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

Received: 24 September 2015
Accepted: 29 September 2015
Published online: 23 October 2015
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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 hand-washing, 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

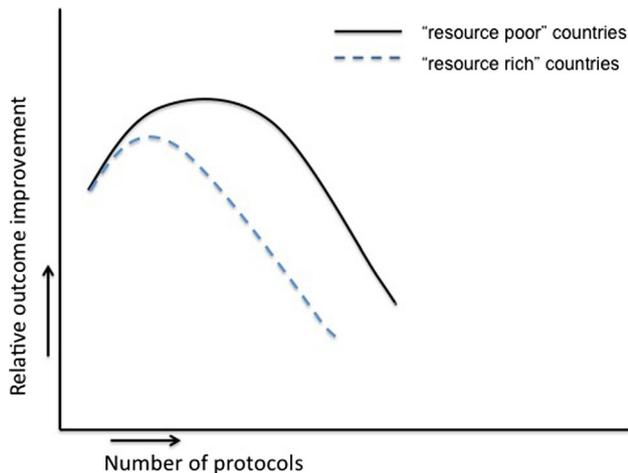


Fig. 1 There is an optimum in terms of subjects and number of protocols to contribute to a relative improvement in outcome. This will depend on outcome results at baseline and on specific environmental factors, which may differ per country, region, and ICU. The improvement of outcome may well be more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

References

1. Pronovost PJ, Angus DC, Dorman T, Robinson KA, Dremsizov TT, Young TL (2002) Physician staffing patterns and clinical outcomes in critically ill patients: a systematic review. *JAMA* 288:2151–2162
2. Kortgen A, Niederprüm P, Bauer M (2006) Implementation of an evidence-based “standard operating procedure” and outcome in septic shock. *Crit Care Med* 34:943–949
3. Ely EW, Baker AM, Dunagan DP, Burke HL, Smith AC, Kelly PT, Johnson MM, Browder RW, Bowton DL, Haponik EF (1996) Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously. *N Engl J Med* 335:1864–1869
4. van Zanten AR, Brinkman S, Arbous MS, Abu-Hanna A, Levy MM, de Keizer NF, Netherlands Patient Safety Agency Sepsis Expert Group (2014) Guideline bundles adherence and mortality in severe sepsis and septic shock. *Crit Care Med* 42:1890–1898
5. Soares M, Bozza FA, Angus DC et al (2015) Organizational characteristics, outcomes, and resource use in 78 Brazilian intensive care units: the ORCHESTRA study. *Intensive Care Med*. doi:10.1007/s00134-015-4076-7
6. Pronovost PJ, Needham D, Berenholtz S et al (2006) An intervention to decrease catheter related bloodstream infections in the ICU. *N Engl J Med* 355:2725–2732
7. Marik PE, Flemmer M, Harrison W (2012) The risk of catheter-related bloodstream infection with femoral venous catheters as compared to subclavian and internal jugular venous catheters: a systematic review of the literature and meta-analysis. *Crit Care Med* 40:2479–2485
8. Sevransky JE, Checkley W, Herrera P, USA Critical Illness and Injury Trials Group-Critical Illness Outcomes Study Investigators et al (2015) Protocols and hospital mortality in critically ill patients: the USA Critical Illness and Injury Trials Group Critical Illness Outcomes Study. *Crit Care Med* 43:2076–2084
9. Bergs J, Hellings J, Cleemput I et al (2014) Systematic review and meta-analysis of the effect of the World Health Organization surgical safety checklist on postoperative complications. *Br J Surg* 101:150–158
10. Rissmiller R (2006) Patients are not airplanes and doctors are not pilots. *Crit Care Med* 34:2869



Peter Isherwood

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

Accepted: 17 November 2015
Published online: 13 January 2016
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Dear Editor,

I read with interest the recent *Intensive Care Medicine* editorial entitled “Protocols: help for improvement but beware of regression to the mean and mediocrity” [1].

I wish to support the authors’ comments highlighting how the use of protocols can lead to improvements in care and outcome, but I have serious concerns with the suggestion that these can not be successfully applied to advanced and experienced organisations and providers. There are echoes of the hubris of medicine as described by Atul Gawande [2].

Girbes et al. reference the benefits of a well-designed checklist for central venous catheter (CVC) insertion [3], yet then continue to illustrate how a badly designed checklist may not be effective, overlooking that this is the result of poor design rather than the use of a checklist.

Checklists are designed to support and complement professional decision-making [4] and as such are critical to improving our outcomes. They are an effective method of creating institutional knowledge.

I have serious concerns that this editorial may result in misconception of the importance of human factors integration into healthcare systems. This is illustrated by the misrepresentation of the Hudson aircraft landing. This landing was not achieved by “knowledge of aeronautics, his skill as a pilot, and his intuition” as stated in the editorial. It was achieved by a pre-flight briefing by two pilots who had never previously flown together, clear communication, the co-pilot running through a series of checklists including that for ditching in water as they were losing altitude, use of the aircraft fly-by-wire system, a high-performing crew and their skills as pilots [5].

It is essential that we as a profession are prepared to ditch our hubris, accept that reducing variation requires a compromise of professional autonomy, stop hiding behind an apparition of human complexity and save our expertise for the relatively rare scenarios in which it is required and then use it in conjunction with well-designed decision support. This is how we will start to really improve our performance.

Sullenberger’s own words following the Hudson incident are worth consideration:

“Everything we know in aviation, every rule in the rule book, every procedure we have, we know because someone somewhere died... We have purchased at great cost, lessons literally bought with blood that we have to preserve as institutional knowledge and pass on to succeeding generations. We cannot have the moral failure of forgetting these lessons and have to relearn them.”

References

1. Girbes AJR, Robert R, Marik PE (2015) Protocols: help for improvement but beware of regression to the mean and mediocrity. *Intensive Care Med* 41: 2218–2220. doi:10.1007/s00134-015-4093-6
2. Gawande A (2014) The problem of hubris. BBC Reith Lectures, 9 Dec 2014
3. Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, Sexton B, Hyzy R, Welsh R, Roth G, Bander J, Kepros J, Goeschel C (2006) An intervention to reduce catheter-related bloodstream infections in the ICU. *N Engl J Med* 355: 2725–2732
4. Gawande A (2010) The checklist manifesto. Profile Books, London
5. Syed M (2015) Black box thinking. John Murray, London

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The dose makes the poison

Received: 29 November 2015
Accepted: 30 November 2015
Published online: 28 January 2016
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Dear Editor,

We appreciate the effort of Dr Isherwood in commenting on our editorial, since the subject is worthy of discussion [1, 2]. We also appreciate the illustration of what we warn against, an overrating of the utilization of protocols and the continuing inappropriate comparison of patients with airplanes or buildings. Protocols and checklists are like medicines and surgery: it is all about the indication, the dose, and knowing when not to use them. Again, as we stated, we encourage the use of protocols and checklists for relatively simple and especially repetitive tasks. We also highlighted that protocols and checklists can improve performance where basics can be improved or where (relatively) inexperienced professionals have to act. However, a protocol can never substitute the deployment of well-trained, experienced professionals. We urge for the awareness that many medical situations in intensive care are too complex for a protocol in order to provide the best possible care. Furthermore, protocols are implicitly superseded. There are multiple examples where checklists

and guidelines have failed, can be wrong, induce excessive unnecessary work, or are even harmful [3–5]. Additionally, strictly enforcing the implementation of protocols and guidelines will impede progress in patient care and may lead to a waste of time and money [5]. The solution for better care and outcome for patients is good individualized treatment by experienced, well-trained professionals where in particular situations the appropriate—in our minds therefore limited—use of protocols and checklists is very helpful. We also acknowledge the importance of human factors, as pointed out by Dr Isherwood and we favor simulation-based team training in intensive care. This refers to permanent education and training of professionals. Protocols and checklists have a limited role in improving care and outcome for the individual patient and we fear the healthcare administrators, regulatory bodies, “quality organizations”, and insurance companies that measure the rate of implementation of insufficiently validated checklists and protocols in order to—as they state—improve patient safety and outcome. This merely reflects their state of mind: “If you can’t measure what is important, you make important what you measure”. There are very few proven effective interventions by protocol or checklist, to improve safety. The evaluation of the efficacy is quasi-impossible because of the complexity and variability of interventions, related to local and individual differences and a lack of reliable measurement instruments [5]. We will have to live with that.

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.

References

1. Isherwood P (2015) Response to: Protocols: help for improvement but beware of regression to the mean and mediocrity. *Intensive Care Med*. doi: [10.1007/s00134-015-4204-4](https://doi.org/10.1007/s00134-015-4204-4)
2. Girbes AR, Robert R, Marik PE (2015) Protocols: help for improvement but beware of regression to the mean and mediocrity. *Intensive Care Med*. doi: [10.1007/s00134-015-4093-6](https://doi.org/10.1007/s00134-015-4093-6)
3. Hawn MT, Vick CC, Richman J, Holman W, Deierhoi RJ, Graham LA, Henderson WG, Itani KM (2011) Surgical site infection prevention: time to move beyond the surgical care improvement program. *Ann Surg* 254:494–499
4. Marik P, Bellomo R (2015) A rational approach to fluid therapy in sepsis. *Br J Anaesth*. doi:[10.1093/bja/aev349](https://doi.org/10.1093/bja/aev349)
5. Zegers M, Wollersheim H (2012) Dutch national safety programme will not lead to a fifty percent reduction in avoidable mortality in hospitals. *Ned Tijdschr Geneesk* 156:A4768

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