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Development of a checklist in risk management in thyroidectomy☆

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KEYWORDS
Thyroidectomy;
Patient safety;
Risk factors;
Risk management;
Root cause analysis;
Comorbidity;
Checklist

Abstract
Introduction: Communication failures may result in inadequate treatment and patient harm, and are among the most common causes of sentinel events. Checklists are part of cycles to improve quality of the care process, promote communication between professionals involved in the different stages, help detect failures and risks, and increase patient safety. The lack of checklists at each stage was identified as a factor contributing to communication failures.
Objective: To design checklists at different stages of the thyroidectomy care process to improve the communication between the professionals involved.
Method: Multidisciplinary working team consisting of specialists in otolaryngology, anesthesiology, and endocrinology. The process of thyroidectomy was divided into three stages (preoperative –A–, operative –B– and postoperative –C–). Potential safety incidents and failures at each stage and their contributing factors (causes) were identified by the literature review and brainstorming. Checklists for each checkpoint were designed by consensus of the working group.
Results: The items correspond to factors contributing to the occurrence of incidents in the perioperative stage of thyroidectomy related to patients, technological equipment, environment, management, and organization. Lists of items should be checked by the appropriate specialist in each stage.
Conclusions: Checklists in thyroid surgery are tools that allow for testing at different checkpoints data related to factors contributing to the occurrence of failures at each stage of the care process.

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PALABRAS CLAVE
Tiroidectomía;
Seguridad del paciente;
Factores de riesgo;
Control de riesgo;
Análisis de causa raíz;
Comorbilidad;
Lista de verificación

Diseño de una lista de verificación en la gestión de riesgos en tiroidectomía

Resumen
Introducción: Los fallos en la comunicación pueden provocar tratamiento inadecuado, daño al paciente y son una de las causas más frecuentes de aparición de eventos centinela. Las listas de verificación son herramientas que forman parte de los ciclos de mejora de la calidad del proceso asistencial, facilitan la comunicación entre los profesionales implicados, ayudan en la detección de fallos y riesgos e incrementan la seguridad del paciente. La falta de listados de verificación en cada etapa es un factor contribuyente en los fallos de comunicación.
Objetivo: Diseñar listas de verificación en distintas etapas del proceso asistencial de tiroidectomía para mejorar la comunicación entre los profesionales implicados.
Método: Equipo de trabajo multidisciplinar constituido por especialistas en otorrinolaringología, anestesiología y endocrinología. El proceso de tiroidectomía se distribuyó en 3 etapas (preoperatoria [A], operatoria [B] y postoperatoria [C]). Se identificaron los posibles incidentes de seguridad y fallos en cada etapa y sus factores contribuyentes (causas) mediante revisión bibliográfica y tormenta de ideas. Se diseñaron listados de verificación para cada punto de control mediante consenso del grupo de trabajo.
Resultados: Los ítems se corresponden con factores contribuyentes en la presentación de incidentes perioperatorios en tiroidectomía relacionados con el paciente, los equipos tecnológicos, el entorno, la gestión y la organización.
Conclusiones: Las listas de verificación en cirugía tiroidea son herramientas que permiten comprobar de forma reiterativa en distintos puntos de control del proceso de tiroidectomía datos que se relacionan con factores contribuyentes en la presentación de fallos en cada etapa del proceso asistencial.

Introduction

The most common incidents after thyroid surgery include hypocalcemia (transient 15.5–19.5%[1]; permanent from 0–0.3%[1] to 4.8%[2]), recurrent laryngeal nerve palsy (transient, 1.8–2.1%[1]; permanent, from 0–0.2%[1] to 5.1%[3]), bleeding (0.5–0.9%),[1] and airway obstruction.[4] Overall mortality of thyroidectomy is however 46–64%,[1] and is associated to multiple factors which have been investigated without reaching definitive conclusions.[5] Treatment should therefore be aimed at improving several aspects from the preoperative period.[6]

The safety incident is the event or circumstance which caused or could have caused an unnecessary damage to the patient[7]; includes the concept of sentinel event (unexpected adverse event related to death, physical or psychological damage or risk of damage[8]). Thus, safety incidents result in actual or potential patient damage, use of treatments and care unusual for the procedure (increased care level, need for additional procedures and treatments), prolonged stay, inadequate stay, readmission, suspension of surgical programming, and increased cost.[8–10]

Complexity and greater instrumentation of care probably influence the occurrence of incidents.[11] Safety incidents usually have multiple causes (system or individual failures[12]) and should be investigated using root cause analysis (RCA) and Healthcare Failure Mode Effects and Analysis (HFMEA).[9,13] HFMEA assesses the criticality (frequency and severity) and detectability of each potential failure.[9]

The number of incidents related to health care has been estimated to range from 2.9% and 16.6%, and that 27.4% to 51.1% of them would be avoidable.[14] Complications occur in 3–16% of surgical procedures requiring admission, leading to mortality or permanent disability rates of 0.4–0.8%. It is thought that such complications could be prevented in at least half the cases.[15,16] In Spain, adverse events are avoidable in up to 42.8% of cases and occur in 9.3% of inpatients for reasons attributable to care, being 1.6 times more common in patients with risk factors and up to 2.5 times more common in patients over 65 years of age.[10] Comorbidity has an impact on incident occurrence, stay, and cost.[17] Assessment of comorbidity before surgery allows for evaluating the preoperative risk of morbidity and mortality based on individual risk factors,[17–19] but does not consider other contributing factors (equipment, environment, management, etc.). Several scales should therefore be used[20] and interpreted with caution, as no gold standard is available.[21]

There are various models which attempt to explain and analyze the causes of safety incidents.[22,23] Clinical risk management systems allow for a systematic solution of problems, contributing to improve the quality and safety of medical action by preventing adverse events, identifying the conditions that expose patients to risk, and preventing or controlling such risk, involving several organizational levels.[13,24] This ''implies practicing health care free from avoidable damages'', which ''involves development of systems and processes aimed at reducing the probability of occurrence of system failures and personal errors and at increasing the probability to detect them when they occur

and to mitigate their consequences''.[25] The safety system allows for establishing criteria to decrease risk of recurrence, which would increase the possibility of serious adverse outcomes.[7,9]

Communication of information from a healthcare professional to another is one of the nine solutions to improve patient safety proposed by the Joint Commission, because ''communication gaps may cause serious interruption in care continuity, inadequate treatment, and potential damage to the patient'', and has been reported to be one of the most common causes of the occurrence of sentinel events.[26]

Checklists (CLs) are tools including a systematic sequence of events related to the care process[27] intended to consolidate safety practices and to promote communication and teamwork between several clinical disciplines.[15]

In this regard, use of the ''surgical safety checklist'' has allowed for decreasing the morbidity (from 11% to 7%) and mortality (from 6.2% to 3.4%) associated to surgery.[15,16] However, the World Health Organization (WHO) guidelines for surgical safety are unevenly applied, even in the most advanced environments.[15]

Adequate communication benefits professionals and patients, but there is no universally accepted model to transmit perioperative critical information in thyroid surgery based on a rational approach.[28]

The purpose of this study was to design CLs for different stages of the thyroidectomy care process in order to improve communication between the professionals involved.

Materials and methods

To develop the CL, the methodology proposed by Stufflebeam,[29] summarized in the following points, was used:

(1) Setting up of the multidisciplinary work team, consisting of specialists in otolaryngology, anesthesiology, and endocrinology.
(2) Identification of the critical stages in the thyroidectomy process: preoperative (A), operative (B), and postoperative (C). In each stage, checkpoints were identified in a logical sequential order.[27]
(3) Identification of incidences, safety incidents, risks, and potential failures in each stage. Safety incidents were defined as those related to sentinel events, any other safety incident, quality indicator failures, incidents recorded in the medical or nursing clinical history, adverse effects of drugs, and patient complaints or claims.[9,12] HFMEA methodology[8,9] was used to select potential failures. The risk matrix was created based on frequency (incidence at our center and in the reviewed literature), severity (impact on the patient[12]), and detectability (difficulty to detect the risk or situations preceding the failure). Incidents of very high severity (catastrophic), undetectable (or difficult to detect) incidents, or highly critical incidents (severity by frequency product) were prioritized.[8,9]
(4) Item identification. Items related to safety incidents and failures in each stage, as well as contributing factors (causes), were selected by brainstorming adapting the taxonomy used in the literature reviewed.[7,9,12] The

Table 1 Recording of comorbidity. Charlson and Elixhauser scales.

Charlson scale	
1	Myocardial infarction
	Congestive heart failure
	Peripheral vascular disease
	Cerebrovascular disease
	Dementia
	Chronic lung disease
	Connective tissue disease
	Peptic ulcer
	Mild liver disease
	Diabetes
2	Hemiplegia–paraplegia
	Severe kidney disease
	Diabetes with organic disease
	Tumor of any type
	Leukemia
	Lymphoma
3	Moderate to severe liver disease
6	Metastatic solid tumor
	AIDS
	Total (groups: 0, 1–2, 3–4, >5)

Elixhauser scale

1. Congestive heart failure
2. Cardiac arrhythmia
3. Heart valve disease
4. Lung circulation disease
5. Peripheral vascular disease
6. High blood pressure
7. Paralysis
8. Other neurological diseases
9. Chronic lung disease
10. Uncomplicated diabetes
11. Complicated diabetes
12. Hypothyroidism
13. Kidney failure
14. Liver disease
15. Peptic ulcer without bleeding
16. HIV disease
17. Lymphoma
18. Metastatic cancer
19. Solid tumor with no metastasis
20. Rheumatoid arthritis or vascular collagen disease
21. Coagulopathy
22. Obesity
23. Weight loss
24. Fluid and body electrolyte impairment
25. Anemia from blood loss
26. Anemia from other deficiencies
27. Alcoholism
28. Drug abuse
29. Psychosis
30. Depression

Source: Charlson et al.[18] and Elixhauser et al.[19]

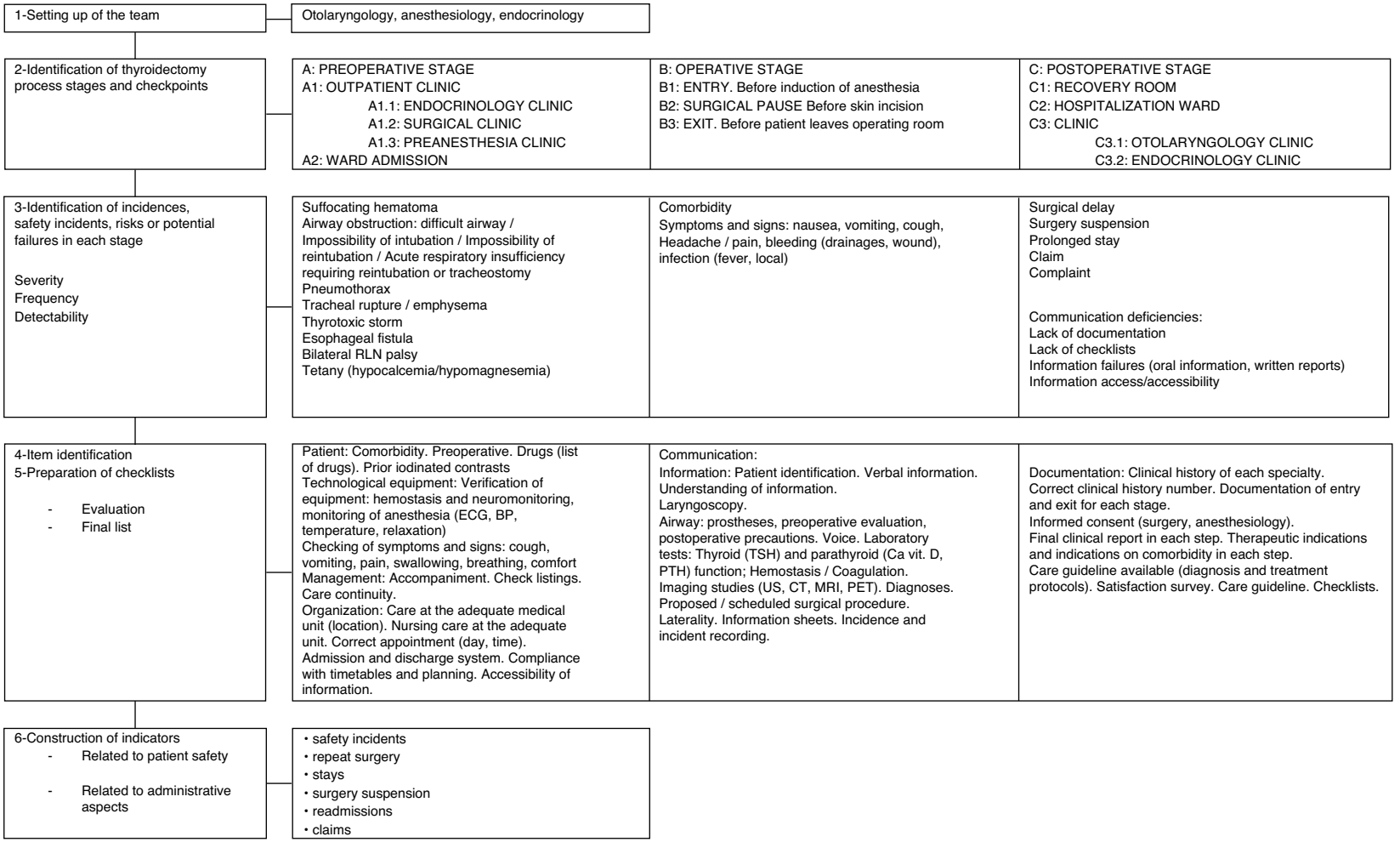

Figure 1 Method: Development of checklists.

Table 2 Checklists in thyroidectomy. Perioperative stage (A).

A: preoperative			
A1: outpatient clinic			
A1.1: endocrinology clinic	A1.2: surgical clinic	A1.3: preanesthesia clinic	A2: ward admission
Entry Adequate unit yes/no Patient identification yes/no Correct clinical history number Entry document yes/no Patient accompanied yes/no Comorbidity (see below [Table 4]) Drug list yes/no Laboratory tests yes/no-Ca/P level yes/no-vitamin D level yes/no-Mg level yes/no-tumor markers yes/no/not applicable) Documented imaging studies yes/no (ultrasonography yes/no/not applicable-CT yes/no/not applicable-MRI yes/no/not applicable) Other yes/no/not applicable	Entry Adequate unit yes/no Patient identification yes/no Correct clinical history number Accompanied patient yes/no Comorbidity (see below [Table 4]) Drug list yes/no Laboratory tests yes/no-Ca/P level yes/no-vitamin D level yes/no-Mg level yes/no-tumor markers yes/no/not applicable) Documented imaging studies yes/no (ultrasonography yes/no/not applicable-CT yes/no/not applicable-MRI yes/no/not applicable) Other yes/no/not applicable Documentation: General clinical history yes/no Endocrinology clinical history yes/no Endocrinology report yes/no Referral form from A1.1 yes/no Iodinated contrast media in prior 6 months yes/no Drug allergies yes/no Anticoagulants/antiaggregants yes/no Coagulopathies yes/no Prosthesis yes/no Prior local surgery yes/no Indirect laryngoscopy yes/no Prior voice disease yes/no Airway evaluation yes/no Neck mobility evaluation yes/no *Exit* Surgical clinical history yes/no Patient information yes/no Surgical clinical report yes/no Informed consent yes/no Indications on comorbidity yes/no/not applicable Referral form to A1.3 Procedure proposed from A1.1 yes/no Programmed procedure yes/no Laterality yes/no	*Entry* Adequate unit yes/no Patient identification yes/no Correct clinical history number Entry form from A1.2 yes/no Accompanied patient yes/no Comorbidity (see below [Table 4]) Drug list yes/no Laboratory tests yes/no (thyroid profile yes/no-Ca/P level yes/no-vitamin D level yes/no-Mg level yes/no-electrolytes-proteins−hepatic and renal profile) *Documentation* General clinical history yes/no Endocrinology clinical history yes/no Endocrinology clinical report yes/no Surgical clinical history yes/no Surgical clinical report yes/no *Exit* Euthyroid yes/no ECG-cardiological assessment yes/no Prior anesthetic incidents yes/no ASA grade Airway risk evaluation yes/no Difficult airway yes/no Anesthesiology clinical history yes/no Anesthesiology clinical report yes/no Patient information yes/no Informed consent yes/no Indications on comorbidity yes/no/not applicable	*Entry* Adequate unit yes/no Patient identification yes/no Correct clinical history number Admission form yes/no Accompanied patient yes/no Drug list yes/no *Documentation* General clinical history yes/no Endocrinology clinical history yes/no Endocrinology clinical report yes/no Surgical clinical history yes/no Anesthesiology clinical history yes/no Informed consent for surgery yes/no Anesthesiology informed consent yes/no Preanesthetic indications and treatment yes/no/not applicable Drugs discontinued yes/no Drugs continued yes/no Anticoagulation regimen yes/no/not applicable Prophylaxis for DVTE yes/no/not applicable *Exit* Vital signs yes/no Nursing history Euthyroid yes/no

Table 3 Checklists in thyroidectomy. Operative stage (B).

B: operative stage		
B1: entry. Before induction of anesthesia	B2: surgical pause Before skin incision	B3: exit. Before patient leaves operating room
Patient has confirmed His/her identity Surgical site Procedure Consent	Confirm that all team members have introduced themselves by name and role	Nurse verbally confirms with the team: The name of the procedure performed That counts of instruments, gauzes, and needles are correct (or not applicable)
Site marking/not applicable	Surgeon, anesthetist, and nurse verbally confirm: Patient identity Surgical site Procedure	Sample labeling (including patient name)
Anesthesia safety control has been completed		If problems related to instrumentation and equipment are pending
Pulse oxymeter placed and active	Prevention of critical events:	
Has the patient known allergies? No/yes	Surgeon reviews: critical or unforeseen steps, operating time, and expected blood loss	Surgeon, anesthetist, and nurse review the main aspects of patient recovery and treatment
Difficult airway/risk of aspiration? No/yes, and instruments and equipment/help available	The anesthesia team reviews: if patient has some specific problem	*Exit* Patent airway yes/no Verification of dressings and surgical wound
Risk of bleeding > 500 mL (7 mL/kg in children? No/yes, and intravenous access and adequate fluids available	The nursing team reviews: if sterility has been confirmed (with results of indicators) and doubts or problems related to instruments and equipment exist	Verification of drainages Surgical procedure report yes/no Anesthesiology report yes/no
	Has antibiotic prophylaxis been administered in the past 60 min? Yes/not applicable	Postoperative control sheets of Ca and PTH are available
	Can essential diagnostic images be visualized? Yes/not applicable	All treatment and postoperative care instructions have been written down
Complete documentation yes/no Hemostasis system available yes/no Neuromonitoring system available yes/no	Patient temperature monitoring Neuromuscular relaxation monitoring Verification of laterality (L1)	
Compliance with fasting yes/no Denture, prosthesis, or metallic objects yes/no Preanesthetic indications and treatment yes/no	Verification of hemostatic system yes/no Verification of neuromonitoring system yes/no Final verification of vagus nerve signal	

Table 4 Checklists in thyroidectomy. Postoperative stage (C).

C: Postoperative			
		C3: clinic	
C1: recovery room	C2: hospitalization ward	C3.1: surgical clinic	C3.2: endocrinology clinic
Entry	*Entry*	*Entry*	*Entry*
Adequate unit yes/no	Adequate unit yes/no	Adequate unit yes/no	Adequate unit yes/no
Patient identification yes/no	Patient identification yes/no	Patient identification yes/no	Patient identification yes/no
Correct clinical history number	Correct clinical history number	Correct clinical history number	Correct clinical history number
All treatment and postoperative care instructions are clear	Accompanied patient yes/no	Accompanied patient yes/no	Accompanied patient yes/no
Drug availability yes/no (Ca-vit D, Mg)	Drug list yes/no	Drug list yes/no	Drug list yes/no
Temperature monitoring	All treatment and postoperative care instructions are clear	*Documentation*	*Documentation*
ECG	Drug availability yes/no (Ca-vit D, Mg, levothyroxine)	General clinical history yes/no	General clinical history yes/no
Blood pressure	Verification of labeling yes/no	Endocrinology clinical history yes/no	Endocrinology clinical history yes/no
Pain	Indications for control of calcemia and alarm signs of hypocalcemia are followed yes/no	Hospital discharge report	Endocrinology clinical report yes/no
Patent airway yes/no		Hospitalization episode	Surgical clinical history yes/no
Emphysema yes/no		Histological report yes/no	Hospitalization episode
Verification of dressings and surgical wound	Surgical care guideline available yes/no	Use of iodinated contrast media yes/no	Hospital discharge report
Verification of drainages	Patent airway yes/no	Control of treatment schemes (adequate drugs and dose: levothyroxine yes/no/not applicable-Ca/vit D yes/no/not applicable-anticoagulation regimen yes/no/not applicable)	Histological report yes/no
General patient state	Voice		Control of treatment schemes (adequate drugs and dose: levothyroxine yes/no/not applicable-Ca/vit D yes/no/not applicable)
Wound: bleeding/hematoma yes/no	Emphysema yes/no		
Paresthesia yes/no	Verification of dressings and surgical wound	Indirect laryngoscopy	See laboratory control
Restlessness yes/no	Verification of drainages	Voice	
Vomiting yes/no	General patient state	Swallowing	Request for ablation therapy with radioiodine yes/no/not applicable
	Wound: bleeding/hematoma yes/no	Scar	
Exit	Paresthesia yes/no		Request for supplemental tests during ablation therapy
Recovery report yes/no	Restlessness yes/no	*Exit*	
Incidents have been recorded yes/no	Vomiting yes/no. Voice	Surgical clinic report	*Exit*
Discharge criteria have been verified yes/no	Swallowing	Verbal information	Issue of endocrinology report
Information to patient and companions yes/no/not applicable	Pain	Patient has understood verbal information	Verbal information
	Blood pressure	Verification of appointment for review by endocrinology C3.2	Patient has understood verbal information
	Exit		
	Indirect laryngoscopy	Satisfaction survey	
	Hospital discharge report	Suggestions-complaints	
	Discharge criteria met		
	Patient understands treatment scheme (levothyroxine yes/no/not applicable-Ca/vit D yes/no/not applicable)		
	Review day for C3.1 and C3.2		
	Request of laboratory control (6 weeks)		

lack of CLs in each stage was identified as a factor contributing to communication failures. Evaluation of comorbidity in the preoperative period was included using the Charlson and Elixhauser scales[18,19] (Table 1). The operative period included the WHO listing.[15]

(5) CL preparation Items for each process stage were ranked by consensus of the work group. A first review of CL contents was done to verify all items, checkpoints, and CL availability, and to assess the mean time needed to verify each point (2 min, 95% CI: 1.14–2.86 min).

Fig. 1 summarizes the methodology used for designing CLs.

Results

CLs are shown in Tables 2–4.

Listings allow for detecting omissions by recall (mnemonics) based on reiteration of points that should be checked.[27]

Checkpoints are planned at each stage in the process (endocrinology clinic before and after surgery; surgical clinic before and after thyroidectomy; anesthesiology clinic before surgery; operating room; recovery room and hospitalization ward before and after surgery) and are verified by the corresponding specialist at each stage.

Item correspond to factors contributing to the potential occurrence of perioperative incidents in thyroidectomies related to the patient, control of symptoms and signs, technological equipment, management, organization, and communication (information and documentation).

Discussion

Patient safety is the sum of management and technological factors at different levels with multiple connections.[5] It is based on a culture of safety aimed at detecting and analyzing incident, search for the root causes in the systems, prepare guidelines to prevent recurrence, and devise prevention plans based on continuous improvement of processes and staff involvement, helping overcome barriers for implementation of changes.[12]

Adverse events are related to all stages in the care process, and their consequences are seen in patients (death, sequelae, complications) and in the process (hospital stay, readmissions, additional treatments) and increase costs.[10] Causes (contributing factors) may be immediate (patient, team, environment) or root causes (management, organization, regulation).[7]

Patient care specialization implies more units and staff, which may make communication difficult[26] Oral communication between professionals appears to be the best way to transfer patients, but the current design of care provision systems does not allow for it.[26]

Each type of failure may have multiple causes, including lack of CLs, computerized systems, or cognitive aids.[27,30] CLs facilitate communication in patient transfers in the process stages, allow for standardized evaluation and transmission of updated information about patient state, decrease confusion, incorporate repetition and re-reading steps, and restrict exchange to the information needed to provide safe care to the patients.[26]

CLs are cognitive aids with an essential role in management of errors which are rarely included for publication.[27]

CLs serve to verify and identify the critical risk points related to the potential occurrence of safety incidents.[12,27]

The Work group of the clinical practice guidelines for safety of surgical patients recommends use of CLs in any surgical procedure to improve safety of surgery and decrease preventable complications with a strong grade of recommendation.[16]

However, use of CLs has a moderate efficacy to promote changes leading to more effective measures, such as organizational measures and process automatization/computerization.[7] On the other hand, excess CLs may complicate the process by overburdening professional activity (the so-called ''checklist fatigue'').[27]

No specific tools have been developed for interdisciplinary communication in thyroid surgery. The American Thyroid Association prepared a listing of information including all essential perioperative data that should be available to the professionals involved, and recommended transmission of information through electronic sheets with a synoptic and narrative report.[28]

The methodology used to develop the CLs presented added to the recommended methods for designing CLs[29] the HFMEA method[8,9] for identification and classification of the safety incidents and potential failures which were the basis of items included. This methodology combines the literature review with concept-sharing by experts for CL design.[27,29] CLs facilitate routine verification of aspects that may contribute to cause critical (severe or frequent) or difficult to detect failures. Non-compliance helps professionals re-evaluate whether or not the process may continue to the next stage.

While application of CLs is not always directly correlated to significant improvements in patient care or error reduction, there are no data suggesting that CLs contribute to adverse event occurrence, and they do contribute to adherence to best practices and reduction of omission errors.[27]

To assess the results of CL implementation in thyroid surgery, we propose using indicators that measure patient safety issues (safety incidents, repeat surgery) and administrative aspects (hospital stay, surgical suspension rate, readmission rates and complaints).[7–10]

In conclusion, it should be emphasized that CLs allow for repeated verification at different checkpoints of the thyroidectomy process of data related to factors contributing to the occurrence of failures in each stage of the care process.

Conflicts of interest

There are no conflicts of interest.

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