Standardised terminology for guidelines, protocols, regimens, procedures and processes: the other side of the "bundle"

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There is an obvious need to develop clear, concise and readable operational manuals to assist clinicians in the daily management of critically ill patients. These manuals are particularly needed now that critical care facilities have expanded to include intensive care units, high dependency units, "hot floors" and medical emergency teams, with a concurrent expansion in the number of clinicians, and inevitable variation in experience and training.

In the absence of clear orientation and training programs, the dynamic environment of critical care facilities is a fertile ground for critical incidents and potential (often preventable) harm to patients. Standardised definitions and formats for operational and procedure manuals have a highly valid place here and will indeed reduce the need to "re-invent the wheel" in many cases.

However, in this time of evidence-based and quality-based health care, clinicians are bombarded almost daily by edicts, policies, protocols, guidelines, regimens, processes-of-care, and therapeutic and procedural "bundles". These emanate from a variety of sources, including international consensus statements, learned colleges and societies, national regulatory authorities, regional departments of health and local hospital authorities. A variety of definitions are used. Clinicians may regard this deluge of documents with indifference and suspicion. While some documents are well constructed and highly applicable, others are designed in jurisdictions unrelated to clinicians' environments, developed from initiatives that are markedly flawed by limited "evidence", promulgated by protagonists ("eminence-based" medicine), or developed in reaction to local incidents and implemented with great enthusiasm by "quality improvement" teams.

Regrettably, processes that were initially developed as *facilitatory* — to help clinicians manage complex patients within complex systems — have become *regulatory*, often with implicit (or explicit) threats of sanction if there is deviation from prescribed recommendations or edicts.

In this context, the development of another set of standardised processes, albeit with laudable aims, requires circumspection. Central to this argument is the terminology itself, particularly the word "guideline", whose meaning in medical language has changed substantially over the past decade. Originally defined by the *Oxford English dictionary* as "a principle guiding or directing an action", guideline has become "a set of statements, directions, or principles presenting current or future rules or policy" (*Online medical dictionary,* http://cancerweb.ncl.ac.uk). The definition provided by Linton and van Heerden differs further by suggesting an overarching "statement of policy or procedure by which to determine facilities, structures and activities".[1]

The evolution of guideline-based documents into policy documents underlies most of the concern expressed by clinicians. Most policies — which imply mandatory compliance — relate to administrative functions and are invariably institution-specific and usually appropriate. Clearly, few areas of clinical practice fall within such a rigid framework, apart from situations where there is incontrovertible evidence — usually of harm — such as the contraindication for corticosteroids[2] or albumin[3] in traumatic brain injury. In other words, policies are useful in directing clinicians what they should *not* do.

With this interpretation of "policy", the inherent danger of incorporating evidence-based guidelines into clinical policy documents becomes obvious. Although there is some evidence that some treatment protocols, such as the Advanced Trauma Life Support (ATLS) protocol,[4] have greatly improved the coordination of management, and potentially the outcomes, of trauma patients, others have extensively documented the limitations of available evidence and make few firm recommendations beyond generic principles. This is exemplified by the protocols for management of severe traumatic brain injury issued by the Brain Trauma Foundation.[5]

In contrast, the Surviving Sepsis Campaign has taken the distillation of evidence-based guidelines for aspects of treatment of severe sepsis into the next phase by recommending treatment "bundles", based largely on the grading of available evidence and opinions of appointed experts in the various fields.[6] The adoption and compliance with these recommended bundles have evolved to become "standards of care", which can be used to benchmark units participating in a quality improvement program. This initiative, which has many laudable and highly appropriate recommendations, exemplifies the transformation of "guidelines" into "policy". However, unless these new policies remain abreast of rapidly emerging studies that may refute some recommendations, the applicability of treatment bundles may rapidly diminish. Examples include the elimination of a role for corticosteroids and vasopressin in septic shock following the publication of the CORTICUS[7]

and VASST[8] studies, and questions regarding the recommendations for tight glycaemic control pending the publication of the NICE-SUGAR study.[9]

Furthermore, the broader community must be considered when recommending international guidelines. Recommendations developed in high-income countries cannot be generalised to low- or middle-income countries. For example, recommendations for the use of dopamine or noradrenaline as first line "vasopressors" in septic shock simply do not apply in parts of the world where adrenaline is the only available drug.[10]

The suggestion to develop a standardised terminology for intensive care operational manuals is laudable, but needs to consider the potential impact of the language used. As an alternative, a simplified classification of three "tiers" of practice, which has been generally adopted by clinicians over the past decade, may be a useful starting point and may avoid the potential upgrading phenomenon highlighted above.

- *Policies* are the principles of practice to which the ICU conforms. Adherence with these policies is mandatory. They relate primarily to the administration of the unit and include admission and discharge policies, documentation in clinical records and attendance of patients, consent and medicolegal procedures, emergency response policies, delegation of procedures and interventions and infection control.
- *Protocols* represent the standard approach to practice in an ICU for a specific intervention or procedure. They represent strategies derived from evidence-based practice, consensus statements and clinical experience, taking into account resource availability. Uniform adherence to these protocols is expected, while recognising that they may differ between institutions. Protocols need to reviewed and updated regularly — at least annually. Protocols apply to common and high-priority interventions and include strategies for cardiopulmonary resuscitation, failed intubation drill, nutrition protocols, thromboprophylaxis, acute stress ulceration, drug infusions, central venous catheter insertion and percutaneous tracheostomy.
- *Guidelines* are strategies designed to assist in clinical management outside set protocols. The development and dissemination of unit guidelines should be integrated into an education program, and the guidelines should be updated annually. Guidelines apply to general principles of intensive care medicine, such as fluid and electrolyte management, antibiotic prescription, weaning from mechanical ventilation, and sedation. Adherence to these guidelines ultimately depends on the clinical situation.

In conclusion, clinicians have been developing protocols and handbooks for many years. Many of these have drawn on their experience, knowledge and pragmatic application to clinical practice, with great effect. The presence of carefully worded sets of protocols is the first step towards improving patient safety. The documents are dynamic and need frequent renewal and revision, in the light of rapidly emerging evidence. A balance between applying clinical experience and adopting evidence from credible sources should form the basis of operational manuals, rather than a "one-stop shop" approach.

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