evident (handwashing) or have questionable benefit (avoiding the femoral site) [6, 7].

Consequently, the introduction of protocols in specific situations and for specific indications is undoubtedly beneficial and the paper by Soares et al. is a good illustration how the presence of protocols may be

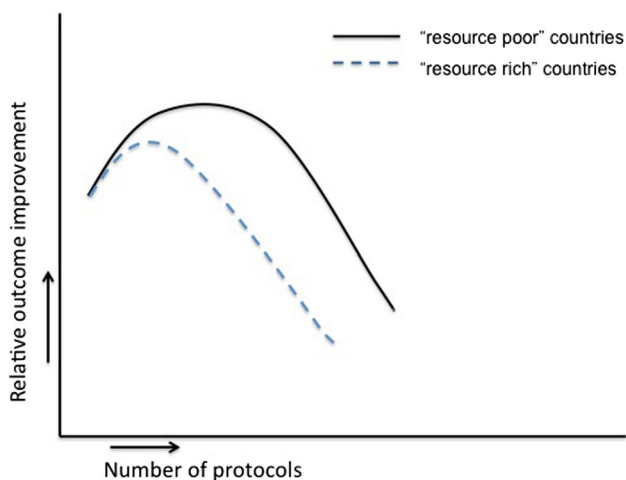


Fig. 1 There is an optimum in terms of subjects and number of protocols to contribute to a relative improvement in outcome. This will depend on outcome results at baseline and on specific environmental factors, which may differ per country, region, and ICU. The improvement of outcome may well be more pronounced in resource-poor countries than in resource-rich countries

associated with improving outcome. The risk, however, we see is that the introduction of protocols will be over the top (Fig. 1). Indeed, with monotonous tedium healthcare administrators, “quality organizations”, insurance companies, and regulatory bodies promote the notion that checklists and protocols should be implemented for all aspects of patient care. The forced nationwide implementation of the Surviving Sepsis Guidelines (in the USA and the Netherlands) is a reflection that we have reached rock bottom. Proponents of universal checklists and protocols neglect several important factors notwithstanding the evidence itself. Recently, Sevransky et al. published a study evaluating the use of protocols in 59 ICUs in the USA [8]. This study demonstrated that while the use of protocols was highly prevalent they were not associated with improved patient outcomes. In one of the largest studies to date conducted in over 200,000 patients in Ontario Canada, surgical checklists were not associated with a reduction in operative mortality or complications [9]. These data suggest that in highly sophisticated environments with highly qualified and experienced physicians, protocols and checklists may not improve patient outcome. It is not unreasonable to assume that in the study by Soares et al. the introduction of protocols is also merely a reflection of how the intensivists work; intensive care patients might benefit from intensivists who work according to standards and uniformly and as a team. Furthermore, there are a number of implicit problems with protocols and checklists, namely, they are usually out of date, they rarely apply to all patients, and may not

be appropriate for all nations across the world that have unique diseases, unique patients, and unique healthcare delivery systems. Furthermore, intensive care medicine is exceedingly complex and algorithms fail to manage complex medical issues such as sepsis. Protocols cause “regression to the mean”; they may help ICUs that perform poorly but will hamper high-performing ICUs and impede progress (which by definition will cause deviation from the protocol). Protocols enforce mediocrity.

The most troubling aspect of enforced bundles and protocols is that they may contain elements that are not supported by medical science or even more disturbingly may contain elements that according to current standards may be harmful. The latter is illustrated by the Institute for Healthcare Improvements (IHI) ventilator bundle (the use of acid suppressive therapy and chlorhexidine mouthwashes) and the Surviving Sepsis Campaign’s resuscitation bundle (inappropriate fluid management and early goal-directed therapy).

We therefore argue for the appropriate use of protocols and checklists. Protocols and checklists are undoubtedly of use for simple and repetitive tasks and in specific circumstances, such as in emerging countries. We reject the analogy that is often made between the airline industry and “patient safety”. This analogy is seriously flawed and potentially dangerous. Patients are not airplanes and doctors are not pilots [10]. No two patients or ICUs are the same. Patients are unique human beings with a unique set of genes, unique comorbidities, unique values, and who respond to illness and its treatment in a unique and unpredictable manner. On the contrary, each Boeing 737-300 is built exactly the same, has the same characteristics, and responds reproducibly and predictably when the same set of buttons are pushed and levers are pulled. Finally, Chesley “Sully” Sullenberger miraculously landed an Airbus A320, which had lost thrust in both engines after a bird strike, on the Hudson River in January 2009 saving the lives of all its passengers. He did not use a checklist that provided guidance on how to land his plane on the Hudson River to perform this remarkable feat; none existed. He used his experience as a commercial pilot for 29 years, his knowledge of aeronautics, his skill as a pilot, and his intuition. Physicians in the ICU face similar crises on a daily basis and require the same skill set as “Sully” to save their patients; there are no checklists to achieve this goal.

Compliance with ethical standards

Conflicts of interest The authors have no real or perceived conflict of interest and have no financial interest in any of the products or companies mentioned in this paper.

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