THE PHARMACEUTICAL CARE BUNDLE: DEVELOPMENT AND EVALUATION OF AN INSTRUMENT FOR INPATIENT MONITORING

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ABSTRACT

Introduction: Care bundles help healthcare professionals provide the best care possible in a structured and reliable way. The purpose of this study was to develop and apply an instrument for inpatient follow-up by clinical pharmacists, and evaluate its results.

Methods: The care bundle was based on previously validated instruments. Population consisted of patients monitored by clinical pharmacists at a general hospital. The study was conducted in two phases: the first involved the development and implementation of the bundle, and the evaluation of pharmaceutical interventions; the second involved analyzing data from patients treated with the bundle over one year.

Results: The bundle included fourteen pharmaceutical follow-up criteria used in different patterns by each area of care. In the first phase of the study, 3263 patients were monitored and 536 pharmaceutical interventions were performed, with an 85.3% compliance rate. In the second phase of the study, follow-up data was collected from 21,214 patients. The bundle criteria were used in a similar way in clinical, surgical and cancer patients. Pharmacotherapy review was the most prevalent intervention in all cases (60.1%). Hospital discharge planning and medication reconciliation were performed with a similar frequency in clinical, surgical, pediatric and general patients.

Conclusions: The development and validation of a bundle aimed at guiding the clinical activities of pharmacists helped standardize procedures and interventions. Pharmacotherapy review was the bundle criterion with the highest rate of application and interventions due to the hospital's complexity and the need to consider individual patient needs and follow institutional policies.

Keywords: Pharmacy service, hospital; clinical pharmacy; pharmaceutical intervention; patient care bundles; patient safety

INTRODUCTION

In hospital settings, 'clinical pharmacy' refers to the contribution of hospital pharmacists to drug therapy as part of the comprehensive care offered to patients in collaboration with physicians and nursing staff. The goal of clinical pharmacy services is to optimize the efficiency, effectiveness and safety of pharmacotherapy. Recent studies concluded that clinical pharmacy interventions contribute to the improvement of patient outcomes¹⁻³. Pharmacist participation in medical rounds, medication reconciliation at admission or discharge, and the provision of specific pharmaceutical services reduces the frequency of adverse drug events and medication errors, improving both treatment adherence and patients' medication knowledge¹. Clinical pharmacy services are also associated with cost savings¹⁻³. A number of studies have demonstrated the clinical and economic benefits of clinical pharmacy interventions in hospital and primary care settings¹⁻³. A Pharmaceutical Risk Score was also developed to assess pharmacological risk factors in hospitalized patients and contribute to pharmaceutical monitoring⁴. The scores can be used to classify patients into risk groups (high, moderate or low)

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ABSTRACT



and help hospital pharmacists direct their efforts more effectively⁴. Once priorities for pharmaceutical monitoring have been identified, the follow-up procedures can be determined. The complexity of new drug therapies and improvement of therapeutic regimens due to the results of pharmaceutical interventions reinforce the importance of quality pharmaceutical care. The Institute of Healthcare Improvement developed the concept of 'bundle' to help healthcare professionals provide the best and most reliable care possible to patients receiving specific treatments with inherent risks⁵.

A bundle is a structured way of improving patient care processes through a set of evidence-based practices that, when performed collectively and reliably, improve patient outcomes⁵. Effective follow-up requires the establishment of standardized pharmaceutical criteria adjusted to patient characteristics. To this end, checklists offer a moderate level of guidance but are still flexible enough to allow healthcare workers to use their own judgment⁶.

Systematic reviews and meta-analyses have assessed the effectiveness of bundles in several areas of health care, including the prevention of catheter infections in neonatology and adverse events in pediatric patients⁷⁻⁹. Most meta-analyses include before-and-after studies whose results demonstrate a reduction in health care risks with the use of bundles relative to usual care⁹.

FASTHUG is a mnemonic designed to systematize the care of critical patients, and is used by intensive care practitioners around the world. It lists seven items that must be reviewed daily to standardize care and prevent omissions in intensive care¹⁰. Notably, the FASTHUG mnemonic was not designed to identify problems related to the drugs commonly used in ICU settings¹⁰. Therefore, a modified mnemonic, FASTHUG-MAIDENS, was developed by clinical pharmacists to ensure that the essential standards of pharmaceutical care would be consistently met in professional practice¹¹.

The purpose of developing a new bundle focused on pharmacotherapy is to provide a more flexible instrument that is applicable to different settings, from pediatric to adult patients in both critical and general care, while also contemplating institutional protocols and allowing for the monitoring of patients with expected discharge dates. Such an instrument could also be useful for training and guiding pharmaceutical follow-up in multi-professional teams.

The objective of this study was to describe the development of a care bundle for inpatient follow-up by clinical pharmacists, and evaluate the results of this protocol in a general hospital.

METHODS

The study was conducted at the Hospital de Clínicas de Porto Alegre (HCPA), a tertiary university hospital accredited by the Joint Commission International. The HCPA has approximately 850 beds and 19 clinical pharmacists, who work in the following areas: clinical care (general practice, clinical specialties and psychiatry); surgery (general surgery, specialties and solid organ transplants); oncology (adult oncohematological patients, pediatric and hematopoietic stem cell transplantation, pediatric cancer); maternal and child care (maternity and neonatology); and critical care (emergency and pediatric/adult intensive care units). Follow-up in these areas is conducted according to patient needs and pre-established criteria for each particular sector.

Development of the pharmaceutical care bundle

The bundle was developed based on validated instruments used at the HCPA, including FASTHUG¹⁰ and FASTHUG-MAIDENS¹¹, which include items that should be reviewed on a daily basis to ensure standardized care and avoid any omissions, thereby meeting the essential goals of pharmaceutical care^{12,13}. Examples of items in these protocols include feeding, analgesia, sedation, institutional protocols, and medication reconciliation.

Population, data collection and outcome measurement

The study population consisted of patients managed by pharmacists from the clinical, surgical, oncological, pediatric, maternal and critical care units. The study was conducted in two phases. The first was a three-month pilot project (May to July 2017) to validate the pharmaceutical care bundle. The bundle was evaluated by correlating each item with the pharmaceutical interventions performed in the same period. The results of the pharmaceutical interventions were assessed based on medical compliance rates.

The pilot project allowed for adjustments to be made to the instrument prior to the next phase of the study, which consisted of monitoring patients treated with the pharmaceutical care bundle for a one-year period (January to December 2018). Information on the patients monitored by clinical pharmacists, as well as the bundle items used in each case, were recorded in a productivity monitoring system consisting of a Microsoft Excel (version 2010) spreadsheet, for further data analysis.

Ethics approval

This study was conducted according to Brazilian National Health Council guidelines (Resolution 466/12) and approved by the HCPA Research and Postgraduate Group.

RESULTS

Table 1 shows the pharmaceutical care bundle and adjustments made after the pilot phase.

Item	Criteria	Description
1	Pharmacotherapy review	Evaluating the list of health problems and prescribing medications according to indications for use and effectiveness and safety parameters, including adverse reactions, drug interactions, therapeutic duplication, allergies and duration of therapy.
2	Medication reconciliation	Performing medication reconciliation on admission, transferring between units/specialties or hospital discharge to identify and resolve discrepancies.
3	Nutrition	Identifying the nutrition administration route (enteral or parenteral) Evaluating alternative dosage forms and suggesting changes in administration routes as needed. Reviewing interaction/incompatibilities between drugs and nutrients.
4	Analgesia	Reviewing the prescribed analgesics according to pain/analgesia protocols (pain characteristics, location and intensity; dose, interval and drug infusion time)
5	Sedation	Reviewing prescribed sedatives according to sedation protocols (sedation rating scale where applicable, dose, interval, and drug infusion time). Evaluating medications with a potential risk of falling and excessive sedation.
6	Anticoagulation/ risk of VTE	Evaluating oral anticoagulant use (monitoring INR and relevant drug interactions) and PTE/DVT treatment with anticoagulant EV and SC (indication of use, dose, route of administration and monitoring aPTT and anti-Xa where applicable). Assessing the risk of PTE/DVT according to thromboembolic event prevention protocol.
7	Delirium	Evaluating drugs with the potential to induce or worsen delirium (hyperactive, hypoactive or mixed) and treatment according to protocols. Checking the history of alcoholism or psychoactive substance use for risk of abstinence and treatment as indicated.
8	Physiological habits/stress ulcer prophylaxis	Checking physiological habits and considering medications that may change them (nausea, vomiting, constipation, diarrhea, urinary retention) and the need for pharmacological management. Evaluating the need for stress ulcer prophylaxis, including doses, monitoring of complications and treatment time.
9	Vital signs	Reviewing vital signs (blood glucose, blood pressure and heart rate, etc.), considering medications that could alter them and verifying the need for pharmacological management.
10	Antimicrobials	Evaluating antimicrobial therapy (empirical, prophylactic or culture-guided treatment/sensitivity testing) based on guidelines. Optimizing therapy (doses, treatment time and decolonization).
11	Dose adjustment	Reviewing renal function, liver tests and other parameters that could alter patient dosage. Therapeutic monitoring of medications
12	Laboratory results	Checking laboratory tests and intervening as necessary, considering drug- induced changes.
13	Hospital discharge	Planning and orienting hospital discharge for priority care lines and/or according to patient requirements. Evaluating access to the medications prescribed at discharge. Providing safety information for medications dispensed for home use.
14	Validation of medications brought by the patient	Evaluating medications brought by the patient, register in the medical record to ensure traceability and safe use during hospitalization.

Table 1: Proposed	pharmaceutical c	are bundle (A	Adapted from t	he FASTHUG-MAIDENS ¹¹)).
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VTE: venous thromboembolism; PTE: Pulmonary thromboembolism; DVP: deep vein thrombosis; INR: international normalized ratio; aPTT: Activated partial thromboplastin time; EV: endovenous; SC: subcutaneous.

The first phase of the study aimed to validate the pharmaceutical bundle. This stage involved 3,263 patients and 536 pharmaceutical interventions, which were then classified according to bundle item (Figure 1).

The mean number of interventions per patient was 0.16 in the first stage, and overall compliance with these interventions was 85.3%. Table 2 presents data on intervention adherence for each bundle item. The categories with the highest frequency of pharmaceutical interventions were medication review (53.4%) and reconciliation (16.8%); the rates of compliance with these interventions were 86.4%

and 86.7%, respectively. Although other bundle items were associated with fewer interventions, they had higher adherence rates; this was the case for venous thromboembolism (VTE) risk (90.5%), delirium, hospital discharge and drug validation (100%) (Table 2).

In the second phase of the study, follow-up data were collected for 21,214 patients treated with the pharmaceutical bundle. Table 3 shows the results of pharmaceutical follow-up and bundle items applied in each area of care. Overall results for the second phase of the study revealed an adherence rate of 71.9%, and a mean of 0.37 interventions per patient.



Figure 1: Pharmaceutical interventions performed in the bundle validation phase (n = 536).

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Pundlo oritorio	Pharmaceutical interventions	Intervention adherence		
	n (%)	n (%)		
Pharmacotherapy review	286 (53.4%)	247 (86.4%)		
Medication reconciliation	90 (16.8%)	78 (86.7%)		
Nutrition	40 (7.5%)	30 (75%)		
Analgesia	36 (6.7%)	22 (61.1%)		
Sedation	4 (0.7%)	3 (75%)		
Anticoagulation/ VTE risk	21 (3.9%)	19 (90.5%)		
Delirium	2 (0.4%)	2 (100%)		

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Table 2: Continuação

Pundla aritaria	Pharmaceutical interventions	Intervention adherence		
Bundle Chteria	n (%)	n (%)		
Physiological habits	5 (0.9%)	4 (80%)		
Vital signs	7 (1.3%)	6 (85.7%)		
Antimicrobials	35 (6.5%)	29 (82.9%)		
Dose Adjustment	35 (6.5%)	27 (77.1%)		
Laboratory results	17 (3.2%)	16 (94.1%)		
Hospital discharge	12 (2.2%)	12 (100%)		
Validation of current patient medications at admission	5 (0.9%)	5 (100%)		

VTE: venous thromboembolism

Care line	Clinical patients	Surgical patients	Cancer patients	Critical patients	Pediatric patients	Maternal and child care	Total (n = 21214)
Bundle criteria	(n = 5735)	(n = 5247)	(n = 1963)	(n = 4884)	(n = 2292)	(n = 1093)	, , ,
Medication reconciliation	873 (15.2%)	723 (13.8%)	918 (46.8%)	0	344 (15.0%)	191 (17.5%)	3.082 (14.5%)
Admission	842 (14.7%)	533 (10.2%)	510 (26.0%)	0	189 (8.2%)	0	2074 (9.8%)
Transference	39 (0.7%)	72 (1.4%)	139 (7.1%)	0	95 (4.1%)	0	345 (1.6%)
Hospital discharge	85 (1.5%)	151 (2.9%)	269 (13.7%)	0	60 (2.6%)	191 (17.5%)	756 (3.6%)
Pharmacotherapy review	3.712 (64.7%)	1.892 (36.1%)	1.835 (93.5%)	4.198 (86.0%)	767 (33.5%)	351 (32.1%)	12.755 (60.1%)
Nutrition	1.434 (25.0%)	950 (18.1%)	818 (41.7%)	1.268 (26.0%)	206 (9.0%)	58 (5.3%)	4.734 (22.3%)
Analgesia	2.243 (39.1%)	910 (17.3%)	1.053 (53.6%)	3.130 (64.1%)	87 (3.8%)	0	7.423 (35.0%)
Sedation	612(10.7%)	56 (1.1%)	176 (9.0%)	552 (11.3%)	11 (0.5%)	0	1.407 (6.6%)
Anticoagulation/ VTE risk	2.551 (44.5%)	1.417 (27.0%)	176 (9.0%)	2.398 (49.1%)	6 (0.3%)	9 (0.8%)	6.557 (30.9%)
Delirium	654 (11.4%)	50 (1.0%)	0	183 (3.7%)	0	0	887 (4.2%)
Physiological habits	1.938 (33.8%)	1.106 (21.1%)	739 (37.6%)	832 (17.0%)	33 (1.4%)	0	4.648 (21.9%)
Vital signs	2.426 (42.3%)	1.622 (30.9%)	782 (39.8%)	176 (3.6%)	93 (4.1%)	0	5.099 (24.0%)
Antimicrobials	1.569 (27.4%)	982 (18.7%)	419 (21.3%)	2.042 (41.8%)	319 (13.9%)	321 (29.4%)	5.652 (26.6%)
Dose adjustment	780 (13.6%)	104 (2.0%)	269 (13.7%)	510 (10.4%)	47 (2.1%)	4 (0.4%)	1.714 (8.1%)
Laboratory results	2.391 (41.7%)	1.688 (32.2%)	468 (23.8%)	2.572 (52.7%)	205 (8.9%)	163 (14.9%)	7.487 (35.3%)
Hospital discharge	572 (10.0%)	444 (8.5%)	362 (18.4%)	103 (2.1%)	232 (10.1%)	269 (24.6%)	1.982 (9.3%)

Table 3: Pharmaceutical follow-up data from 2018 according to pharmaceutical bundle items and areas of care (n = 21,214).

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Care line Bundle criteria	Clinical patients (n = 5735)	Surgical patients (n = 5247)	Cancer patients (n = 1963)	Critical patients (n = 4884)	Pediatric patients (n = 2292)	Maternal and child care (n = 1093)	Total (n = 21214)
Anticoagulant	178 (3.1%)	129 (2.5%)	19 (1.0%)	3 (0.1%)	2 (0.1%)	5 (0.4%)	336 (1.6%)
Oral chemotherapy	14 (0.2%)	14 (0.3%)	100 (5.0%)	0	8 (0.3%)	0	136 (0.6%)
Hospital discharge planning	151 (2.6%)	189 (3.6%)	99 (5.0%)	97 (2.0%)	164 (7.1%)	169 (15.5%)	869 (4.1%)
Other discharge orientation	136 (2.4%)	203 (3.9%)	303 (15.4%)	8 (0.2%)	144 (6.3%)	209 (19.1%)	1003 (4.7%)
Drug dispensing	66 (1.1%)	68 (1.3%)	0	4 (0.1%)	40 (1.7%)	140 (12.8%)	318 (1. +5%)

Table 3: Continuação

DISCUSSION

In the first stage of the study, the instrument was developed and validated by analyzing interventions implemented with the pharmaceutical care bundle.

The item with the highest frequency of interventions was pharmacotherapy review, followed in descending order by medication reconciliation, nutrition, analgesia, antimicrobials and dose adjustment (Figure 1 and Table 2). Interventions in these categories may have been more frequent because they are associated with the initial review performed on hospitalization and to pharmaceutical monitoring, as well as the adjustment of prescription dosage according to institutional protocols (e.g. analgesia, antimicrobial policy, serum vancomycin levels, monitoring of oral anticoagulants), which can affect laboratory results and prompt the need for further pharmacological interventions.

Adherence rates and the mean number of interventions per patient were consistent with the results of previous studies¹⁴⁻¹⁶. Pharmaceutical interventions were fully implemented for the items delirium, hospital discharge and validation of medication use. The small number of interventions for the item "delirium" is justified by the fact that this symptom is more frequent in clinical wards, where health care workers are also better able to detect it. Interventions at hospital discharge, including medication reconciliation, aim to ensure appropriate pharmacotherapy and help patients access the health system by providing the appropriate prescriptions and documents. The validation of medications brought by the patient for use in the hospital provides an opportunity for a review of past prescriptions, and for an assessment of patients' habits regarding the acquisition, use, and conservation of the medication, which could lead to interventions to promote safer medication use^{17,18}.

A review of laboratory parameters showed that adherence to the interventions was high, likely due to their relevance to treatment efficacy and drug safety. These are often structured interventions that are already systematically implemented by the hospital pharmacy service. The adherence rates for other interventions remained above 60%, similar to previous studies^{16,19}. It is important to note that many pharmaceutical interventions are educational in nature, which may have contributed to the variations in acceptability rates¹⁵.

The distribution of interventions related to each item was consistent with patient profiles. The most prevalent bundle category in all areas of care was medication review, which is performed using medical prescription data and patient records. Clinical pharmacists perform this assessment to prevent or resolve drug-related problems, which are the main cause of adverse events and could lead to outcomes such as increased length of stay, morbidity, mortality and greater hospital costs¹⁴.

Clinical, surgical and cancer patients had similar follow-up profiles. The most prevalent interventions in these departments were associated with institutional protocols (analgesia, venous thromboembolism prophylaxis and oral anticoagulation management); the next most frequent interventions were the assessment of vital signs, laboratory results, physiological functions and nutritional status. The analysis of these items contributes to the evaluation of the efficacy and safety of pharmacotherapy and could reveal the need for further pharmaceutical interventions. Examples include dose adjustment; discontinuing medication due to suspected adverse reactions identified in vital signs or altered laboratory tests; and assessing potential interactions between medications and enteral nutrition.

Analgesia interventions were more prevalent in critical, clinical and cancer patients. Compliance with the pain management scale and appropriate use of analgesics are important strategies in these populations, and especially in cancer pain management. Pain is reported by 39.3 to 55% of cancer patients undergoing treatment and 66.4% of advanced cancer patients^{20,21}.

The comparison of clinical and surgical patients revealed that the latter were less likely to require a medication review due to their high turnover rates. Pharmaceutical follow-up was more frequent in surgical patients, since pharmacists must review the laboratory results of transplant recipients to examine their immunosuppressant levels and make any necessary adjustments, as well as monitor and adjust the doses of any other prescriptions.

Patients admitted to adult or pediatric intensive care units and those seen in emergency services share a similar feature: an unstable clinical condition that may lead them to become chronically critically ill over time. The most prevalent interventions in critically ill patients were associated with organ dysfunction. Issues observed in this population included hemodynamic instability, ventilatory insufficiency, acute renal failure, poor perfusion, high risk of thrombosis due to prolonged bed rest, suspected sepsis or septic shock, and other complications that occur during hospitalization in clinical, surgical or specialized wards. Emergency services treat patients who meet criteria for stroke, acute coronary syndrome and infarction protocols. This underscores the need to systematically monitor laboratory tests at least once a day for severe cases in emergency wards and ICUs; to ensure patient comfort during mechanical ventilation; and provide adequate pain management. However, the frequency with which some items were used in emergency care as compared to ICU settings differed, probably because the oral route is available in most patients in emergency care, while most ICU patients receive full enteral nutrition^{10,11}.

Although the profile of pediatric ICU patients is similar to that of adults, the need to monitor the risk of VTE is mostly associated with adult patients. The incidence of VTE in pediatric populations is not known. The first data on the subject were published in 1994 based on the Canadian Childhood Thrombophilia registry, which reported an incidence of 0.07 per 10 000 children from 1 month to 18 years old. In Europe, the estimated incidence is 0.07 to 0.14 per 10 000 children, which is much lower than that observed in adults (5.6 to 16 per 10 000)²².

Antimicrobial monitoring in neonatology was very frequent, since the most common diseases in this population include those identified using a neonatal sepsis protocol (early or late onset), as well as STORCH infections (e.g. measles, toxoplasmosis, rubella, cytomegalovirus, herpes), and necrotizing

enterocolitis. Thus, the monitoring of laboratory results was also common in this population, though not as frequent as the prescription of antimicrobials due to the impossibility of further follow-up. Antimicrobial monitoring in the pediatric patient group included interventions performed in general pediatric wards and the treatment of common childhood diseases, as well as the use of antimicrobials by patients with short bowel syndrome, cystic fibrosis and recent liver transplantation, since the HCPA is a reference hospital for these conditions. It is also important to note that the 'nutrition' bundle item in pediatric patients included the consideration of alternative pharmaceutical formulations, since liquid formulations are often unavailable for these patients¹⁷. Vital signs in the maternal and child care group were not monitored by pharmacists; neonatal patients and pregnant women are closely monitored by the medical and nursing teams according to pre-established protocols, allowing pharmacists to concentrate on other aspects of pharmacotherapy that receive less attention from the rest of the multidisciplinary team.

Hospital discharge planning and medication reconciliation were similarly frequent in clinical, surgical, pediatric and general patients since the procedures involved in reconciliation, planning and education at hospital discharge are the same in these departments. Some issues addressed by interventions in these populations were the use of anticoagulants, oral chemotherapy, polypharmacy and medication adherence difficulties. Pediatric discharge planning includes counseling patients with chronic polypharmacy about fractional dosing, and providing information on liver transplantation, fibrocystic drugs, and intestinal rehabilitation, as needed. During discharge from the maternal and child health department, pharmacists must also consider the guidelines for pregnant and puerperal women receiving antimicrobial treatments, prophylaxis for vertical transmission of HIV and issues related to the discharge of newborns who have been prescribed different types of medications, including anticonvulsants.

All departments had to discharge patients with complex needs, provide guidance about medication acquisition, and inform patients about administration tubes and pharmaceutical formulations adapted for home use.

Medication reconciliation upon hospital discharge was more frequent among surgical and cancer patients due to the orientations and educational materials given to transplant recipients (i.e., to help organize the medications they will be using at home). In neonatology, medication reconciliation is only necessary on hospital discharge, while in pediatric patients, it must be carried out at all three points; previous studies have shown that drug-related problems are more likely to occur when reconciling medications at admission, discharge and transfer^{23,24}.

Limitations and expectations

This study had limitations related to institutional characteristics. The data were obtained from the secondary records of clinical pharmacists, which includes professionals in training, since our institution is a teaching hospital. Additionally, the demands of the multiprofessional team may lead pharmacists to focus on patient care rather than on the reporting of items considered essential to the bundle.

The proposed pharmaceutical care bundle is a comprehensive instrument which was tested locally at a tertiary university hospital. The results suggested that it may serve as a guide for pharmaceutical education and the training of new professionals in the institution, as well as contribute to the planning and adjustment of pharmaceutical interventions according to the profile and specialty of each department. The bundle can also be used by other hospitals with a similar health care profile in order to implement or improve a clinical pharmacy service.

We suggest that future studies pursue the development of specific bundles for different specialties or areas of care considering the characteristics and profile of each patient group.

This study aimed to develop and apply a pharmaceutical evaluation instrument to guide the clinical activities of pharmacists and help standardize their conduct and interventions. The proposed bundle is a comprehensive instrument which can serve as a guide for pharmaceutical education and the training of new professionals. The bundle category with the most interventions was medication review, likely due to the hospital's complexity, differences between patients, and institutional policies.

This instrument can be used as the basis for instruments tailored to different specialties or areas of health care with different levels of complexity and patient profiles.

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Conflict of Interests

The authors declare no conflict of interests.

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