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Utilization and Effectiveness of Surgical Safety Checklist in European Region

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ABSTRACT

Year 2018 marks as the decade of introduction of WHO Surgical Safety Checklist into the world of modern surgery. Surgical safety checklist, a set of items vital within the perioperative patient's safety checkup, easy to be performed in any of the operating theatres and under any circumstances, is proven to be an effective tool in fight against preventable adverse events in surgical care. The aim of our study was to present the results of implementation of the SSC to surgical wards in European Region -in terms of utilization and effectiveness. We analyzed substantial articles on implementation and challenges of surgical checklist in European centres from period 2008-2017. Within 308 articles of PubMed database, 8 substantial articles on utilization and effectiveness of SSC were identified and reviewed. 50% of research was performed in Central Europe. 75% of articles measured the effectiveness with one method, either documents/checklist evaluation or questionnaires among health care professionals. Presented research showed significant changes in patient safety, decrease in post-surgical complications and mortality rates. The utilization of the checklist did not reach the ideal 100% in all procedures, ranging between 55-95%, with maximum compliance of 80% of all items. Main challenges in completion and participation of professionals in the studies were lack of training and audit options, as well as limited financial resources towards ensuring patient safety in surgical wards. Despite 10 years of introduction to the surgical field, the data on utilization and effectiveness of SSC is still insufficient among countries of the European region. Potential ways of

improvement, such as training, monitoring and financial resources could result in further reduction of complication rates and mortality.

Keywords: surgical safety checklist, surgical safety, patient safety

1. INTRODUCTION

1. 1. Beginnings of surgical safety

From the beginning of the history of medicine, generations of physicians solemnly pledged firstly upon Apollo the Healer in Hippocratic Oath, nowadays upon the Declaration of Geneva, the foremost promise to the mankind, that “Health and well-being of my patient will be my first consideration”. [1,2] For centuries, health care professionals were struggling with battles against epidemics, septic wounds, safe child delivery and painless surgeries, fighting against the unknown opponents. In 19th century, Hungarian obstetrician Ignaz Semmelweis discovered one of the weapons to fight the causes the puerperal fever, at that time fatal disease of the mothers. [3] Semmelweis invention - chlorine handwashing was proved to be an effective mean in preventing puerperal fever, however due to pride of surgeons, neglecting the possibility of iatrogenic infections, his efforts were discarded and the beginnings of antiseptics began dozen years later with works of Louis Pasteur and Joseph Lister. [4,5] Nowadays, more than a century after the introduction of patient safety techniques, newest anesthesiology and surgical treatment, modern medicine still faces old and new iatrogenic mistakes.

One of International Patient Safety Goals for healthcare is to ensure safe surgery for all, taking into consideration the fact that surgical adverse events still constitute between 25-50% of all adverse events in medicine, with at least 50% of those being preventable. [6] Communication in healthcare, patients identification, proper anaesthesiological monitoring and safe usage of surgical equipment are vital steps in provision of safe surgery. [7] In order to assure safe surgery settings under all circumstances, in 2008 the WHO Surgical Safety Checklist was introduced, as a result of Safe Surgery Saves Lives campaign. [8]

1. 2. WHO Surgical Safety Checklist

Surgical safety checklist was created as a set of items vital within the perioperative patient’s safety checkup, easy to be performed in any of the operating theaters and under any circumstances. The checklist consists of 3 sections: sign in (to be performed before induction of anaesthesia), time out (before skin incision part) and sign out (before patient leaves the operating room). [9]

In the beginning of the checklist - the sign in procedure - Patient/Side/Procedure is confirmed for the first time and the side of the surgery is marked. Anaesthesiological team performs the anaesthesia and pulse oximeter safety check. The team confirms significant patient-associated risks including allergies, possible airway difficulties, aspiration and estimated blood loss risk. Second part - the time out - begins with the confirmation of roles and names of each member of the operating team, and all 3 sub-teams - Surgical Team, Anaesthesiologist Team and Nurses Team confirm Patient-Side-Procedure details again. Each team describes key concerns about possible critical events, antibiotic prophylaxis within last

60 minutes and the availability of the necessary imaging are also included in this section. Last part - sign out phase - starts with confirmation from nursing team about the performed procedure, amount of instruments used, labeling of taken specimen. Lastly, key concerns from all the subteams regarding performed surgery are being discussed before patient leaves the OR. [10]

Table 1. Phases of the Surgical Safety Checklist. Prepared by authors.

Phase	Time of the procedure	Items checked	Person responsible
Sign in	Before induction of anaesthesia	Identity of patient and site of surgery Anaesthesia safety check Pulse oximeter Allergies/airway difficulties/blood loss risk	Leader + anaesthesia team
Time out	Before skin incision	Patient/Site/Procedure Team introduction and confirming roles Critical events possibility Antibiotics and imaging	Leader + All Teams (Surgical, Anaesthesia, Nursing Teams)
Sign out	Before patient leaves the theater	Procedure performed, Counting instruments, Labeling the specimen, Key concerns	Leader + Nursing Team

One of the first studies on the successful worldwide implementation of the Surgical Safety Checklist has been performed by Haynes et al. in 2009 in eight cities (London, England; Toronto, Canada; New Delhi, India; Manila, Philippines; Amman, Jordan; Auckland, New Zealand; Ifakara, Tanzania; Seattle, USA). Each of the chosen facilities represented different economic development model and diverse population of patients. The data has been separated to lower-income and higher-income countries and respectively measured the rate of inpatient complications 30 days after the surgery as well as the death rate. Within data from 3773 before implementation of SSC and 3955 patients after implementation of the checklist, rate of complication decreased in both groups (from 10,3% pre to 7,1% post implementation in higher-income countries, 11,7% to 6,8% in lower-income countries - in both groups $P < 0.001$). The death rate decreased in both groups, (higher-income countries from 0,9% to 0,8% - $P = 0.18$, and in lower-income countries from 2,1% to 1,0% - $P = 0.006$). The results of this research encouraged next countries to participate in reduction of patient post-surgical complications and death rate, in order to provide safe surgery for all. [11]

2. AIM OF THE STUDY

The aim of the study is to present the utilization and effectiveness of implementation of Surgical Safety Checklist in European Region.

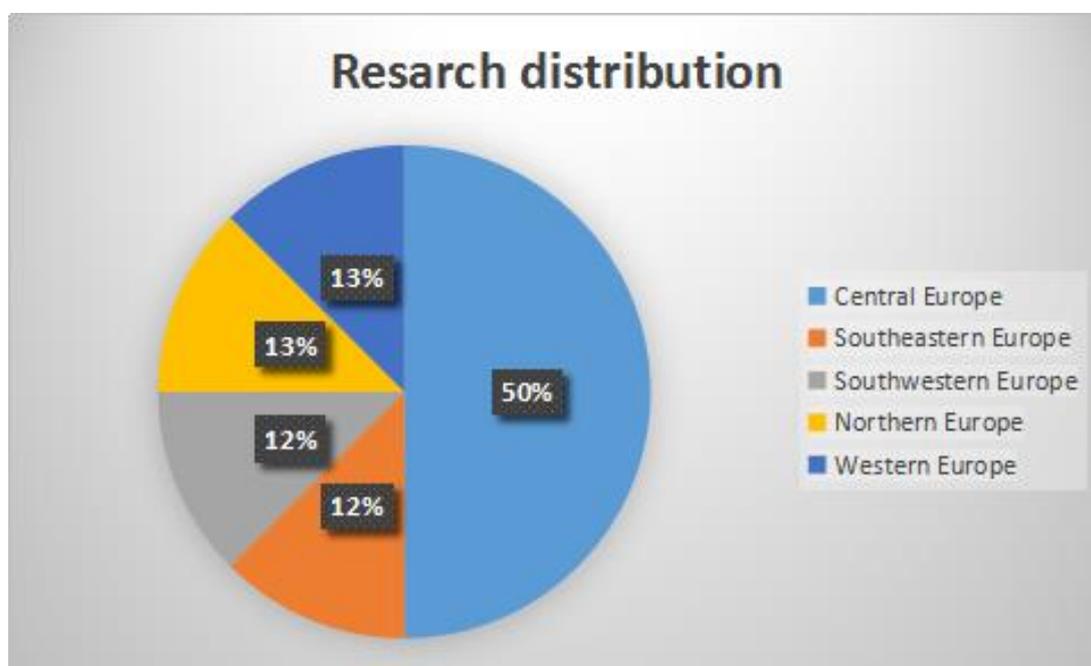
3. METHODS

Substantial articles on checklist implementation in European Region from period 2008-2017 have been analyzed. Among 308 articles in PubMed Medline database, 8 articles were selected for analysis, excluding articles not related to the regional focus or topics other than usage, compliance and effectiveness.

4. RESULTS

4. 1. Research distribution, environment and target group specification

Among 8 articles, the most of research studies were conducted in Central Europe (50%), and in Northern, Western, Southeastern and Southwestern regions only 1 research per region was performed.



Graph 1. Research geographical distribution. Prepared by authors.

Within 8 articles 50% of papers included all surgical specialties within the facilities, the rest 50% focused on only one specialty within a hospital or country. Single-specialty research included: general surgery, pediatric surgery, urology and podology. 25% of articles included also the anaesthesia and ICU wards in the analysis.



Graph 2. Research methodology. Prepared by authors.

As for methodology of the research, 75% used only one method of evaluation of the effectiveness, with two research studies combining two methods. Two main subgroups was analysis of documentation and completed checklists in 50% of cases, and in 75% different questionnaires were used, either self-designed or variation of psychometric standards, such as eg. Healthcare Research and Quality Hospital Survey on Patient Safety Culture or Mascherek et al. Survey for Surgical Safety Checklist.

4. 2. Detailed results in particular countries

Table 1. Summary of the results of the reviewed research. Prepared by authors.

Authors	Country	Target group	Amount of cases	Aim of the study	Results	Additional Comments
De Vries et al. (2010)	Netherlands	All specialties (mostly general surgery, trauma, vascular, renal procedures)	8751 procedures in intervention hospitals, 5982 procedures in control hospitals	Measurement of total number of complications, proportion of patients with complications, in-hospital mortality	10,7% decrease in total number of complications, 4,8% decrease in proportion of patients with complications 0,7% decrease in in-hospital mortality	Outcomes in control hospitals did not change

Garcia-Paris J. et al. (2015)	Spain	Podiatric ward	134 cases	Measurements of compliance before SSC, after (with and without usage of SSC)	Improvement in deep venous thromboembolic prophylaxis protocol, antibiotic prophylaxis, reduction of post-operative days	
Borgman N.H. et al. (2015)	Germany	Urology	234 department	Measurement of checklist utilization and defining characteristics of users and non-users	91% of departments were using the SSC Perioperative checkup took less time and fewer people were involved in users than non-users group	Increase of financial resources could improve the utilization of the checklist
Cullati et al. (2014)	Switzerland	Surgery	152 professionals	Measurement of utilization and attitudes	65% respondents used the checklist, majority claims improvement in intraoperative safety and safety culture	
McGinlay et al. (2015)	Romania	Pediatric surgery	40 surgeries	Completeness of utilization	None of the SSC were completed, with average 55% of items performed, 40% of professionals received training on SSC	Limitations: small amount of data, lack of information about patient outcomes, insufficient financial resources for SSC
Haugen et al. (2013)	Norway	All specialties	349 participants pre and 292 post-intervention	Measurement of compliance and safety culture improvements	Decreased frequency of reported events, increased adequate staffing in checklist group. Compliance variable depending on specialty	Limitations: low response rate (61% pre and 51% post implementation)

Sendlhofer et al. (2015)	Austria	All specialties	305 surgeries, 164 professionals	Checklist utilization and professionals satisfaction and compliance	Completion of SSC above 90%, decreasing in further audits Most of staff very satisfied or somewhat satisfied with SSC usage	Constant monitoring and training needed
Sendlhofer et al. (2016)	Austria	All specialties	171 professionals	Checklist utilization and professionals satisfaction and compliance	Actual compliance 93,1%, individual perception 99,4%, most of staff satisfied with checklist usage	

First research performed in 2010 by de Vries et al. in Netherlands was the biggest study conducted in European region. Research focused on measurement of implementation of SURPASS - Surgical Patient Safety System, digital safety checklist, used in the Netherlands for day care surgery, elective clinical procedures and emergency procedures. Study included 8751 procedures in intervention hospitals, 5982 procedures in control hospitals. Most of the procedures were general surgeries - gastrointestinal surgeries (over 30% in both groups), trauma cases (over 18% in both groups), vascular or renal procedures (over 11%). Within the amount of checklist implementation, checklist sample was collected from 1146 of cases (26% of all procedures of post-implementation in intervention hospitals), with median amount of items completed 80%. Study design included measurement of total number of complications, proportion of patients with complications and in-hospital mortality. Implementation of the checklist resulted in 10,7% decrease in total number of complications (27,3% pre-implementation, 16,7% post-implementation), 4,8% decrease in proportion of patients with complications (15,4% of patients with one or more complication before implementation to 10,6% post-implementation). The 0,7% decrease in in-hospital mortality was noted (from 1,5% to 0,8%). Outcomes did not change in the control group, which additionally proves the effectiveness of implementation of the checklist. [12,13]

Spanish study by Garcia Paris J. et al. measured the effectiveness of implementation of SSC in podiatric ward. Effectiveness of the implementation process was observed with increased performance of deep venous thromboembolic prophylaxis protocol (DVTTP), antibiotic prophylaxis and reduction of post-operative days. Within DVTTP, it was found that the non-compliance rate of perioperative checkup reduced from 68 % SSC pre-implementation period to 24 % in the group without SSC and to 8 % in group using SSC. The changes within both groups are most likely associated with both Hawthorne effect and increased awareness about benefits of perioperative safety measures which introduced the clinical changes in the ward. The study confirmed also the relationship between utilization of SSC and correct usage of antibiotic prophylaxis ($p = 0.049$), which was also associated with

the reduction of the surgical site infection ($p = 0.019$). Lastly, there was found a correlation between the utilization of SSC and reduction of post-operative days. [14]

Within German study by Borgmann et al., the aim was to assess the amount of urology wards- users and non-users of the checklist, as well as to define their characteristics and significant differences. Among the target group of 234 urology wards, 91% claimed to be users and 9% the non-users of SSC. The users considered the checklist as a reasonable and not very laborious tool in 79% of responses. The three main specialties integrated in checklist implementation are anesthesiologists (87%), surgeons (85 %), and surgical nurses (75 %). The main reasons for non-usage remained unclear or other nature rather than the financial reasons (10%). 58% of the departments had no financial budget for patient safety purposes. As for the main differences between two groups, the perioperative care took less time ($p < 0.001$), and required less human resources ($p = 0.008$) in the SSC user group than in the non-user group. [15]

In Romania (McGinlay et al. 2015), among data from 40 surgeries (62,5% elective, 47,5% emergency) none of the SSCs were fully completed with average 55% of all items performed. The completeness did not correlate with number of staff, specialty of surgery or type of surgery (elective/emergency). Only 40% of professionals claimed to receive training on SSC prior to implementation, and here the significant differences of awareness between specialties - SSC training was more common in nurses than in doctors. 93% of professionals considered the checklist as a useful tool. [16]

Swiss study by Cullati et al. (2015) focused on knowledge on SSC implementation among participants of surgical congress. Out of 433 questionnaires distributed the response rate was 35,1% (152 responses). The respondent group consists in majority of male German speaking surgeons (61,6%). The checklist has been used by 65% of respondents, with slight differences on utilization depending on the public and private sector factor (73% in public sector vs. 56% in private sector; $p = 0.048$). Majority replied that checklist is a “*valuable tool for improving intraoperative safety (89.5%), developing a safety culture among surgical teams (75.4%) and fostering team communication (68.8%)*”, simultaneously disagreeing with statements that *checklist brings no added value to the safety procedures (61,5%)*. As for the compliance of individual sections of the checklist, sign in was completed in 91,5%, time out in 96% and sign out in 50%. For the frequency of performance of the sections, respondents rated to be completed *very often or quasi systematically* in terms of sign in (89,9%) and time out (82,5%); however for sign out, 45,2% said it was *never or rarely* performed. [17]

Norwegian study by Haugen et al. focused on both checklist compliance and healthcare attitudes towards its implementation. The study group of perioperative personnel from 10 surgical departments and the accompanying anaesthesia and intensive care unit departments was divided into intervention group (Neurosurgery, Thoracic Surgery and Orthopedic wards) and control group (other surgical wards). The intervention applied to the hospital settings was the introduction of Norwegian modification of SSC, adapted to Norwegian surgical flow of care. Among intervention group the average checklist compliance was 75%, between the wards the value ranged from 55% to 80% (highest frequency in orthopedic ward, least frequent in neurosurgery ward). The compliance of individual sections was 85% for sign in, 84% for time out and 77% for sign out procedures. Within healthcare attitudes, the methodology included Norwegian version of the Healthcare Research and Quality Hospital Survey on Patient Safety Culture. This survey measures perception of safety cultures with five point agreement or frequency scale of 12 principle factors, eg. “overall patient safety”, “frequency

of events reported”, “unit manager/leader promoting safety”, “teamwork within units”, “communication openness” etc. Response rate of professionals towards the culture safety questionnaire was 61% at baseline and 51% post-intervention. The analysis showed significant effect in two factors “frequency of events (near misses) reported”, where decrease in Checklist group and increase in control group was reported and “adequate staffing”, with increase in the Checklist group (the control group remained unchanged). [18]

The most comprehensive research on all stages of implementation and monitoring of SSC by Sendlhofer et al. - the utilization of the checklist in one of the Austrian centers- has been preceded with training on its usage. At the time of implementation, about 50% out of 900 surgical field employees were reached in educational aspect with several means such as through training, role play or focus group discussions, and within the year after beginning of the trial all disciplines of the center were using the SSC in their operating theaters. First utilization period has been monitored with pilot unit - 2 test runs, altogether 305 surgeries observed. Total usage of the checklist was 77,1% in test run 1, 99,2% in test run 2, however the completion rates were significantly lower - respectively 36,3% and 1,6%. Further monitoring in next two years time span included three audits - unannounced visits to the operating theaters and further analysis of documentation. Within those three examinations it was discovered that the utilization and completion decreased in time (utilization in 95.3%, 91.9% and 89.9%, completion in 81.7% to 60.6% and 53.2%). As a last step, employee knowledge and satisfaction survey was being launched. For this purpose, Surgical Safety Checklist questionnaire by Mascherek et al., validated by Patient Safety Foundation, was used as a psychometric method. [19]

Survey consisted of questions regarding professionals’ satisfaction from SSC usage and individuals subjective opinion on their knowledge on SSC. Objectively, knowledge was verified with 10 true/false statements. The respondents rate was 18,4%. 91,3% of staff confirmed using SSC in the surgeries, with consultants’ using more often than nurses teams ($p = 0.038$). Consultants were more satisfied with implementation of SSC (75%) than nursing staff (54%). Subjective knowledge assessment on level very good or rather good was similar in both groups (consultants-83%, nursing-82%). Within objective assessment of knowledge, the median number of correct questions was 8 in both groups. [20]

In the next research from the same center a year later, Sendlhofer et al. decided to measure actual compliance and individual perception of the compliance. The actual utilization was 93,1% with compliance of 42,8%. The individual perception of the utilization was higher, 99,4%. Satisfaction levels remained the same among both consultants and nursing staff comparing to previous year. Nursing staff consider their subjective knowledge performance as very good or rather good in 95,8% - higher in comparison to year 2014 (82%). The median number of correct questions remained unchanged. [21]

5. DISCUSSION

5. 1. Limitations of the studies and possible methods of improvement of participation

Presented studies faced several limitations. The main source of concern for most of the teams was low participation in the research of the healthcare professionals, ranging between 18-31%. [15,17,20] The utilization the checklist in audited centres didn’t reach the ideal 100% of all surgeries, ranging between 55 to 95%, and very low completion of all items of

the SSC. [16,20] Two studies especially underlined the lack of “sign out” procedures compliance, with potential main reason for this situation the dilemma on when to perform the phase (in the end of the main part of surgery, last stitch part or dressing). [16,17] Lack of participation of the healthcare in the checklist checkup could be potentially resolved in increased financial resources towards patients safety and the checklist implementation solely, as noted by Borgman et al. [15] The main remedy for the lack of awareness is the efficient training of healthcare. In Romania, the lack of awareness on the procedural part as well as benefits of the checklist were considered by participants as most important factors in poor and improper checklist implementation. When asked on what actions could improve the performance - utilization - respondents answered with formal training, presentations as best learning options. Formal training, presentations and also regular audits were considered a significant way to assure the compliance of the checklist. [16] Stepwise implementation is highly suggested as per Austrian example - firstly the education and implementation with focus group discussions with Department of Quality and Risk Management representative, role play and introduction of contact persons in surgical departments; later monitoring with pilot units and audits; lastly the measurement of satisfaction from SSC utilization and knowledge performance of the professionals. This research set one of the first examples of standardized implementation and monitoring process for the safety surgical procedures checkup. [20,21]

6. CONCLUSIONS

The Surgical Safety Checklist unites the efforts of all frontline caregivers to avoid human error in surgery at all costs. Despite 10 years of introduction to the surgical field, the data of utilization and effectiveness is still insufficient among countries of the European region. Within reviewed research, the main difficulties in implementation, such as lack of awareness and compliance could be solved with introduction of formal training techniques, proper monitoring of usage and completeness, as well as increased financial resources towards improving patients safety. With those improvements, we believe that it will be possible to provide surgical procedures without avoidable iatrogenic mistakes, and as a result - reduce complication rates and associated mortality.

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