

Development and Implementation of a Computerized Decision Support Systems in the Interdisciplinary Treatment of Stage IV Pressure Injury in Patients with Spinal Cord Injury: A Real Life Two-Group Parallel Design

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Abstract

Background: Treatment of pressure injury (PI) stage III and IV in patients with spinal cord injury (SCI) requires complex interdisciplinary and inter-professional management described in comprehensive concepts. Although the implementation of these concepts in the clinical management is still difficult due to practical aspects as information and coordination challenges for example. The aim of this study was to develop, implement and test a computerized decision support system (CDSS) to increase concept adherence, improve inter-professional collaboration and optimize clinical outcome compared to usual care.

Method: We implemented a CDSS picturing the Basel Decubitus Concept in an acute and rehabilitation clinic specialized for SCI as part of a quality improvement project in a real life two-group parallel design. We randomly allocated patients with SCI and PI stage III/IV for inpatient treatment to usual or CDSS supported care. We used an inclusive participatory development process, a qualitative focus group-based (30 participants) approach to capture the user perspective and prospective chart analyses to compare complication rates, length of stay and costs.

Results: In both groups 15 patients were included showing no differences in SCI characteristics, comorbidities, and PI characteristics (localisation: ischium (19 PI, 63%), sacrum (10 PI, 33%), recurrent PI in 21 patients (70%)). Twenty-seven patients received surgical treatment (rotation flap in 12 patients (40%), posterior thigh flap in 15 patients (50%)). No statistically significant group differences were observed in the frequency of major (20% vs 13% between CDSS and control group) and minor (33% vs 27%) complications and length of stay (98 (\pm 28) vs 81 (\pm 23) days). The costs were similar. Although, health care professionals experienced the CDSS as helpful, high workload and difficulties in the information technology processes hindered its implementation.

Conclusion: The introduction of a CDSS in the treatment of PI stage III/IV in patients with SCI was feasible, but technical and application problems limited its effectiveness. During the implementation and testing we learned that a clear definition of the whole treatment concept includes milestones, interventions and outcome definition. Technical requirements should include efficient reminder systems and clear visibility for all disciplines of the whole process.

Trial registration: As a quality assurance study, this project holds a declaration of no objection by the Ethics Committee northwest/central Switzerland (EKNZ UBE-16/003) and received an ethical approval (EKNZ Req-2017-00860).

Introduction

Process based management is discussed as an innovative methodological step [1–7], in order to shape and structure different clinical settings and to improve guideline adherence. Nevertheless, the implementation of process management in many clinical settings appeared often challenging due to missing clinical awareness, knowledge translation and complexity of treatment [2]. Hence, computerized decision support systems (CDSS) were developed to help by leading through the process, reminding relevant steps and controlling involved health care professionals (HCP) in their specific duties [3]. These CDSS optimized the adherence with the treatment processes, reduced the workload for the team and consequently total treatment costs [1, 3]. Most importantly, the standard treatment process could be re-evaluated and continuously improved by using data from daily clinical management. So far, CDSS were mainly evaluated in the management of acute clinical situations and lead to reduced complication rates [8] as well as increased employee satisfaction [9, 10], better communication during interdisciplinary visits and a better overview of information [11, 12]. Although CDSS count as tools for quality improvement and influence quality indicators [12, 13], contradictory results were obtained from process-based management and CDSS implementation in the clinical context [5, 8].

According to the European Pressure Ulcer Advisory Panel (EPUAP) the treatment of pressure injuries (PI) stage III and IV in patients with spinal cord injury (SCI) consists of acute care and rehabilitation in an interdisciplinary and inter-professional team. Due to the complexity this treatment could benefit from process-based management and CDSS supported care to achieve clearly structured procedure. PIs are among the most frequent and cost-intensive complications in people with SCI [14, 15], often aggravated by early and late post-surgical complications [16–20], leading to long hospital stays and reduced quality of life [21, 22]. Internationally, it is accepted that PI grade III and IV require flap reconstruction [17, 19, 22, 23], post-surgical immobilisation [23] and antibiotic therapy [24]. Because complications during the early post-surgical treatment occur more often in patients with a high-risk profile individual risk analyses are recommended [19].

The Basel Decubitus Concept is a historically developed treatment concept and includes different therapeutic elements like risk analysis, transfer training and evaluation of assistive devices, etcetera [21, 25–28]. Due to the complexity of this concept, implementation and adherence in the clinical setting remained difficult [18, 21, 26, 29]. A CDSS supported process based management might therefore increase adherence to the Basel Decubitus Concept and thus increase quality [30].

The aim of the study was to describe the development of a CDSS in the clinical management of PI in patients with SCI, to explore HCPs' perspective on the use of this CDSS and to compare performance of examination, interventions and complication rates, hospitalization duration as well as overall and specific costs between usual care and CDSS supported care.

Methods

Design

A development of a CDSS as well as its implementation and a real-life two group parallel design study in an ongoing clinical setting in the field of SCI and PI was performed.

Setting

This study took place in an acute and rehabilitation clinic specialized for SCI in Switzerland with an integrated plastic surgery team. The clinic is specialized in the treatment of PI in patients with SCI using the modified Basel Decubitus Concept. The Basel Decubitus Concept [25, 26] had been defined with the following five main principles 1. pressure relief, 2. debridement, 3. treatment of risk factors, 4. flap surgery and 5. prevention of secondary complication. Single interventions such as nutritional and psychological counselling were redefined and integrated into the Basel Decubitus Concept [27–29].

The treatment concept for PI includes interventions by paraplegiology, plastic surgery, infectious diseases, specialized acute and rehabilitation care, physical, occupational and nutrition therapy as well as psychotherapy [21, 26, 27, 29].

Development of the "Use Case" in the CDSS

For the development of the CDSS, a core team (a specialised physician, the wound care nurse, the quality management expert and an IT specialist) defined the goal of the CDSS.

Consensus conferences with specialists from all involved disciplines were conducted to describe the "Use Case" based on the main principles of the Basel Decubitus Concept. IT specialists were responsible for the conversion of the "Use Case" into a „Business Process Modeling Notation" (BPMN). The CDSS was pilot tested and the involved professions were trained before implementation. Time effort of the project development was monitored.

Evaluation of the user perspective

We conducted four, profession-specific focus groups (junior physicians; nurses; physical and occupational therapists and senior physicians) during November and December 2017 lasting about 60 minutes with five to eight participants (Appendix Table 1). All participants had experience with the implemented CDSS during the pilot testing. The semi-structured interview guide covered questions concerning the experiences, advantages and challenges of the newly implemented CDSS. These focus groups were audio recorded, verbatim transcribed, anonymised and analysed using a thematic analysis [31]. We encoded the data using the "ATLAS.ti" software (ATLAS.ti Scientific Software Development GmbH, Berlin, Germany) and grouped the obtained codes into subthemes and identified recurring themes in an iterative process (KK, PL,AS).

Participants

We included patients with SCI or similar syndromes (e.g. multiple sclerosis) presenting with a PI stage III and IV according to the EPUAP classification over ischium, sacrum or trochanter admitted for inpatient treatment including plastic surgery. Patients with a malignant disease, complicated local skin disease like fungal infection or who denied retrospective use of their data were excluded.

Between July 2016 and May 2017 30 patients meeting the inclusion criteria were randomly assigned to care as usual or treatment at specially trained wards using the CDSS during inpatient treatment.

Patient related data collection

Data was gathered manually from the hospital records – patient, SCI and PI characteristics, osteomyelitis, examinations, interventions according to defined milestones and outcome parameters (minor and major complications, length of stay). Data of the following examinations, interventions and milestones were collected: SCI neurological impairment with the ASIA impairment scale, electrocardiogram, pulse oximetry, spirometry, nutrition laboratory, range of motion; registrations of plastic surgery, physiotherapy, occupational therapy, nutritional counseling, psychology, music and art therapy, flap surgery; beginning of physiotherapy, occupational therapy, psychology, music and art therapy and nutritional counseling; performance of flap surgery, moving legs and first mobilization in wheelchair. The workload of physicians per patient was documented in five-minute steps for different tasks (direct patient contact, inter-professional exchange, documentation). Complications were divided into three categories: 1. no complications, 2. minor complications (prolonged bedrest) and 3. major complications (re-surgery) directly related to the surgical intervention and other, independent complications such as pneumonia or urinary tract infection.

Cost analysis/calculation

The length of hospital stay was used to calculate the total costs as the reimbursement uses day taxes. Individual real costs were collected as patient cost calculation from the finance department. Specific treatment costs were analysed in costs of the plastic surgical care, therapies, nursing, laboratory, medication as well as physicians' workload.

The study complies principles of good clinical practice and was approved by the hospital's institutional review board. The reporting of the study followed the SQUIRE 2.0 criteria.

Statistical analyses

Categorical variables were presented with absolute and relative frequencies separately for the CDSS group, the control group and in total. Continuous variables were presented with median, lower and upper quartile for each group. The continuous variables were divided into respective categories ranging from normal value, slightly deviant value, to strongly deviant value BMI (< 17, 17–24, > 24 m/kg²) (Wong 2017), haemoglobin (< 80, 80–120, > 120 g/l), vitamin D (< 30, 30–75, > 75) and GFR (< 30, 30–90, > 90 mm/l). A time-to-event analysis was carried out to assess the mean time between admission and milestones or interventions of the "Basel Decubitus Concept" between the CDSS and the control group. P-values for group comparison were computed using Chi-square tests and Fisher's exact test for categorical and rank-sum tests as well as unpaired two-sample t-test for continuous variables. The alpha-level for statistical significance was set at 0.05. Data preparation and statistical analysis were conducted using Stata SE 15 (Stata for Windows, College Station, TX, USA).

Results

"Use Case" Decubitus Process

During a preparation phase from 2015 to 2016, the core team met monthly for coordination and counselled different HCPs. They defined that the CDSS should guide the professions through the treatment process and make the process visible. The physicians should see a list of required activities at the beginning (initiate different assessments, examination and other therapies). The inter-professional team should see the complex treatment process with relevant milestones and integrate these reminder in their clinical management. In case of clinically indicated individually adaptations, the IT process and milestones should be adaptable.

Measurement of baseline assessments, milestones, timelines and outcomes in the modified Basel Decubitus Concept were defined (table 1). The process combined the following milestones: admission, debridement, bone biopsy, flap surgery, suture removal, mobilisation and discharge (figure 1). For the "Use Case", nine general therapeutic overall interventions, seven assessments, five consultations, and professional orientated responsibilities were defined (Appendix table 1). In case of osteomyelitis, a specialist for infectious diseases was involved.

During four consensus conferences the specialists from all involved disciplines evaluated the "Use Case" description and several adaptations were necessary, including feedback systems, dependencies/interactions between different sub-processes, demand of and controlling for assessments, consultations and visibility. After conversion into the BPMN and test in three pilot cases,

dependencies between suture removal and change of mattresses was not any longer automatically connected due to often occurring individual changes.

In the CDSS three key aspects of the process were visible: treatment elements, consultations and milestones (Appendix figure 2) and HCPs had an overview concerning the general complex process, they could click in the CDSS picture in a field showing the different principles and were led to initiate the different consultations. As soon as these consultations were demanded, the colour of the field turned green and as soon as every consultation was initiated the colour in the overview also turned green.

After the development phase, inter-professional information sessions on team level and a specific training based on a structured manual were organized in June 2016. The development of the CDSS required about 300 hours of inter-professional engagement and about 10,000 hours IT workload.

Feedback from health care professionals and evaluation of user perspective

The focus groups included 30 HCPs (26 female, (87%)): eight nurses, six physical therapists, three occupational therapists, seven physician residents and six senior consultants with overall 405 years of working experience including 231 years in this clinic. (Appendix table 4) Participants in all groups mentioned topics concerning IT process requirements and workload, clinical relevance and meaningfulness of the CDSS (table 2). Despite numerous negative experiences, a benevolently willingness to use the CDSS became apparent (Q1, Q2, Q3). The CDSS was acknowledged to allow the integration of guideline recommendations (Q4). HCPs expressed their awareness to direct the system (Q5). While different HCPs underlined the opportunity of having a good inter-professional overview using the CDSS (Q6), others criticized the poor overview (Q7). HCPs often experienced the grade of detail as too high (Q8, Q9).

All HCPs complained about the high time effort for the active maintenance of the CDSS (Q10), the speed of IT performance (Q11) and stability of the IT system (Q12). The whole process was not automatically initiated and not self-explanatory (Q13). Automatic reminders were not yet technically feasible (Q14). An immense problem appeared concerning the duplicity in documentation and information of different IT systems used in parallel (Q15, Q16, Q17, Q18). Collected data could not be automatically displayed at different places and used in different processes (Q19).

HCPs could not develop a routine in clinical management due to rare use of CDSS in only a small number of patients per ward (Q20). Therefore, the CDSS did not support information exchange in staff shift change (Q21). For some users, the purpose of the CDSS was perceived as to collect data for research, leading to less motivation and more resistance (Q19, Q22). Finally, HCPs were used to paper based process management (Q23) and did not experience an improved quality by using the CDSS (Q24) or being only a duty (Q25).

Initiating of interventions and milestones in the management

A trend towards more registrations, therapies and examinations under CDSS was observed (Table 3). However, neither there was a statistically significant difference in the proportion of the CDSS vs. the control group nor was there a statically significant relationship indicating independence of the interventions and milestones of the modified Basel Decubitus Concept (Table 3).

Patient and disease characteristics

In both groups, 15 patients were included. Patient characteristics are displayed in table 4. Twenty-two participants were males (73%), median age was 56 years, (interquartile range (IQR) 42-70 years). Nineteen patients had a complete SCI (63%) and eleven a cervical SCI (37%). In both groups, comorbidities as diabetes, hypertonia and renal failure occurred in similar frequency. Time since injury was similar between the groups (median of 18 years in the CDSS group, 23 years in the control group) as well as the body mass index (Median of 20.8 kg/m² and 24.6 kg/m² in CDSS and control group, respectively) (Table 4).

PI characteristics including the localisation (19 PI over the ischium (63%)), recurrence in 21 patients (70%) and treatment with a rotation flap in 12 patients (40%) and a posterior thigh flap in 15 patients (50%) did not statistically differ between groups (Table 5). Complications with five major (16%) and nine minor (39%) complications were distributed similarly between groups. Likewise, length of stay (90 days average), overall and detailed intervention costs did not differ significantly between groups (Appendix table 5).

Discussion

To our knowledge, this is the first real-life, controlled, quality improvement project in the treatment of PI in patients with SCI. During the pilot phase, all HCPs showed interest and willingness to integrate the CDSS into their clinical routine. HCPs endorsed the CDSS for additional benefit in quality of patient care by integrating guideline recommendations, performing individual adaptations and supporting the interdisciplinary and inter-professional treatment. However, technical difficulties and time-consuming tasks appeared while using the CDSS mostly due to the extra IT system. The registrations and therapies were carried out in roughly equal numbers. Nevertheless, in the CDSS group the registrations and therapies were generally performed faster than in the control group. The use of the CDSS did not improve clinical and economic outcomes during this pilot phase.

Development of CDSS

Although, the discussions took place monthly in the core team and in four inter-professional consensus conferences [3] and the IT team participated during the development process [3], different attitudes and principles between the clinical and the IT management manifested themselves [3]. As known in the literature, the clinical decision-making in its complexity and flexibility was contradictory to the IT culture of causalities and dependencies being clear and defined [3]. To overcome these challenges, it was necessary to find a consensus in the clinical management, to clarify the relevant aspects of the treatment concept and to increase inter-professional coordination. During the development of this CDSS the intensive interdependencies between activities from different professions became apparent. Inter-professional dependencies had to be clearly defined to transform the collaborative processes into a strict IT logic. This quality improvement initiative demonstrated that use cases development was feasible in an interdisciplinary and inter-professional treatment processes [3]. The description of a PI treatment concept in patients with SCI should therefore include detailed information about the inter-professional and interdisciplinary interventions, milestones and treatment elements [17, 19]. The relevant milestones and treatment elements for example in the Basel Decubitus Concept are the debridement, surgical procedures, diagnosis and therapy of osteomyelitis, time of immobilisation, risk analyses and additional interventions based on the bio-psycho-social model.

Use of CDSS by HCPs

The CDSS was judged as relevant and feasible from the HCPs' side compared to other projects [10], but different challenges hindered the successful integration of this project in the clinical routine. As known from other projects [10], IT problems, the rare use of the CDSS in the treatment of PI stage III and IV and the increased time consumption for additional documentation overlaid the positive aspects of this project [7]. HCPs engagement and acceptance of CDSS was also reduced, because the main advantage of automatic data use for different purposes was not yet possible and analysis of "Big Data" in the continuous improvement process was not achieved [32].

Resistance against the new CDSS was also formulated due to misunderstandings. HCPs interpreted the quality assurance project and the use of the CDSS as part of a scientific study. This underlines the need for communication to users in order to reduce misunderstandings and resistance in an innovative quality project [32].

Due to these complex consequences and awareness of the investment in costs and workload during the development of involved professions, process innovation and development of such CDSS should be chosen carefully [3]. The commitment from different professions, the support from the executive board of the clinic and the cultural change in the clinic to a process based organisation were helpful [3]. However, this project was the only project in the acute and rehabilitation care that used a CDSS in an extra IT system [11, 32]. Consequently, the implementation was challenged due to infrequent use of the application [11, 32]. Integration in a broader context and different quality initiatives could have increased the impact. It appeared that several learning cycles were necessary to change clinical management from disease oriented to process based management and to develop the adequate IT capacity. The gained principle knowledge in the development of the Basel Decubitus Concept was transferred to other CDSS development in the setting of the clinic. Further, the findings can be applied to other complex care settings.

Clinical outcome using CDSS

The overall goal of a quality improvement project using a CDSS is to optimize clinical processes and consequently clinical outcomes [11]. Our study hypothesis was that the use of the CDSS would increase the quality of the treatment including optimal coordination, intervention and risk prevention and consequently reduce complication rates and length of stay. But neither complication rates nor time expenses of physicians, total costs per patient or hospitalization time of patients were reduced when using the CDSS. For the

latter, it can be concluded that although there was no significant difference in the distribution of minor and major complications, the CDSS group had more minor complications that delayed initial mobilization and discharge. Furthermore, due to the complex situation of the patients the effect of CDSS supported care might take longer to show effects on complication rates by changing the whole culture of process-based management [1]. The implementation took place in an established environment and a team culture that worked with paper-based structures for many years. The paper-based management was faster and more established than IT based solutions [11]. Nevertheless, the registrations and therapies were performed quicker in the CDSS group vs. the control. The detected milestones were somehow known and experienced HCPs reminded each other already during the weekly meetings. Even single interventions were integrated and for example nutritional support and blood examination happened as recommended [28]. A CDSS may be more important in unexperienced teams with reduced exchange time and less experiences when HCPs turnover occurs [3]. In the future, when the shortage of experienced HCPs will be an increasing problem for health systems, CDSS based treatment may become more important.

Study Limitations

The small sample size of observed patients is one of the main study limitations and conclusions concerning the effect of this CDSS. Because a new IT system for the whole clinic was introduced soon after, this special program was not developed further. Nevertheless, experiences from this development project were included in the development of the new clinic information software system. We decided to analyse clinical outcome parameters and to not document process quality elements, some interesting aspects of this project might be missing. Still, the combined analyses of the HCPs' perspective and clinical parameters lead to a comprehensive description of the project. The invested time from physicians was documented manually and interventions were not analysed, the workload was not qualified and a better-tailored individualized support with better care for the patient could not be detect. Therefore, the interpretation of the quality concerning the management process and the collected time is reduced.

Conclusion

When milestones, key HCPs and processes are defined, CDSS can be developed for complex treatment procedures. HCPs perspectives should always be integrated in development processes, especially in clinical processes with low evidence and a need for consensus-based management. Good IT processes should include reminder systems, multiple data use for different purposes and performance speed increase the acceptance in HCPs' management. For future innovation, a wise selection of processes using the combined experience from different CDSS projects could be successful. Clinical data could be used in a second step for monitoring and continuous improvement of the concept.

Abbreviations

BPMN	Business Process Modeling Notation
CDSS	Clinical Decision Support System
EPUAP	European Pressure Ulcer Advisory Panel
HCPs	Health Care Professionals
ICF	International Classification of Functioning Disability and Health
PI	Pressure Injury
SCI	Spinal Cord Injury

Declarations

Ethics approval and consent to participate

As a quality assurance study, this project holds a declaration of no objection by the Ethics Committee northwest/central Switzerland (EKNZ UBE-16/003) for the focus group interviews. The study received an ethical approval (EKNZ Req-2017-00860) and patients who

denied retrospective use of their data were excluded.

Consent for publication

All coauthors drafted the last version of the manuscript and consented for publication.

Availability of data and material

Data are available at the corresponding author.

Competing interests

All authors declared no conflicts of interest.

Funding

The authors received no funding.

Authors' contributions

All authors drafted the study and developed the study design. Anke Scheel-Sailer, Kamran Koligi, Patricia Lampart, Carina Fährndrich and Armin Gemperli collected the data and performed the statistical and qualitative analyses. All authors discussed the results and the clinical relevance. All authors drafted the manuscript and approved the final version.

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Tables

Table 1: The “modified Basel Decubitus Concept” structured to focus, profession and content:

Focus	Profession	Content
Classification of PI	Paraplegiologist	Classification of PI according to definition of the EPUAP and NPUAP (reference).
	Plastic Surgeon Nurse	Documentation following international recommendations (reference) including photos
Pressure relief	Paraplegiologist Plastic Surgeon Nurse	Immediate immobilization after admission for inpatient treatment either on airflow mattresses or with supine ventral positioning, if possible.
Local dressing	Paraplegiologist	Application of dressing according to the TIME concept.
	Plastic Surgeon Nurse	Removal of necroses, treatment of infection (local disinfection and/ or surgical debridement) and negative pressure therapy or three times per day wet dressings.
Diagnostic and treatment of risk factors	Paraplegiologist	Standard blood analyses: inflammation, anaemia, electrolytes, kidney and liver function and nutrition profile
	Dietitian	The SNST (Spinal Cord Nutrition Tool) is administered to detect nutrition and nutrition. Counselling is added to address the special needs during the treatment of the PI and respect the changed protein and caloric requirements
	Paraplegiologist	Screening of neurological changes and examination of the international standard for neurological classification in SCI.
	Paraplegiologist Nurse Physiotherapy	Examination of pulmonary function. Breathing therapy and exercise.
	Paraplegiologist Physiotherapy Occupational therapy	Examination of the lower extremities (range of motion) and of the spine (scoliosis?) and evaluation of the seating position.
	Psychologist	Screening of psychological risk factors and integrated psychotherapy by individual indication.
Flap surgery	Plastic surgeon	Closure of PI with fasciocutaneous tissue if possible: os ischium – posterior thigh flap, os sacrum/ coccygis – gluteal rotation flap, os trochanter – lateral thigh flap/tensor fasciae latae flap.
Diagnosis and therapy of osteomyelitis	Plastic surgeon Paraplegiologist Infectiologist	Bone biopsies during the surgical debridement or flap surgery. Bacterial diagnostic and empirical and targeted infection treatment with antibiotics about 6 weeks if osteomyelitis.
Postsurgical immobilisation	Plastic surgeon Paraplegiologist	According to the diagnosis of osteomyelitis and recurrence the postsurgical bed rest is 4 or 6 weeks.
Prevention of secondary complication	Interdisciplinary and interprofessional team	Individual risk analyses Evaluation of seating position and cushion Evaluation of transfer techniques and strengthening of the upper extremity

Table 2: Quotes about experiences using the CDSS (advantages and challenges)

1.	Overall I think it is useful (resident physician)
2.	For me the outline of the process for the Dekubitus was valuable. (senior consultant)
3.	The overview as a sort of checklist was good (resident physician)
4.	I thought it was like guidelines. You were reminded whether it is time to change something – I asked myself the questions: is it correct, can we do this now? It is like following a standard process (nurse expert)
5.	You don't necessarily have to do it then, you can also reset or change it. (nurse expert)
6.	When the tool was presented, I was very optimistic. I had the feeling this could be very interesting, especially knowing what phase the patient is in or what the physio is doing and what ergotherapy is he receiving? (nurse expert)
7.	It is extremely confusing. I continue to read the processes from Medfolio. The PMC is very unclear. (resident physician)
8.	On the one hand a ton of potential, also for handovers between different steps, on the other hand a huge risk to get lost in detail. (therapy expert)
9.	I think this may be the biggest issue, it is too detailed (senior consultant)
10.	Filling in the required information in the system took up more time than we saved through the process, this is a complete no-go. (senior consultant)
11.	For me the accessibility and speed of our IT system are completely useless. (senior consultant)
12.	In the end things did not work as we planned. For example, logging into the system did not always work. (nurse expert)
13.	You need to look for the patient, then you have to click management, then you need to go somewhere else [in the system]... somehow there is no overview (resident physician)
14.	You always have to take the extra step to open it. It does not automatically open to remind you that something is still red. You actively have to open it (resident physician)
15.	Doing this twice, or rather duplication is definitely a big topic for our IT-system. It would be great if we could get rid of this, e.g. by things populating automatically once the information is filled in in one location. (nurse expert)
16.	And then, it does not autocomplete, you need to activate and confirm it. It does not simply happen once you entered the information . (nurse expert)
17.	the main issue was that it is various systems in which we work. (senior consultant)
18.	since we work in so many different programs it eats up your time to work according to this process. (resident physician)
19.	I want to work scientifically. Instead of the system getting the required information itself, you need to go from one section to another to get the data yourself. In the end you feel like Sisyphus. (senior consultant)
20.	One did not really look at the system. It was simply used for the others, so they could draw conclusions. (nurse expert)
21.	I would claim you have also witnessed it when you substituted me. The regular employee did not do anything with the system. It was only the team-leader when he visited the patient, not the regular employee who is actually affected, who used the system. The regular employee had no clue. (therapy expert)
22.	I have the impression that in this process we want to collect data, as you said, and want to analyze and use it for research. (resident physician)
23.	After a while we noticed that other departments or also we forgot to enter the information. Things are just done so automatically. One is caught up in old behavior patterns. (nurse expert)
24.	It just takes longer but the quality is not better. (therapy expert)
25.	It was simply completing a task. It did not help us in our clinical day to day work, it was simply an externally imposed duty. (therapy expert)

Table 3: Absolute and relative frequencies of ordered interventions and time from admission to intervention by intervention and control group

Interventions	Frequencies		Ratio	Odds Ratio		Mean Time-to-Event in Days				Mean Difference	
	CDSS Group N=15 n(%)	Control Group N=15 n(%)	CDSS1 CDSS0	OR	CI (95%)	CDSS Group		Control Group		$\mu_1 - \mu_0$	CI (95%)
						μ_1	CI (95%)	μ_0	CI (95%)		
Registration Physiotherapy	15 (100%)	13 (86.67%)	1.15			0.87	-0.33- 2.07	0.08	-0.55- 0.70	-0.79	-2.14- 0.57
Begin Physiotherapy	15 (100%)	15 (100%)	1.00			1.53	0.53- 2.53	1.00	0.34- 1.66	-0.53	-1.68- 0.61
Registration Occupational Therapy	15 (100%)	13 (86.67%)	1.15			0.87	-0.33- 2.07	0.08	-0.55- 0.70	-0.79	-2.14- 0.57
Begin Occupational Therapy	15 (100%)	15 (100%)	1.00			1.47	0.34- 2.59	3.20	-0.67- 7.06	1.73	-2.11- 5.57
Registration Psychology	12 (80%)	9 (60%)	1.44	2.67	0.41- 20.45	10.25	0.16- 20.37	20.67	-3.16- 44.50	10.42	-11.2- 32.07
Begin Psychology	11 (73.33%)	9 (60%)	1.33	1.83	0.31- 11.63	13.36	8.30- 18.43	27.56	6.14- 48.97	14.19	-4.13- 32.52
Registration Music & Art therapy	8 (53.33%)	4 (26.67%)	2.00	3.14	0.55- 19.56	26.50	4.18- 48.82	19.25	-20.51- 59.01	-7.25	-42.99- 28.49
Begin Music & Art therapy	7 (46.67%)	4 (26.67%)	1.75	2.41	0.416- 15.02	35.71	15.17- 56.26	29.00	-15.46- 73.46	-6.71	-41.13- 27.70
Registration Nutritional Counseling	15 (100%)	13 (86.67%)	1.15			0.53	-0.25- 1.31	1.08	-0.93- 3.09	0.54	-1.39- 2.48
Begin Nutritional Counseling	14 (93.33%)	12 (80%)	1.17	3.50	0.23- 196.59	5.86	3.33- 8.39	5.83	3.64- 8.03	-0.02	-3.26- 3.21
Nutrition Laboratory	15 (100%)	15 (100%)	1.00			0.87	-0.55- 2.28	0.07	-0.08- 0.21	-0.80	-2.16- 0.56
Registration Pulse Oximetry	8 (53.33%)	6 (40%)	1.33	1.71	0.32- 9.25	18.00	-3.29- 39.30	19.00	-1.89- 39.89	1.00	-26.44- 28.44
Examination Pulse Oximetry	7 (46.67%)	5 (33.33%)	1.40	1.75	0.32- 9.92	24.29	-3.75- 52.32	27.60	1.95- 53.25	3.31	-31.75- 38.38
Registration Spirometry	6 (40%)	5 (33.33%)	1.20	3.33	0.11- 235.24	4.33	-0.66- 9.33	35.40	-15.71- 86.51	31.07	-6.84- 68.97
Examination Spirometry	4 (26.67%)	2 (13.33%)	2.00	2.36	0.27- 30.02	8.00	-3.55- 19.55	38.00	-381.30- 457.30	30.00	-28.11- 88.11
ASIA	5 (33.33%)	7 (46.67%)	0.71	0.57	0.10- 3.13	35.40	-15.41- 86.21	41.00	21.29- 60.71	5.60	-34.45- 45.65
Joint status	15 (100%)	14 (93.33%)	1.07			12.13	1.94- 22.33	24.00	3.61- 44.39	11.87	-9.38- 33.11
Registration ECG	9 (60%)	10 (66.67%)	0.90	0.75	0.13 - 4.23	2.00	-0.34- 4.34	9.70	-10.32- 29.72	7.70	-12.14- 27.54
Examination ECG	9 (60%)	9 (60%)	1.00	1.00	0.18- 5.46	3.56	0.97- 6.14	11.00	-11.78- 33.78	7.44	-13.63- 28.52

Registration Plastic Surgery	12 (80%)	10 (66.67%)	1.20	2.00	0.29-15.84	1.58	-0.05-3.22	0.00	-0.34-0.34	-1.58	-3.31-0.15
Flap Surgery	15 (100%)	15 (100%)	1.00			22.27	15.91-28.63	21.53	11.60-31.47	-0.73	-12.00-10.53
Ordinance 4 / 6 Week Schedule	15 (100%)	14 (93.33%)	1.07			22.27	15.91-28.63	22.00	11.31-32.69	-0.27	-11.92-11.39
Moving Legs	14 (93.33%)	15 (100%)	0.93			63.79	52.40-75.18	54.53	43.88-65.19	-9.25	-24.10-5.60
First Mobilization in Wheelchair	15 (100%)	15 (100%)	1.00			74.20	61.80-86.60	62.07	51.44-72.69	-12.13	-27.73-3.47
Discharge						98.07	-0.33-2.07	81.33	-0.55-0.70	-16.73	-38.95-2.49

Abbreviation: CDSS = Clinical Decision Support System, μ_0 = mean of control group, μ_1 = mean of CDSS group

Table 4 Patient characteristics overall, in the process management group and in the standard care group (gender, etiology, completeness and level of lesion, comorbidities, years since injury, body mass index)

Parameter	Category	Total (N=30)	CDSS Group (N=15)	Control Group (N=15)	P-value
<i>Categorical Parameters – n (%)</i>					
Sex	Male	22 (73.3)	10 (66.7)	12 (80.0)	0.409
	Female	8 (26.7)	5 (33.3)	3 (20.0)	
Etiology of SCI	Transport Activity	8 (26.7)	4 (26.7)	4 (26.7)	0.844
	Sports/Leisure Activity	4 (13.3)	3 (20.0)	1 (6.7)	
	Fall	4 (13.3)	2 (13.3)	2 (13.3)	
	Other Accident Cause	4 (13.3)	2 (13.3)	2 (13.3)	
	Other or Unknown*	10 (33.3)	4 (26.7)	6 (40.0)	
Completeness of Lesion	Complete	19 (63.3)	8 (53.3)	11 (73.3)	0.256
	Incomplete	11 (36.7)	7 (46.7)	4 (26.7)	
Lesion Level	C1-C4	5 (16.7)	3 (20.0)	2 (13.3)	0.512
	C5-C8	6 (20.0)	4 (26.7)	2 (13.3)	
	T1-S5	19 (63.3)	8 (53.3)	11 (73.3)	
<i>Comorbidities – n (%)</i>					
Diabetes Mellitus		6 (20.0)	1 (6.7)	5 (33.3)	0.068
Coronary Heart Diseases		5 (16.7)	2 (13.3)	3 (20.0)	0.624
Arterial hypertension		13 (43.3)	6 (40.0)	7 (46.7)	0.713
Vitamin D Deficiency		24 (80.0)	12 (80.0)	12 (80.0)	1.000
Anemia		23 (76.7)	12 (80.0)	11 (73.3)	0.666
Arterial occlusive disease		6 (20.0)	2 (13.3)	4 (26.7)	0.361
Arteriosclerosis		5 (16.7)	2 (13.3)	3 (20.0)	0.624
Psychiatric Diagnosis		7 (23.3)	5 (33.3)	2 (13.3)	0.195
<i>Continuous Parameters – Median (Q1,Q3)</i>					
Age (years)		56.2 (42.0,69.7)	53.7 (36.7,74.4)	56.5 (51.7,69.7)	0.419
Years since SCI		19.4 (9.2,33.1)	17.8 (9.1,25.0)	22.9 (10.7,34.7)	0.395
BMI (kg/m ²)		23.1 (19.8,26.0)	20.8 (16.6,25.8)	24.6 (22.7,27.3)	0.065

* Includes multiple sclerosis, inflammatory and iatrogenic caused by surgical intervention

Table 5 Characteristics of PI (number of PIs, recurrent or primary PI, grade, localization), intervention (type of flap surgery) and outcome parameters (flap and general complications)

Parameter	Category	Total (N=30) n (%)	CDSS Group (N=15) n (%)	Control Group (N=15) n (%)	P- value
Total Number of	1	19 (63.3)	8 (53.3)	11 (73.3)	0.321
Pressure Injuries	2	6 (20.0)	3 (20.0)	3 (20.0)	
	3+	5 (16.7)	4 (26.7)	1 (6.7)	
Number of recurrence of Pressure Injuries		21 (70.0)	10 (66.7)	11 (73.3)	0.690
Grade of Pressure Injury	III	5 (16.7)	3 (20.0)	2 (13.3)	0.624
Osteomyelitis	IV	25 (83.3)	12 (80.0)	13 (86.7)	
		22 (73.0)	11 (73.0)	11 (73.0)	
Localization	Ischium	19 (63.3)	10 (66.7)	9 (60.0)	0.484
	Sacrum	10 (33.3)	4 (26.7)	6 (40.0)	
	Trochanter	1 (3.3)	1 (6.7)	0	
Type of Flap	Gluteal Fasciocutaneous Rotational Flap (Sacrum)	12 (40.0)	5 (33.3)	7 (46.7)	0.693
	Posterior Thigh Flap (Ischium)	15 (50.0)	8 (53.3)	7 (46.7)	
	Other	3 (10.0)	2 (13.3)	1 (6.7)	
Complications	None	16 (53.3)	7 (46.7)	9 (60.0)	0.755
	Minor (Prolonged Bedrest)	9 (30.0)	5 (33.3)	4 (26.7)	
	Major (Resurgery)	5 (16.7)	3 (20.0)	2 (13.3)	
Type of Additional Complications	None	24 (80.0)	13 (86.7)	11 (73.3)	0.558
	Pneumonia	4 (13.3)	1 (6.7)	3 (20.0)	
	Urinary Tract Infection	2 (6.7)	1 (6.7)	1 (6.7)	
Length of Stay (days)	Mean (SD)	90 (26.6)	98 (28.3)	81 (22.8)	0.124
	Median (Q1, Q3)	80 (71, 117)	89 (76, 120)	78 (71, 86)	
	Min, Max	54, 147	55, 147	54, 140	

Abbreviation: CDSS = Clinical Decision Support System

Supplementary

Appendix Table 5 not available with this version

Figures

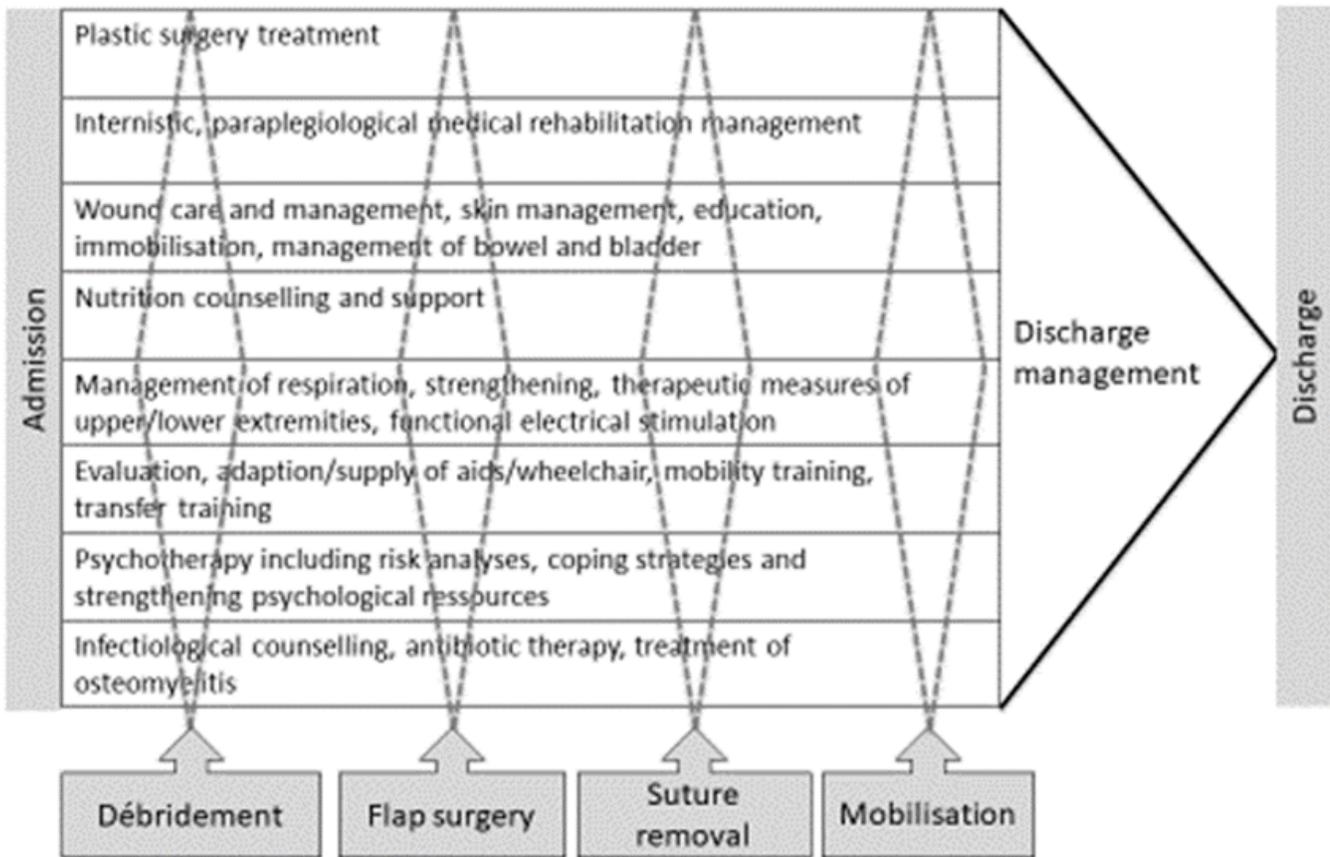


Figure 1

Treatment principles and milestones in the "modified Basel Decubitus Concept"

Supplementary Files

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