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Evaluation of an implemented new insulin chart to improve quality and safety of diabetes care in a large University Hospital: a follow-up study

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Evaluation of an implemented new insulin chart to improve quality and safety of diabetes care in a large University Hospital: a follow-up study

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Strengths and limitations of this study:

- A strength of the study is that improvements in documentation quality were connected with beneficial clinical outcome.
- Moreover, the project was performed within daily routine work as an essential quality assurance project
- Nevertheless, a lesson learnt from the present work was that training of the nursing and medical staff is a real challenge in a typical hospital setting.
- Another critical aspect when designing a new insulin chart is an early review of the necessity of all fields on the new insulin chart. It can be assumed that, similar to the Scottish study, the more fields that need to be filled-in the less likely any of them will be charted.

Objectives: To evaluate structure, documentation, and treatment quality of a new implemented standardized insulin chart in adult medical inpatient wards at a University Hospital.

Design: A before-after study (3-5 months after implementation) was used to compare the quality of old vs. new insulin charts

Setting: University Hospital Graz, Styria, Austria

Participants: Health-care-professionals (n=237) were questioned regarding structure quality of blank insulin charts.

Interventions: Health-care-professionals were trained regarding features of the new insulin chart. Data from insulinized inpatients were evaluated regarding documentation and treatment quality of filled-in insulin charts (n=108 old insulin charts vs. n=100 new insulin charts).

Main Outcomes and Measures: Attitudes of internal and external physicians in terms of target group, content and health literacy

Results: Health-care-professionals reported an improved structure quality of the new insulin chart with a Likert-type-response-scale increase in all nine items. Documented insulin administration errors (primary endpoint) occurred more often on old than on new insulin charts (77% vs. 5%, $p < 0.001$). Insulin prescription errors were more frequent on old insulin charts (100% vs. 42%) whereas insulin management errors rarely occurred in any group (10% vs. 8%). Patients of both chart evaluation groups (age: 71 ± 11 vs. 71 ± 12 years, 47% vs. 42% female, 75% vs. 87% type-2-diabetes for old vs. new charts, respectively) had a mean of 4 ± 2 good diabetes days. Overall, 26 vs. 18 hypoglycemic episodes (BG < 72 mg/dL), including seven vs. two severe

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hypoglycemic episodes (BG <54 mg/dL) were documented on old vs. new insulin charts.

Conclusions: The implementation of a structured documentation form together with training measures for health-care-professionals led to less documentation errors and safe management of glycemic control in hospitalized patients in a short time follow-up. A roll-out at further medical wards is recommended, and sustainability of the beneficial effects in the long term has to be demonstrated.

Trial registration: This open monocentric retrospective study was approved by the ethical board of the Medical University of Graz (EK-No. 29-153 ex 16/17) and performed according to principles of good clinical practice.

INTRODUCTION

Up to 22-30% of hospitalized patients have diabetes and occurring hyperglycemia and hypoglycemia can lead to adverse outcomes and even to death,(1–4).

To reduce high blood glucose (BG) values, insulin is often considered to be the first choice in the hospital setting,(4,5). Despite good treatment effects, insulin is also listed as a high-alert medication by the Institute for Safe Medication Practices,(6) because it can cause serious harm to patients when used incorrectly,(5,7,8).

Errors in insulin prescription and administration are common,(5,9) and include for example missed or wrongly administered insulin doses, incorrect prescription of insulin name, dose or type, abbreviations in insulin prescription, or illegible handwriting,(5,7,9–13). The UK National Patient Safety Agency reported 3881 incidents with incorrect insulin doses from 2003 to 2009. Most commonly, abbreviations in insulin prescription and errors in using insulin syringes were identified that led to harm and in some cases even to death,(9). In England and Wales, the National Diabetes Inpatient Audit (NDIA) determined that in 31% of inpatients a medication error and in 18% an insulin error occurred during hospital stay,(14).

The main documentation tool for diabetes therapy in a hospital setting is the insulin chart. On this documentation sheet, insulin prescription, insulin administration, BG values, treatment for hypoglycemia and all other relevant information should be documented,(5,11). The insulin chart is used by different health care professionals for documentation, interpretation and communication. Differences in the design of insulin charts could impact the quality of inpatient diabetes care,(11). Therefore, international guidelines recommend a standardized documentation of diabetes management,(4,5,15). Previous studies reported improvements in inpatient diabetes care after implementation of a newly developed insulin chart,(10,16).

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At the University Hospital Graz, a new standardized insulin chart was developed due to previously identified quality deficits, such as heterogeneity in the structure of 20 different blank insulin charts and existing medication errors in filled-in insulin charts. The lack of structure quality features was shown to have an impact on documentation and treatment quality in the previous study,(17). The aim of the present investigation was to evaluate structure, documentation, and treatment quality when using the newly implemented insulin chart compared to the old insulin charts in patients receiving insulin therapy in adult medical wards.

METHODS

Ethics statement

This open monocentric retrospective study was approved by the ethical board of the Medical University of Graz (EK-No. 29-153 ex 16/17) and performed according to principles of good clinical practice.

Reporting

The research and reporting methodology was performed according the Squire 2.0 checklist.

Study design and setting

The evaluation of insulin charts was performed in nine adult medical wards at the Department of Internal Medicine at the University Hospital of Graz, Austria. At the time of this study the general wards were all using paper-based fever and insulin charts in routine patient care.

Implementation of new insulin chart

The newly developed insulin chart (Figure 1) was implemented at the nine adult medical wards. For the implementation, a training concept was developed by an interdisciplinary project team and together with each ward training schedules were arranged. The training regarding the use of the new insulin chart was done separately on each ward by an interdisciplinary team. Physicians and nurses were trained together presenting the main features of the new insulin chart by using practical examples. Based on learning by doing, health care professionals themselves filled in

the new insulin chart using practical examples. Further time for questions and ambiguities was provided. The training duration ranged from 45 to 60 minutes. Additional training material, such as a training manual, folder and poster were generated to support the implementation process. If needed, further diabetes training with focus on insulin therapy was offered by a diabetes nurse specialist for each ward.

Data collection

A before-after comparison regarding the quality of the old insulin charts (tested in phase 1) and the new insulin charts (tested in phase 2, 3-5 months after implementation of the new insulin chart) was conducted (Figure 2). Overall, there were four different old insulin charts (see supplement) in use at the nine evaluated wards vs. one new insulin chart after implementation. Blank and filled-in insulin charts were evaluated. Data on structure, documentation, and treatment quality of the insulin charts were collected.

Evaluation of blank insulin charts

In a before-after comparison the subjective perception of health care professionals regarding structure quality of blank old insulin charts vs. blank new insulin charts was evaluated. A paper-based questionnaire was developed by an interdisciplinary team including relevant quality indicators identified in a previous study,(17). Physicians and nurses of all participating wards were asked to complete the questionnaire by assessing the quality indicators. Each item was rated on a four-point Likert type response scale, with the four categories “I disagree”, “I agree to some extent”, “I partially agree” and “I agree” coded as one to four.

Evaluation of filled-in insulin charts

Documentation and treatment quality were evaluated by reviewing filled-in old vs. new insulin charts based on methodological elements used by the National Diabetes Inpatient Audit,(18).

Insulin charts from adult inpatients who were treated with insulin and who were admitted at one of the nine wards for at least one day were evaluated for a maximum of seven days. A before-after comparison was conducted, in which the evaluation of the filled-in old insulin charts was compared to evaluation of the filled-in new insulin charts. For both evaluations a paper-based data entry form was developed including relevant quality indicators,(10,11,16,18,19). The primary objective was to compare the number of insulin administration errors (primary endpoint). The following four items were generated according to the definition of insulin errors of NDIA,(19):

- name of insulin was not written complete/legible/comprehensible,
- unclear dose,
- no initialing when insulin was administered,
- time of administration was not clearly documented.

Any chart with at least one insulin administration error in the seven day audit period was counted as one insulin administration error. Secondary endpoints included insulin prescription errors, insulin management errors, clinical patient characteristics, good diabetes day (calculated according to NDIA,(18)), hypoglycemia management, patient identification as well as specific parameters of the new insulin chart.

Data management

All patient-related data were pseudonymized with subject numbers following data protection guidelines. As data were collected by one scientist, a validation was conducted to ensure data plausibility. Therefore, 20 old insulin charts and 20 new

insulin charts were randomly chosen and evaluated regarding the primary endpoint “errors in insulin administration” by two independent raters. A percent agreement of 90% (95% exact confidence interval: 76% - 97%) was observed. In order to check and ensure completeness, correctness and accuracy of data entry, an internal quality control with four-eye-principle was performed.

Patient and Public Involvement

Patients were not directly involved in the study..

Statistical analysis

For the primary endpoint comparison a sample size calculation was conducted. A Chi-square test was used to check for differences in quality of old and new insulin charts. A total of 93 old insulin charts and 93 new insulin charts were needed to obtain a power of 80%. An absolute reduction of 20% in insulin administration errors, and an error rate of 70% for the old insulin charts, which was based on previous study results,(17), were assumed. Depending on availability, in a first step up to 15 filled-in old insulin charts and in a second step up to 15 filled-in new insulin charts were collected per ward. Data on structure quality were analyzed by using EvaSys, a digital survey tool,(20) and data on documentation and treatment quality were analyzed by using IBM SPSS Statistics 23,(21). Data were summarized with descriptive statistics. For numerical data – depending on distribution – mean, standard deviation, median, minimum and maximum were calculated. Categorical data are presented as relative and absolute frequency. Number of old insulin charts and new insulin charts with insulin

administration errors was compared using a Chi-square test. A two-sided significance level of 5% indicates statistical significance.

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3 **RESULTS**
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6 **Structure quality of blank old vs. new insulin charts**
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8 The Likert type response scale indicates a shift towards agreeing answers by health
9 care professionals (phase 1: 84 vs. phase 2: 153) for improved structure quality of
10 the new insulin chart for all nine items (Figure 3). For overall comparison of blank old
11 vs. new insulin charts health care professionals indicated that documentation of
12 prescription and administration of BG lowering medication was more clearly arranged
13 (2.3±1.0 vs. 3.0±0.9), the correction scheme was better integrated (1.7±1.0 vs.
14 3.1±1.0), boxes for documentation of measured BG values were more clearly
15 visualized (2.8±1.0 vs. 3.4±0.8), more space for insulin prescriptions (2.3±1.0 vs.
16 3.3±0.8) and for documentation of hypoglycemia treatment (2.0±0.9 vs. 2.8±0.9) was
17 found on new insulin charts. Transparency of insulin prescription and insulin
18 administration (2.6±0.9 vs. 3.1±0.8), as well as support of confirmation of both
19 processes with initials was increased (2.5±1.2 vs. 3.3±0.8), and documentation of all
20 relevant information regarding BG management was easier (2.1±0.9 vs. 3.0±0.9) on
21 new insulin charts. As a single item, difficulties with nursing and medical
22 responsibilities in completing the insulin chart were found to be almost constant
23 (2.6±1.0 vs. 2.7±1.1).
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48 **Documentation and treatment quality of filled-in old vs. new insulin charts**
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50 A total of 108 filled-in old insulin charts and 100 filled-in new insulin charts of inpatients
51 receiving insulin were evaluated (phase 1 vs. phase 2). Patient characteristics and
52 treatment modalities of both groups are given in Table 1.
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Table 1: Patient characteristics and treatment modalities of 208 inpatients treated with insulin

	Patients with old insulin charts (n=108)	Patients with new insulin charts (n=100)
Age, years (mean \pm SD)	71 \pm 11	71 \pm 12
Female (n (%))	51 (47)	42 (42)
Admission type: emergency (n (%))	63 (58)	66 (66)
Reasons for admission (n (%))		
Medical non diabetes specific reasons (e.g. resp., cardiovasc.)	89 (82)	81 (81)
Diabetes specific reasons for admission	19 (18)	19 (19)
Nights in the hospital (median (min-max))	8 (1-86)	7 (1-66)
Foot disease (previous ulcer, amputation, Charcot) (n (%))	17 (16)	18 (18)
Renal replacement therapy (n (%))	10 (9)	7 (7)
Diabetes type (n (%))		
Diabetes type 1	6 (6)	2 (2)
Diabetes type 2	81 (75)	87 (87)
Other diabetes type	6 (6)	9 (9)
Not documented	15 (14)	2 (2)
HbA1c (mmol/mol) (mean \pm SD)	62 \pm 14	67 \pm 21
BG per patient (mg/dL) (mean \pm SD)	186 \pm 50	186 \pm 44
BG measurement frequency per day (mean \pm SD)	3 \pm 1	3 \pm 1
Treatment modalities (n (%))		
Premixed insulin	43 (40)	42 (42)
Basal insulin	28 (26)	26 (26)
Basal-bolus insulin	12 (11)	13 (13)
Prandial insulin	4 (4)	2 (2)
Correctional bolus insulin	57 (53)	51 (51)
DPP-4 inhibitor	31 (29)	25 (25)
Metformin	14 (13)	15 (15)
Sulfonylurea	4 (4)	6 (6)

SD standard deviation, BG blood glucose

The number of insulin administration errors, the primary endpoint, was significantly higher for the old insulin charts compared to the new insulin charts (83 (77%) vs. 5 (5%)) ($p < 0.001$). Each parameter of insulin administration errors was distinctly higher

on old insulin charts than on new insulin charts. Insulin prescription errors were more frequent on old insulin charts (108 (100%) vs. 42 (42%)), whereas insulin management errors rarely occurred in any group (11 (10%) vs. 8 (8%)). A detailed breakdown of listed parameters for insulin errors is shown in Table 2.

Table 2: Insulin errors with detailed listed parameters for seven days of inpatient stay

Insulin error type	Old insulin charts (n=108)	New insulin charts (n=100)
Insulin administration errors (n (%))		
Name of insulin was not written complete/legible/comprehensible	17 (16)	3 (3)
Unclear dose	25 (23)	1 (1)
No initialing when insulin was administered	55 (51)	3 (3)
Time of administration was not clearly documented	46 (43)	0
Insulin prescription errors (n (%))		
Insulin was not written up	27 (25,0)	0
Name of insulin was not written complete/legible/comprehensible	19 (18)	0
Unclear dose	32 (30)	1 (1)
Unit was written unclear	30 (28)	0
No initialing when insulin was prescribed	108 (100)	42 (42)
Insulin was administered/prescribed at the wrong time	0	0
Insulin management errors (n (%))		
Insulin not increased when BG persistent >198 mg/dL and a better control was appropriate for patient	10 (9)	7 (7)
Insulin was not reduced when unexplained BG <72 mg/dL	1 (1)	1 (1)
Inappropriate omission of insulin after hypoglycemic episode	0	0

Both groups had a mean of 4±2 good diabetes days scaled to hospital stay days. Most frequently BG values >198 mg/dL were responsible for not achieving good diabetes

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3 day criteria, whereas BG values <72 mg/dL and inappropriate BG measurement
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5 frequency occurred less. Overall, 26 vs. 18 hypoglycemic episodes (BG <72 mg/dL),
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7 including seven vs. two severe hypoglycemic episodes (BG <54 mg/dL) were
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9 documented on old vs. new insulin charts, respectively. Treatment of severe
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11 hypoglycemia was documented in six out of seven cases on old charts vs. in both
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13 cases on new charts, respectively. Documented treatment modalities included four
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15 times infusion of iv dextrose on old charts, whereas in all remaining cases oral
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17 carbohydrates were given.
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21 Moreover, 12% absolute improvement in documentation of patient identification (78%
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23 vs. 90%) was achieved by implementing the new insulin chart. Documentation of
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25 HbA1c value on insulin charts was rare in both groups (1% vs. 7%). Additionally,
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27 diabetes type was documented on 47%, pre-diabetes therapy on 17%, correction
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29 scheme on 28% and glomerular filtration rate on 6% of the filled-in new insulin charts.
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DISCUSSION

The results of this study indicate that improved inpatient diabetes care was achieved by implementing a new insulin chart.

Erroneous documentation of insulin administration was significantly lower in new compared to old insulin charts. The design of the new chart was found suitable to improve all parameters of insulin administration errors. For example, errors regarding initialing of insulin administration by nurses were distinctly lower on new insulin charts compared to the previously used insulin charts. Our finding (3%) is similar to a rate of 4% not signed as given on audited drug charts at the NDIA,(14). Thus, a comprehensible documentation of mandatory administration data for effective and safe glucose management was guaranteed by implementation of this new insulin chart. A Scottish study, which identified evidence-based subcutaneous insulin care clusters to develop a new insulin chart showed similar improvements in the correct documentation of insulin administration after implementing a new insulin chart,(10).

Regarding insulin prescription errors, we identified half as many errors on the new insulin charts. The detailed analysis of insulin prescription errors indicated that all but one parameter, the initialization of the prescription, were sufficiently improved on new insulin charts and comparable to most recent data of the NDIA,(14). None of the previously used insulin charts at our institution had provided a dedicated area for the initialing of therapy which is reflected in 100% error rate in the baseline evaluation. Although the new design supports this legal prerequisite of documentation, a sufficient practice change among physicians has not yet been achieved. Similarly, the Scottish study did not report a significant change in insulin prescription by implementing a new insulin chart. The authors argued, that this may arise from longstanding practice on the wards which is not easily changed,(10). The same challenge may also apply to our

hospital and hence further training should be offered to health care professionals to improve initialing of prescription.

Insulin management errors were rare in both groups and remained lower than the average error rate reported in a recent NDIA report,(14). The number of good diabetes days, an indicator for established glycemic control without the occurrence of hypoglycemia, remained at a higher level compared to the benchmark of insulin treated patients in the NDIA audit,(14). Of note, the number of hypoglycemic events, including severe episodes, was lower in new insulin charts and treatment of severe hypoglycemia was documented in all cases on new insulin charts. Thus, regarding treatment quality, the use of the new insulin chart seems to be clinically safe and beneficial to hospitalized patients that need insulin therapy to control glycemia.

Our evaluation of structural quality features showed a shift towards agreeing answers by nurses and physicians for improved structure quality of the new insulin charts for all nine items. Most of the structural improvements led to the desired positive changes in documentation quality. However, not all offered documentation possibilities were used to the same extent in clinical routine. As discussed above, there was a distinct difference in the authorization of prescription or confirmation of administration through initializing on the new insulin chart by physicians and nurses, respectively.

In this regard it is important to emphasize the potential limitation that the evaluation of filled-in insulin charts may not reflect the entire actual care at the wards. Similar to the Scottish study it can be assumed that there is a potential gap between the actual quality of care and the documentation,(10). The implementation report of a national subcutaneous insulin chart in the Australia project observed a decrease in the proportion of doses initialed as having been administered and orders where the prescriber had signed. The authors argued, that this does not necessarily mean that

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the insulin doses were not given, as otherwise this would be seen in increasing BG values,(16).

Furthermore, the observed beneficial effects in the current investigation may not be solely attributed to the use of the new insulin chart as the implementation was accompanied by extensive training measures to improve compliance of medical and nursing staff. The limitation of a missing control group, which has undergone comparable training measures with the previous insulin charts in order to assess the impact of the new form on its own, is acknowledged. The sole effect of the new insulin chart on the clinical care of patients could also be determined by repeating our survey of documentation and care quality after a "wash out period" of several months. This reassessment would also allow to determine sustainability of the effects that were observed in the current study (up to five months use of new insulin chart).

Moreover, the implementation and subsequent effects of the new insulin chart to other, e.g. surgical disciplines may be different. However, insulin prescription and administration should not differ between conservative and surgical disciplines and accompanying training measures should allow a safe and effective implementation.

A strength of the study is that improvements in documentation quality were connected with beneficial clinical outcome. Moreover, the project was performed within daily routine work as an essential quality assurance project. Hours spend for implementation were covered out of general employment and, thus, feasibility of a roll out in comparable hospital institutions can be assumed.

Nevertheless, a lesson learnt from the present work was that training of the nursing and medical staff is a real challenge in a typical hospital shift rotation system.

Another critical aspect when designing a new insulin chart is an early review of the necessity of all fields on the new insulin chart. It can be assumed that, similar to the Scottish study, the more fields that need to be filled-in the less likely any of them will be charted,(10). In our case the item glomerular filtration rate will be removed from the chart as the degree of filling-in was low and importance for the actual treatment process in daily routine care has been scrutinized.

Finally, we agree with the conclusion of the Australian Quality Initiative that further optimization of specific endpoints, such as initialing of physician's prescription or documentation of hypoglycemia treatment should be addressed through effective change management processes and more explicit training and education for health care professionals, rather than further modification of chart design,(16). The insulin chart, as a standardized documentation of diabetes management, is only one component for good diabetes inpatient care. It is also important to address the knowledge gaps regarding insulin therapy among health care professionals,(5,9). International guidelines further recommend electronic diabetes documentation as necessary for optimizing diabetes inpatient care,(4,15). This is also confirmed by NDIA, where hospitals that were prescribing diabetes medication electronically were less likely to have prescription errors,(14). Electronic systems with clinical decision support have the potential to reduce errors and to increase treatment quality,(22).

CONCLUSION

Inpatient diabetes care was optimized through implementation of the new insulin chart. Structural changes on the new insulin chart along with accompanying training measures throughout the implementation process, not only led to better quality of

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insulin chart structure, but also improved documentation quality of filled-in new insulin charts and clinical outcome data. The present work supports a roll-out of the new insulin chart at further departments, and sustainability of the beneficial effects in the long term has to be demonstrated in further investigations.

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The University Hospital Graz supported the investigation of evaluating the new insulin chart.

Author contributions

JK, GS, KML, BS, TRP and JP designed and performed the study, interpreted data and contributed to discussions, RR performed statistical analysis, JP, GB, CT and TRP supervised the project and JP is the guarantor of this work.

Prior presentation of data

Prior presentations of the data include the 6th Grazer Risk Day 2018, Austria, the Annual Meeting of the ÖDG 2017 and 2018 Salzburg, Austria and as abstract (published only) at Diabetes 2019 from the American Diabetes Association.

Reference List

1. Umpierrez GE, Isaacs SD, Bazargan N, et al. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. *J Clin Endocrinol Metab* 2002;87:978–82.
2. Draznin B, Gilden J, Golden SH, et al. Pathways to quality inpatient management of hyperglycemia and diabetes: A call to action. *Diabetes Care* 2013;36:1807–14.
3. Fritsche A. Diabetes Mellitus in der Klinik - Mehr Strukturen schaffen - Die Anforderungen an die stationäre Behandlung von Diabetespatienten wird unterschätzt. *Dtsch Arztebl* 2017;114:16–9.
4. ADA. 14. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. *Diabetes Care* 2018;41:144–51. Available at: <http://care.diabetesjournals.org/lookup/doi/10.2337/dc18-S014>. Accessed December 18, 2019.
5. Fowler D, Rayman G. Safe and Effective use of Insulin in Hospitalised Patients. London; 2010.
6. ISMP. ISMP List of High-Alert Medications in Acute Care Settings. Inst Safe Mediat Pract 2018; Available at: <https://www.ismp.org/sites/default/files/attachments/2018-08/highAlert2018-Acute-Final.pdf>. Accessed December 18, 2019.
7. Cox AR, Ferner RE. Prescribing errors in diabetes. *Br J Diabetes Vasc Dis* 2009;9:84–8. Available at: <http://dvd.sagepub.com/cgi/doi/10.1177/1474651409103902>. Accessed

December 18, 2019.

8. Kolanczyk DM, Dobersztyn RC. Challenges with insulin in the inpatient setting. *Diabetes Spectr* 2016;29:146–52.
9. Lamont T, Cousins D, Hillson R, et al. Safer administration of insulin: summary of a safety report from the National Patient Safety Agency. *BMJ* 2010;341:882–7.
10. Rushmer R, Voigt D. Measure it, improve it: the safer patients initiative and quality improvement in subcutaneous insulin therapy for hospital in-patients. *Diabet Med* 2008;25:960–7.
11. Christofidis MJ, Horswill MS, Hill A, et al. Task analysis and heuristic analysis of insulin charts: final report for the Australian Commission on Safety and Quality in Health Care. Sydney 2012. Available at: <https://safetyandquality.gov.au/wp-content/uploads/2012/06/56679-Insulin-charts-heuristic-analysis-2-Feb-2011-Final-Report.pdf>. Accessed December 18, 2019.
12. Cobaugh DJ, Maynard G, Cooper L, et al. Enhancing insulin-use safety in hospitals: Practical recommendations from an ASHP Foundation expert consensus panel. *Am J Heal Pharm* 2013;70:1404–13.
13. Cousins D, Rosario C, Scarpello J. Insulin, hospitals and harm: a review of patient safety incidents reported to the National Patient Safety Agency. *Clin Med (Northfield Il)* 2011;11:28–30. Available at: <http://www.clinmed.rcpjjournal.org/content/11/1/28.full.pdf>. Accessed December 18, 2019.

14. NDIA. National Diabetes Inpatient Audit 2017 - Full report. England and Wales 2018. Available at: <https://files.digital.nhs.uk/pdf/s/7/nadia-17-rep.pdf>. Accessed December 18, 2019.
15. Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of hyperglycemia in hospitalized patients in non-critical care setting: An endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 2012;97:16–38.
16. Australian Commission on Safety and Quality in Health Care. Development and evaluation of a new chart for subcutaneous insulin administration in acute care settings. 2017.
17. Kopanz J, Lichtenegger KM, Sendlhofer G, et al. Limited Documentation and Treatment Quality of Glycemic Inpatient Care in Relation to Structural Deficits of Heterogeneous Insulin Charts at a Large University Hospital. *J Patient Saf* 2018.
18. NDIA. National Diabetes Inpatient Audit 2016 - Full report. England and Wales 2017. Available at: <https://digital.nhs.uk/catalogue/PUB23539>. Accessed December 18, 2019.
19. NDIA. National Diabetes Inpatient Audit 2013. National Summary. England and Wales 2013. Available at: <http://content.digital.nhs.uk/catalogue/PUB13662/nati-diab-inp-audi-13-nat-rep.pdf>. Accessed December 18, 2019.
20. Electric Paper. EvaSys 6.0 - Electric Paper Evaluationssysteme GmbH. Lüneburg Deutschland 2013. Available at: <https://www.evasys.de>. Accessed December 18, 2019.

- 1
2
3 21. IBM Analytics. IBM SPSS-Statistics Version 23. 2018. Available at:
4
5 <https://www.ibm.com/analytics/at/de/technology/spss/>. Accessed December 18,
6
7 2019.
8
9
10
11 22. Neubauer KM, Mader JK, Höll B, et al. Standardized Glycemic Management
12
13 with a Computerized Workflow and Decision Support System for Hospitalized
14
15 Patients with Type 2 Diabetes on Different Wards. *Diabetes Technol Ther*
16
17 2015;17:685–92. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/26355756>.
18
19 Accessed December 18, 2019.
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Figure Legend

Figure 1: The newly designed standardized insulin chart

Figure 2: Timeline of study phases to identify structure, documentation and treatment quality

Figure 3: Structure quality of insulin charts assessed by physicians and nurses on a four-point Likert type response scale (“I disagree”, “I agree to some extent”, “I partially agree” and “I agree” coded as one-four)

Supplement

Supplement: Different insulin charts in use at the nine wards before implementation of the new insulin chart

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

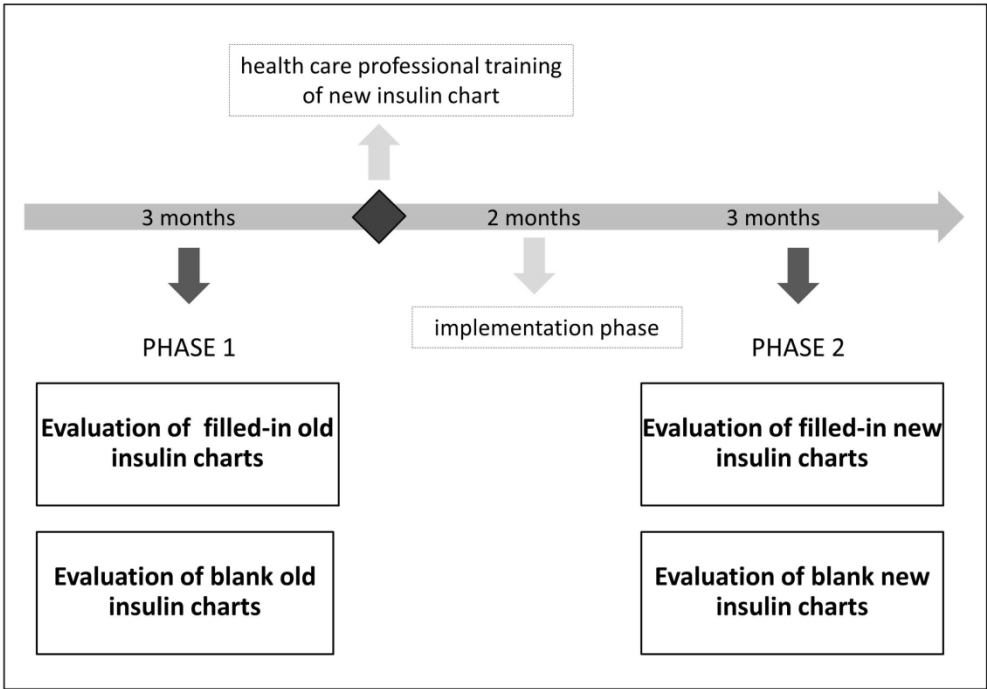


Figure 2: Timeline of study phases to identify structure, documentation and treatment quality

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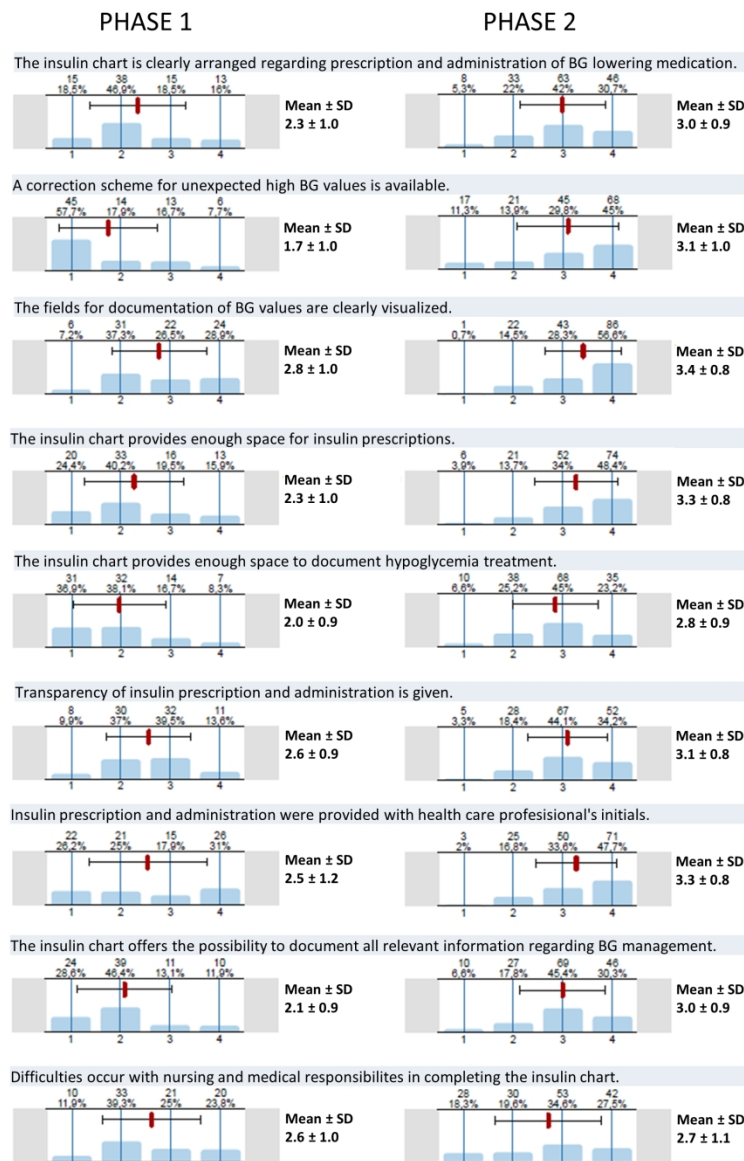


Figure 3: Structure quality of insulin charts assessed by physicians and nurses on a four-point Likert type response scale ("I disagree", "I agree to some extent", "I partially agree" and "I agree" coded as one-four)

190x274mm (284 x 284 DPI)

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SQUIRE 2.0 Checklist

Text Section and Item Name	Section or Item Description	Reported on page #
Title and Abstract		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	"improve quality and safety of diabetes care", title page 1
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	Abstract, page 2 (structure: objective, methods, results, conclusions)
Introduction	<i>Why did you start?</i>	
3. Problem description	Nature and significance of the local problem	Introduction, page 3
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	Introduction, page 3-4
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	Introduction, page 3-4
6. Specific aims	Purpose of the project and of this report	Introduction, page 4
Methods	<i>What did you do?</i>	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	Implementation of new insulin chart, methods, page 5
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	a. Methods, page 5-7, Figure 1 – the new insulin chart b. Interdisciplinary project team, methods page 5
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	a. and b. Methods, page 6-7
10. Measures	a. Measures chosen for studying processes and outcomes of the	a. Methods, page 6-7 b. Implementation of new

	intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	insulin chart, page 5 (no cost measures) c. Data management, methods, page 7
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	a. Statistical analysis, methods, page 8 b. Methods, page 6-7
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	Ethical approval, methods, page 5
Results	<i>What did you find?</i>	
13. Results	a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data	a. Figure 2 – timeline of study phases, no intervention modifications were needed b. Results, page 9-12 c. Results, page 9-10 d. Results, page 9-12 e. Results, page 9-12 (no cost evaluation) f. No missing data
Discussion	<i>What does it mean?</i>	
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project	a., b. Discussion, page 13-15
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs	a., b., c., d Discussion, page 13-16 e. Discussion and Conclusion, page 16

16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations	a., b, c Discussion, page 15
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps	a., b, c., d., e. Conclusion, page 16 b. Not given
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	Funding, page 17

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Evaluation of an implemented new insulin chart to improve quality and safety of diabetes care in a large University Hospital: a follow-up study

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Number of tables: 2

Number of figures: 3

Strengths and limitations of this study:

- A strength of the study is that improvements in documentation quality were connected with beneficial clinical outcome.
- The project was performed during regular working hours as an essential quality assurance project.
- A lesson learnt from the present work was that training of the nursing and medical staff is a real challenge in a typical hospital setting.
- When designing a new insulin chart an early review of the necessity of all fields on the new insulin chart should be done. It can be assumed that the more fields that need to be filled-in the less likely any of them will be charted.

Objectives: To evaluate structure, documentation, treatment quality of a new implemented standardized insulin chart in adult medical inpatient wards at a University Hospital.

Design: A before-after study (3-5 months after implementation) was used to compare the quality of old vs. new insulin charts

Setting: University Hospital Graz, Styria, Austria

Participants: Health-care-professionals (n=237) were questioned regarding structure quality of blank insulin charts.

Interventions: A new standardized insulin chart was implemented and health-care-professionals were trained regarding features of this chart. Data from insulinized inpatients were evaluated regarding documentation and treatment quality of filled-in insulin charts (n=108 old insulin charts vs. n=100 new insulin charts).

Main Outcomes and Measures: The primary endpoint was documentation error for insulin administration.

Results: Health-care-professionals reported an improved structure quality of the new insulin chart with a Likert-type-response-scale increase in all nine items. Documentation errors for insulin administration (primary endpoint) occurred more often on old than on new insulin charts (77% vs. 5%, $p < 0.001$). Documentation errors for insulin prescription were more frequent on old insulin charts (100% vs. 42%) whereas documentation errors for insulin management rarely occurred in any group (10% vs. 8%). Patients of both chart evaluation groups (age: 71 ± 11 vs. 71 ± 12 years, 47% vs. 42% female, 75% vs. 87% type-2-diabetes for old vs. new charts, respectively) had a mean of 4 ± 2 good diabetes days. Overall, 26 vs. 18 hypoglycemic episodes (BG < 4.0

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mmol/L (72 mg/dL), $p=0.28$), including seven vs. two severe hypoglycemic episodes (BG <3.0mmol/L (54 mg/dL), $p=0.17$) were documented on old vs. new insulin charts.

Conclusions: The implementation of a structured documentation form together with training measures for health-care-professionals led to less documentation errors and safe management of glycemic control in hospitalized patients in a short time follow-up. A rollout at further medical wards is recommended, and sustainability in the long term has to be demonstrated.

Trial registration: The study has not been registered in any clinical trial registry.

peer review only

INTRODUCTION

Up to 22-30% of hospitalized patients have diabetes and occurring hyperglycemia and hypoglycemia can lead to adverse outcomes and even to death,(1–4).

To reduce high blood glucose (BG) values, insulin is often considered to be the first choice in the hospital setting,(4,5). Despite good treatment effects, insulin is also listed as a high-alert medication by the Institute for Safe Medication Practices,(6) because it can cause serious harm to patients when used incorrectly,(4,5,7,8).

Errors in insulin prescription and administration are common,(4,5,9) and include for example missed or wrongly administered insulin doses, incorrect prescription of insulin name, dose or type, abbreviations in insulin prescription, or illegible handwriting,(4,5,7,9–13). The UK National Patient Safety Agency reported 3881 incidents with incorrect insulin doses from 2003 to 2009. Most commonly, abbreviations in insulin prescription and errors in using insulin syringes were identified that led to harm and in some cases even to death,(9). In England and Wales, the National Diabetes Inpatient Audit (NaDIA) determined that in 31% of inpatients a medication error and in 18% an insulin error occurred during hospital stay,(14).

In many hospital settings the main documentation tool for diabetes therapy is still a paper-based insulin chart. On this documentation sheet, insulin prescription, insulin administration, BG values, treatment for hypoglycemia and all other relevant information should be documented,(4,5,11). The insulin chart is used by different health-care-professionals for documentation, interpretation and communication. Differences in the design of insulin charts could impact the quality of inpatient diabetes care,(11). Therefore, international guidelines recommend a standardized documentation of diabetes management,(4,5,15) and efforts are undertaken to identify safe and effective insulin charts,(16). Previous studies reported improvements in

inpatient diabetes care after implementation of a newly developed insulin chart,(10,17–20).

At the University Hospital Graz, a new standardized paper-based insulin chart (Figure 1) was developed by an interdisciplinary project team including nurses, physicians, researchers and a quality manager due to previously identified quality deficits (e.g. missing transparency between insulin prescription and administration process, unclear patient identification, missing guidance for treatment of hypoglycemia) as well as international and local standards,(4,5,10,11,21). In an iterative process pre-clinical piloting of the prototype was performed by health-care-professionals, who worked with insulin charts every day. All relevant features of the new insulin chart were discussed and feedback from health-care-professionals was integrated in the development until a consensus was found regarding design and content. The new insulin chart only relates to paper-based subcutaneous insulin prescription and comprises the following main components: patient identification, BG control, insulin prescription, insulin administration, integrated correction scheme, guidance for treatment of hypoglycemia and hyperglycemia. Electronic prescription systems and intravenous (iv) insulin prescription were not in the scope of this evaluation. We separated the documentation of insulin prescription and insulin administration to allow a transparent verification of clinical authorisation and notification of administration. The aim of the present investigation was to evaluate structure, documentation, and treatment quality when using the newly implemented paper-based insulin chart compared to the old insulin charts in patients receiving insulin therapy in adult medical wards.

METHODS

Ethics statement

This open monocentric retrospective study was approved by the ethical board of the Medical University of Graz (EK-No. 29-153 ex 16/17) and performed according to principles of good clinical practice.

Reporting

The research and reporting methodology was performed according the Squire 2.0 checklist.

Study design and setting

The evaluation of insulin charts was performed in nine adult medical wards at the Department of Internal Medicine at the University Hospital of Graz, Austria. At the time of this study the general wards were all using paper-based fever and insulin charts in routine patient care.

Implementation of new insulin chart

The rollout of the newly developed insulin chart (Figure 1) was conducted stepwise at the nine adult medical wards on behalf of the hospital management board. In general, the organizational readiness for lean management projects and patient safety topics is assured in our hospital,(22). Therefore, the use of one standardized instead of several insulin charts was very well supported by hospital management.

Before the rollout took place in a ward, the head of the ward and the chief nurse were introduced to the new insulin chart by representatives of the developers. For the implementation, a training concept was developed by the interdisciplinary project team and training schedules were arranged together with each ward. The training regarding the use of the new insulin chart was done separately on each ward by the interdisciplinary team. Overall, 49% of physicians and nurses were trained together in group sessions during regular working hours by presenting them the main features of the new insulin chart using practical examples. Based on learning by doing, health-care-professionals themselves filled in the new insulin chart using practical examples. Further time for questions and ambiguities was provided. The training duration ranged from 45 to 60 minutes. The remaining health-care-professionals were trained individually or in small groups by an authorized representative on each ward, who was also responsible for implementation and available to answer any questions. Additional training material, such as a training manual, folder and poster, was generated to support the implementation process. In addition, a diabetes nurse specialist held courses regarding diabetes management with a focus on insulin therapy using the new insulin chart. All nine wards made use of this service.

Data collection

A before-after comparison regarding the quality of the old insulin charts (tested in phase 1) and the new insulin charts (tested in phase 2, 3-5 months after implementation of the new insulin chart) was conducted (Figure 2). Overall, there had been four different old insulin charts (see supplement) in use at the nine evaluated wards vs. one new insulin chart after implementation. Regarding the four different old insulin charts, one insulin chart was used by five wards, one by two wards, and the

remaining two by one ward each. Blank and filled-in insulin charts were evaluated. Data on structure, documentation, and treatment quality of the insulin charts were collected.

Evaluation of blank insulin charts

In a before-after comparison the subjective perception of health-care-professionals regarding structure quality of blank old insulin charts (n=4) vs. blank new insulin charts was evaluated. A paper-based questionnaire was developed by the interdisciplinary team including relevant quality indicators identified in a previous study,(23). To improve face validity and content, six nurses at the Division of Endocrinology and Diabetology completed the questionnaire individually in a pilot testing. The questionnaire was adapted based on their feedback regarding content, clarity, appropriateness, and design. Subsequently, physicians and nurses of all participating wards were asked to complete the adapted questionnaire by assessing the quality indicators. Each item was rated on a four-point Likert type response scale, with the four categories “I disagree”, “I partially disagree”, “I partially agree” and “I agree” coded as one to four.

Evaluation of filled-in insulin charts

Documentation and treatment quality were evaluated by reviewing filled-in old vs. new insulin charts based on methodological elements used by the National Diabetes Inpatient Audit,(24,25) and, if needed for clarification, by referring to clinical notes for further explanations.

Paper-based insulin charts from adult inpatients who were treated with insulin and who were admitted at one of the nine wards for at least one day were evaluated for a maximum of seven days. A before-after comparison was conducted, in which the evaluation of the filled-in old insulin charts was compared to the evaluation of the filled-

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in new insulin charts. For both evaluations a paper-based data entry form was developed including relevant quality indicators,(10,11,17,24,25). The primary objective was to compare the number of documentation errors for insulin administration (primary endpoint). The following four items were generated for the definition of documentation errors for insulin administration:

- name of insulin was not written complete/legible/comprehensible,
- unclear dose,
- no initialing when insulin was administered,
- time of administration was not clearly documented.

Any chart with at least one documentation error for insulin administration in the seven-day audit period was counted as one documentation error for insulin administration. Secondary endpoints included documentation errors for insulin prescription, documentation errors for insulin management, clinical patient characteristics, good diabetes day (calculated according to NaDIA,(24,25)), hypoglycemia management, patient identification as well as specific parameters of the new insulin chart. Documentation errors for insulin prescription (as defined by NaDIA,(24,25) but excluding the item “insulin not signed as given” and adapting the item “insulin given/prescribed at the wrong time” to “insulin was prescribed at the wrong time”) and documentation errors for insulin management (as defined by NaDIA,(24,25)) were counted as one error when any chart had at least one documentation error for insulin prescription or documentation error for insulin management in the seven-day audit period.

Data management

All patient-related data were pseudonymized with subject numbers following data protection guidelines. As data were collected by one scientist, a validation was

conducted to ensure data plausibility. Therefore, 20 old insulin charts and 20 new insulin charts were randomly chosen and evaluated regarding the primary endpoint “documentation errors for insulin administration” by two independent raters. A percent agreement of 90% (95% exact confidence interval: 76% - 97%) was observed. In order to check and ensure completeness, correctness and accuracy of data entry, an internal quality control was performed by two persons. All data relevant to the study are included in the article or uploaded as supplementary information.

Data sharing statement

No additional data available.

Patient and Public Involvement

Patients were not directly involved in the study.

Statistical analysis

For the primary endpoint comparison a sample size calculation was conducted. A Chi-square test was used to check for differences in the quality of old and new insulin charts. A total of 93 old insulin charts and 93 new insulin charts were needed to obtain a power of 80%. An absolute reduction of 20% in documentation errors for insulin administration, and an error rate of 70% for the old insulin charts, which was based on previous study results,(23), were assumed. Depending on availability, in a first step up to 15 filled-in old insulin charts and in a second step up to 15 filled-in new insulin charts were collected per ward. Data on structure quality were analyzed by using EvaSys, a digital survey tool,(26) and data on documentation and treatment quality were analyzed

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by using IBM SPSS Statistics 23,(27). Data were summarized with descriptive statistics. For numerical data – depending on distribution – mean, standard deviation, median, minimum and maximum were calculated. Categorical data are presented as relative and absolute frequency. Number of old insulin charts and new insulin charts with documentation errors for insulin administration and number of hypoglycemic episodes were compared using a Chi-square test or Fishers exact test. A two-sided significance level of 5% indicates statistical significance.

RESULTS

Structure quality of blank old vs. new insulin charts

In phase 1 a total of 84 health-care-professionals (51 physicians, 32 nurses, and one not specified) completed the questionnaire regarding structure quality of blank old insulin charts and in phase 2 a total of 153 health-care-professionals (28 physicians, 123 nurses, and two not specified) completed the same questionnaire for blank new insulin charts. The Likert type response scale indicated a shift towards agreeing answers (code 3 and 4) by health-care-professionals for improved structure quality of the new insulin chart for all nine items (Figure 3). Comparing the blank old vs. new insulin charts, health-care-professionals indicated that the documentation of prescription and administration of BG lowering medication was more clearly arranged (2.3 ± 1.0 vs. 3.0 ± 0.9), the correction scheme was better integrated (1.7 ± 1.0 vs. 3.1 ± 1.0), boxes for documentation of measured BG values were more clearly visualized (2.8 ± 1.0 vs. 3.4 ± 0.8), there was more space for insulin prescriptions (2.3 ± 1.0 vs. 3.3 ± 0.8) and for documentation of hypoglycemia treatment (2.0 ± 0.9 vs. 2.8 ± 0.9) on new insulin charts. Transparency of insulin prescription and insulin administration (2.6 ± 0.9 vs. 3.1 ± 0.8), as well as support of confirmation of both processes with initials was increased (2.5 ± 1.2 vs. 3.3 ± 0.8), and documentation of all relevant information regarding BG management was easier (2.1 ± 0.9 vs. 3.0 ± 0.9) on new insulin charts. As a single item, difficulties with nursing and medical responsibilities in completing the insulin chart were found to be almost constant (2.6 ± 1.0 vs. 2.7 ± 1.1).

Documentation and treatment quality of filled-in old vs. new insulin charts

A total of 108 filled-in old insulin charts and 100 filled-in new paper-based insulin charts of inpatients receiving insulin were evaluated (phase 1 vs. phase 2). Patient characteristics and treatment modalities of both groups are given in Table 1.

Table 1: Patient characteristics and treatment modalities of 208 inpatients treated with insulin

	Patients with old insulin charts (n=108)	Patients with new insulin charts (n=100)
Age, years (mean ± SD)	71±11	71±12
Female (n (%))	51 (47)	42 (42)
Admission type: emergency (n (%))	63 (58)	66 (66)
Reasons for admission (n (%))		
Medical non diabetes specific reasons (e.g. respiratory, cardiovascular)	89 (82)	81 (81)
Diabetes specific reasons for admission	19 (18)	19 (19)
Nights in the hospital (median (min-max))	8 (1-86)	7 (1-66)
Foot disease (previous ulcer, amputation, Charcot) (n (%))	17 (16)	18 (18)
Renal replacement therapy (n (%))	10 (9)	7 (7)
Diabetes type (n (%))		
Diabetes type 1	6 (6)	2 (2)
Diabetes type 2	81 (75)	87 (87)
Other diabetes type	6 (6)	9 (9)
Not documented	15 (14)	2 (2)
HbA1c (mmol/mol) (mean ± SD)	62±14	67±21
BG per patient		
mmol/L (mean ± SD)	10.3±2.8	10.3±2.4
mg/dL (mean ± SD)	186±50	186±44
BG measurement frequency per day (mean ± SD)	3±1	3±1
Treatment modalities (n (%))		
Premixed insulin	43 (40)	42 (42)
Basal insulin	28 (26)	26 (26)
Basal-bolus insulin	12 (11)	13 (13)
Prandial insulin	4 (4)	2 (2)
Correctional bolus insulin	57 (53)	51 (51)
DPP-4 inhibitor	31 (29)	25 (25)

Metformin	14 (13)	15 (15)
Sulfonylurea	4 (4)	6 (6)

SD standard deviation, BG blood glucose

The number of documentation errors for insulin administration (primary endpoint) was significantly higher for the old insulin charts compared to the new insulin charts (83 (77%) vs. 5 (5%)) ($p < 0.001$). Each parameter of documentation errors for insulin administration was distinctly higher on old insulin charts than on new insulin charts. Documentation errors for insulin prescription were more frequent on old insulin charts (108 (100%) vs. 42 (42%)), whereas documentation errors for insulin management rarely occurred in any group (11 (10%) vs. 8 (8%)). A detailed breakdown of listed parameters for documentation errors is shown in Table 2.

Table 2: Documentation errors for insulin administration, prescription and management with detailed listed parameters for seven days of inpatient stay

Documentation error type	Old insulin charts (n=108)	New insulin charts (n=100)
Documentation error for insulin administration (n (%))	83 (77)	5 (5)
Name of insulin was not written complete/legible/comprehensible	17 (16)	3 (3)
Unclear dose	25 (23)	1 (1)
No initialing when insulin was administered	55 (51)	3 (3)
Time of administration was not clearly documented	46 (43)	0
Documentation error for insulin prescription (n (%))	108 (100)	42 (42)
Insulin was not written up	27 (25,0)	0
Name of insulin was not written complete/legible/comprehensible	19 (18)	0
Unclear dose	32 (30)	1 (1)
Unit was written unclear	30 (28)	0
No initialing when insulin was prescribed	108 (100)	42 (42)
Insulin was prescribed at the wrong time	0	0

Documentation error for insulin management (n (%))	11 (10)	8 (8)
Insulin not increased when BG persistent >11.0 mmol/L (198 mg/dL) and a better control was appropriate for patient	10 (9)	7 (7)
Insulin was not reduced when unexplained BG <4.0 mmol/L (72 mg/dL)	1 (1)	1 (1)
Inappropriate omission of insulin after hypoglycemic episode	0	0

Both groups had a mean of 4±2 good diabetes days scaled to hospital stay days. Most frequently BG values >11.0 mmol/L (198 mg/dL) were responsible for not achieving good diabetes day criteria, whereas BG values <4.0 mmol/L (72 mg/dL) and inappropriate BG measurement frequency occurred less. Overall, 26 vs. 18 hypoglycemic episodes (BG <4.0 mmol/L (72 mg/dL), p=0.28), including seven vs. two severe hypoglycemic episodes (BG <3.0 mmol/L (54 mg/dL), p=0.17) were documented on old vs. new insulin charts, respectively. Treatment of severe hypoglycemia was documented in six out of seven cases on old charts vs. in both cases on new charts, respectively. Documented treatment modalities included four times infusion of iv dextrose on old charts, whereas in all remaining cases oral carbohydrates were given.

Moreover, 12% absolute improvement in documentation of patient identification (78% vs. 90%) was achieved by implementing the new insulin chart. Documentation of HbA1c value on insulin charts was rare in both groups (1% vs. 7%). Additionally, diabetes type was documented on 47%, pre-diabetes therapy on 17%, correction scheme on 28% and glomerular filtration rate on 6% of the filled-in new insulin charts.

DISCUSSION

The results of this study indicate that improved inpatient diabetes care was achieved by implementing a new insulin chart.

Erroneous documentation of insulin administration was significantly lower in new compared to old insulin charts. The design of the new chart was found suitable to improve all parameters of documentation errors for insulin administration. For example, errors regarding initialing of insulin administration by nurses were distinctly lower on new insulin charts compared to the previously used insulin charts. Our finding (3%) is similar to a rate of 4% not signed as given on audited drug charts at the NaDIA,(14). Thus, a comprehensible documentation of mandatory administration data for effective and safe glucose management was guaranteed by implementation of this new insulin chart. A Scottish study, which identified evidence-based subcutaneous insulin care clusters to develop a new insulin chart showed similar improvements in the correct documentation of insulin administration after implementing a new insulin chart,(10).

Regarding documentation errors for insulin prescription, we identified half as many errors on the new insulin charts. The detailed analysis of documentation errors for insulin prescription indicated that all but one parameter, the initialization of the prescription, were sufficiently improved on new insulin charts and comparable to recent data of the NaDIA, (14). None of the previously used insulin charts at our institution had provided a dedicated area for the initialing of therapy which is reflected in 100% documentation error rate in the baseline evaluation. Although the new design supports this legal prerequisite of documentation, a sufficient practice change among physicians has not yet been achieved. Similarly, the Scottish study did not report a significant change in insulin prescription by implementing a new insulin chart. The authors argued, that this may arise from longstanding practice on the wards which is not easily

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changed,(10). The same challenge may also apply to our hospital and hence further training should be offered to health-care-professionals to improve initialing of prescription. Additionally, pharmacists should be involved in the insulin prescription process when possible to review charts and to indicate any concerns to physicians and nurses to improve insulin error reduction strategies,(28–30).

Documentation errors for insulin management were rare in both groups and remained lower than the average error rate reported in a recent NaDIA report,(14). The number of good diabetes days, an indicator for established glycemic control without the occurrence of hypoglycemia, remained at a higher level compared to the benchmark of insulin treated patients in the NaDIA audit,(14). Of note, the number of hypoglycemic events, including severe episodes, was, although non-significantly, lower in new insulin charts and treatment of severe hypoglycemia was documented in all cases on new insulin charts. Thus, regarding overall treatment quality, the use of the new insulin chart seems to be clinically safe and beneficial to hospitalized patients that need insulin therapy to control glycemia.

Our evaluation of structural quality features showed a shift towards agreeing answers by nurses and physicians for improved structure quality of the new insulin chart for all nine items. Most of the structural improvements led to the desired positive changes in documentation quality. However, not all offered documentation possibilities were used to the same extent in clinical routine. As discussed above, there was a distinct difference in the authorization of prescription or confirmation of administration through initializing on the new insulin chart by physicians and nurses, respectively.

In this regard it is important to emphasize the potential limitation that the evaluation of filled-in insulin charts may not reflect the entire actual care at the wards. Similar to the

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3 Scottish study it can be assumed that there is a potential gap between the actual quality
4 of care and the documentation,(10). The implementation report of a national
5 subcutaneous insulin chart in the Australian project observed a decrease in the
6 proportion of doses initialed as having been administered and orders where the
7 prescriber had signed. The authors argued, that this does not necessarily mean that
8 the insulin doses were not given, as otherwise this would be seen in increasing BG
9 values,(17). Of note, an appropriately documented insulin dosing on an insulin chart
10 solely does not guarantee that all system and human factors have been adequately
11 respected when the insulin dosing has been performed,(28,31). The preparation and
12 administration process is complex, errors are multifaceted and may be related to e.g.
13 missed resuspension of NPH insulin, inappropriate mixtures of different insulins when
14 using a syringe, overdosing due to use of wrong insulin concentration, use of an
15 improper injection site, injection of a prandial insulin despite omission of nutritional
16 intake or delayed injection due to excessive workload of the nursing staff. Education
17 and resource availability have been claimed as important interventions by health-care-
18 professionals to administer insulin in a timely and safe way for every patient,(29). To
19 reduce the workload of the nursing staff a policy regarding self-administration and self-
20 management and it's standardized documentation on the new chart has been
21 developed.

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23 Furthermore, the observed beneficial effects in the current investigation may not be
24 solely attributed to the use of the new insulin chart as the implementation was
25 accompanied by extensive training measures to improve compliance of medical and
26 nursing staff. The limitation of a missing control group, which has undergone
27 comparable training measures with the previous insulin charts in order to assess the
28 impact of the new form on its own is acknowledged. Usefulness of a control group can
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be limited when evaluating a complex intervention in an open system such as a ward area in a hospital, where it is challenging to control for multiple confounders.

To ensure that our new insulin chart is empirically and theoretically well founded for our institutional setting we integrated results of previous audit data, followed international and local standards when developing the new insulin chart and performed pre-clinical piloting of the prototype,(23). However, we acknowledge that using the concise methodology of the Medical Research Council framework,(32) could have further improved several phases of our complex intervention e.g. the phase of assessing feasibility and piloting by performing clinical testing of the new chart or the phase of evaluation by using focus groups and in-depth interviews to explore the implementation of the intervention, contextual factors and potential mechanisms of action. Additionally, the implementation of one standardized insulin chart per se in our institution may have contributed to a reduction of documentation errors, as junior doctors rotating between wards have to deal with one insulin chart instead of four. It can be expected that similar to observational charts, variations in prescription chart design are related to different prescription error frequency and through chart standardization prescription error rates can be reduced in insulin charts as well,(33).

Moreover, the implementation and subsequent effects of the new insulin chart to other, e.g. surgical disciplines may be different. However, insulin prescription and administration should not differ between conservative and surgical disciplines and accompanying training measures should allow a safe and effective implementation. When implementing any type of insulin chart, the integration within the standard prescription chart process needs to be secured. In particular, the process of documentation and administration of iv insulin necessitate cautiousness,(34). The use

of electronic prescription systems with integrated insulin charts may help to reduce interface errors between different prescription systems. International guidelines recommend electronic diabetes documentation as necessary for optimizing diabetes inpatient care,(4,15). This is also confirmed by NaDIA, where hospitals that were prescribing diabetes medication electronically were less likely to have prescription errors,(14). Electronic systems with clinical decision support have the potential to reduce errors and to increase treatment quality,(35).

A strength of the study is that improvements in documentation quality were connected with beneficial clinical outcome. Moreover, the project was performed in daily clinical routine work as an essential quality assurance project. The hours spent for implementation were covered out of general employment and, thus, feasibility of a rollout in comparable hospital institutions can be assumed.

Nevertheless, a lesson learnt from the present work was that training of the nursing and medical staff is a real challenge in a typical hospital shift rotation system.

Another critical aspect when designing a new insulin chart is an early review of the necessity of all fields on the new insulin chart. It can be assumed that, similar to the Scottish study, the more fields that need to be filled-in the less likely any of them will be charted,(10). In our case the item glomerular filtration rate will be removed from the chart as the degree of filling-in was low and importance for the actual treatment process in daily routine care has been scrutinized.

Finally, we agree with the conclusion of the Australian Quality Initiative that further optimization of specific endpoints, such as initialing of physician's prescription or documentation of hypoglycemia treatment should be addressed through effective change management processes and more explicit training and education for health-

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care-professionals, rather than further modification of chart design,(17). The insulin chart, as a standardized documentation of diabetes management, is only one component for good diabetes inpatient care. It is also important to address the knowledge gaps regarding insulin therapy and insulin use among health-care-professionals,(4,5,9,28,29).

CONCLUSION

Inpatient diabetes care was optimized through implementation of the new insulin chart. Structural changes on the new insulin chart along with accompanying training measures throughout the implementation process, not only led to better quality of insulin chart structure, but also improved documentation quality of filled-in new insulin charts and supported safe management of glycemic control. The present work supports a rollout of the new insulin chart at further departments, and sustainability of the beneficial effects in the long term has to be demonstrated in further investigations.

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Author contributions

JK, GS, KML, BS, TRP and JP designed and performed the study, interpreted data and contributed to discussions, RR performed statistical analysis, JP, GB, CT and TRP supervised the project and JP is the guarantor of this work.

Prior presentation of data

Prior presentations of the data include the 6th Grazer Risk Day 2018, Austria, the Annual Meeting of the ÖDG 2017 and 2018 Salzburg, Austria and as abstract (published only) at Diabetes 2019 from the American Diabetes Association.

Reference List

1. Umpierrez GE, Isaacs SD, Bazargan N, et al. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. *J Clin Endocrinol Metab* 2002;87:978–82.
2. Draznin B, Gilden J, Golden SH, et al. Pathways to quality inpatient management of hyperglycemia and diabetes: A call to action. *Diabetes Care* 2013;36:1807–14.
3. Fritsche A. Diabetes Mellitus in der Klinik - Mehr Strukturen schaffen - Die Anforderungen an die stationäre Behandlung von Diabetespatienten wird unterschätzt. *Dtsch Arztebl* 2017;114:16–9.
4. ADA. 15. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes-2020. *Diabetes Care* 2020;43:193–202. Available from: https://care.diabetesjournals.org/content/43/Supplement_1/S193. Accessed September 01, 2020.
5. JBDS-IP. A good inpatient diabetes service. 2019. Available from: https://abcd.care/sites/abcd.care/files/site_uploads/JBDS_A_Good_Inpatient_Service_Updated_060720.pdf. Accessed September 01, 2020.
6. ISMP. ISMP List of High-Alert Medications in Acute Care Settings. *Inst Safe Medicat Pract* 2018; Available from: <https://www.ismp.org/sites/default/files/attachments/2018-08/highAlert2018-Acute-Final.pdf>. Accessed September 01, 2020.
7. Cox AR, Ferner RE. Prescribing errors in diabetes. *Br J Diabetes Vasc Dis* 2009;9:84–8. Available from:

<http://dvd.sagepub.com/cgi/doi/10.1177/1474651409103902>. Accessed September 01, 2020.

8. Kolanczyk DM, Dobersztyn RC. Challenges with insulin in the inpatient setting. *Diabetes Spectr* 2016;29:146–52.
9. Lamont T, Cousins D, Hillson R, et al. Safer administration of insulin: summary of a safety report from the National Patient Safety Agency. *BMJ* 2010;341:882–7.
10. Rushmer R, Voigt D. Measure it, improve it: the safer patients initiative and quality improvement in subcutaneous insulin therapy for hospital in-patients. *Diabet Med* 2008;25:960–7.
11. Christofidis MJ, Horswill MS, Hill A, et al. Task analysis and heuristic analysis of insulin charts: final report for the Australian Commission on Safety and Quality in Health Care. Sydney; 2012. Available from: <https://safetyandquality.gov.au/wp-content/uploads/2012/06/56679-Insulin-charts-heuristic-analysis-2-Feb-2011-Final-Report.pdf>. Accessed September 01, 2020.
12. Cobaugh DJ, Maynard G, Cooper L, et al. Enhancing insulin-use safety in hospitals: Practical recommendations from an ASHP Foundation expert consensus panel. *Am J Heal Pharm* 2013;70:1404–13.
13. Cousins D, Rosario C, Scarpello J. Insulin, hospitals and harm: a review of patient safety incidents reported to the National Patient Safety Agency. *Clin Med (Northfield Il)* 2011;11:28–30. Available from: <http://www.clinmed.rcpjournals.org/content/11/1/28.full.pdf>. Accessed September 01, 2020.

14. NDIA. National Diabetes Inpatient Audit 2017. Full report. England and Wales 2018. Available from: <http://www.hscic.gov.uk/catalogue/PUB06279/nati-diab-inp-audi-11-nat-rep.pdf>. Accessed September 01, 2020.
15. Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of hyperglycemia in hospitalized patients in non-critical care setting: An endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 2012;97:16–38.
16. Dashora U, Sampson M, Castro E, et al. Rowan Hillson Insulin Safety Award 'best in class' insulin prescription chart competition. *Br J Diabetes Vasc Dis* 2015;15:135–8. Available from: <http://bjdvd.co.uk/index.php/bjdvd/article/view/87/187>. Accessed September 01, 2020.
17. Australian Commission on Safety and Quality in Health Care. Development and evaluation of a new chart for subcutaneous insulin administration in acute care settings. 2017.
18. Bain A, Hasan SS, Babar ZUD. Interventions to improve insulin prescribing practice for people with diabetes in hospital: a systematic review. *Diabet Med* 2019;36:948–60.
19. Hamilton P, Nation M, Penfold S, et al. Reducing insulin prescription errors in hospital: more stick than carrot? *Pract Diabetes* 2013;30:370–3.
20. McIver FB, Mitchell CA, Finn CP, et al. Standardising practices through form design and education improves insulin management. *Aust Health Rev* 2009;33:434–41. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/20128759>. Accessed September 01, 2020.

21. Horswill MS, Hill A, Christofidis M, et al. Development and initial evaluation of a new subcutaneous insulin form: final report. Australia 2015. Available from: <http://www.safetyandquality.gov.au/wp-content/uploads/2015/08/Development-and-initial-evaluation-of-a-new-subcutaneous-insulin-form-Final-Report.pdf>. Accessed September 01, 2020.
22. Sendlhofer G, Brunner G, Tax C, et al. Systematic implementation of clinical risk management in a large university hospital: the impact of risk managers. *Wien Klin Wochenschr* 2015;127:1–11.
23. Kopanz J, Lichtenegger KM, Sendlhofer G, et al. Limited Documentation and Treatment Quality of Glycemic Inpatient Care in Relation to Structural Deficits of Heterogeneous Insulin Charts at a Large University Hospital. *J Patient Saf* 2018.
24. NDIA. National Diabetes Inpatient Audit 2013. National Summary. England and Wales 2013. Available from: <http://content.digital.nhs.uk/catalogue/PUB13662/nati-diab-inp-audi-13-nat-rep.pdf>. Accessed September 01, 2020.
25. NDIA. National Diabetes Inpatient Audit 2015. National Report. England and Wales 2016. Available from: <http://www.hscic.gov.uk/catalogue/PUB06279/nati-diab-inp-audi-11-nat-rep.pdf>. Accessed September 01, 2020.
26. Electric Paper. EvaSys 6.0 - Electric Paper Evaluationssysteme GmbH. Lüneburg Deutschland 2013. Available from: <https://www.evasys.de>. Accessed September 01, 2020.
27. IBM Analytics. IBM SPSS-Statistics Version 23. 2018. Available from: <https://www.ibm.com/analytics/at/de/technology/spss/>. Accessed September

- 01, 2020.
28. Lee MKS, Liu Z, Quek TPL, et al. Insulin-related knowledge among health care professionals at a tertiary hospital. *Diabetes Spectr* 2013;26:187–93.
29. Bain A, Kavanagh S, McCarthy S, et al. Assessment of Insulin-related Knowledge among Healthcare Professionals in a Large Teaching Hospital in the United Kingdom. *Pharmacy* 2019;7:16.
30. Bain A, Hasan SS, Kavanagh S, et al. Strategies to reduce insulin prescribing errors in UK hospitals: results from a national survey. *Diabet Med* 2020;37:1176–84.
31. Robb A, Reid B, Laird EA. Insulin knowledge and practice: a survey of district nurses in Northern Ireland. *Br J Community Nurs* 2017;22:138–45.
32. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: Following considerable development in the field since 2006, MRC and NIHR have jointly commissioned an update of this guidance to be published in 2019. 2019. Available from: <https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/>. Accessed September 01, 2020.
33. Horswill MS, Preece MH. W, Hill A, et al. Human factors research regarding observation charts: Research project overview. Sydney Australia 2010. Available from: <https://www.safetyandquality.gov.au/wp-content/uploads/2012/01/35986-HumanFactors.pdf>. Accessed September 01, 2020.
34. JBDS-IP. The use of variable rate intravenous insulin infusion (VRIII) in medical

inpatients. 2014. Available from:

https://abcd.care/sites/abcd.care/files/resources/JBDS_IP_VR111.pdf. Accessed September 01, 2020.

35. Neubauer KM, Mader JK, Höll B, et al. Standardized Glycemic Management with a Computerized Workflow and Decision Support System for Hospitalized Patients with Type 2 Diabetes on Different Wards. *Diabetes Technol Ther* 2015 Oct;17:685–92. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26355756>. Accessed September 01, 2020.

Figure Legend

Figure 1: The newly designed standardized insulin chart

Figure 2: Timeline of study phases to identify structure, documentation and treatment quality

Figure 3: Structure quality of insulin charts assessed by physicians and nurses on a four-point Likert type response scale (“I disagree”, “I partially disagree”, “I partially agree” and “I agree” coded as one-four)

Supplement

Supplement: Different insulin charts in use at the nine wards before implementation of the new insulin chart

a) front

patient identification label

medication chart marked ☐
 diabetes: type1 ☐ type2 ☐ other ☐

Insulin Chart No.: _____

A1c: _____ mmol
 GFR: _____ ml/min

Year: 20	prevalence		prevalence		prevalence		prevalence		prevalence	
	pre-meal	fasting BG	pre-meal	fasting BG	pre-meal	fasting BG	pre-meal	fasting BG	pre-meal	fasting BG
2019	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other
2020	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other
2021	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other
2022	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other
2023	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other
2024	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other
2025	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other
2026	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other
2027	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other
2028	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other
2029	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other
2030	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other	22-90h	Other

b) back

Recommended procedure for hypoglycaemia (<70 mg/dl)

If the patient is **conscious** and **p.o. administration possible**:

- Administration of 2 Carbohydrate Units (CU) of Fast-Acting Carbohydrates and BG-control after 15 min.
- Repeat the procedure if BG persists <70 mg/dl

If the patient is **conscious** and **no p.o. administration possible**:

- Administration of 100 ml of 20% glucose IV access
- Recheck BG after 15 min.
- If BG persists <70 mg/dl, re-administration of 100 ml of 20% glucose IV

If the patient is **unconscious/drowsy**:

- Ensure vital functions
- Immediate notification of the responsible medical personnel
- Administration of 100 ml of 20% glucose IV
- Recheck BG after 5 min., if still conscious/drowsy, or after 15 min., if conscious
- If BG persists <70 mg/dl, ensuring an IV access and re-administration of 100 ml of 20% glucose IV
- Continuous monitoring of patient until consciousness regained

Further procedure:

- Administration of 1U long-acting Carbohydrates, if BG >70 mg/dl increased and patient became conscious
- Evaluation of the cause
- Documentation of hypoglycaemia-treatment
- Medical planning of further BG-monitoring
- Recheck BG after 1 hour
- In case of a causative long-acting blood glucose lowering medication (e.g. sulfonylureas, basal insulin) ensure a longer control period

Fast-Acting Carbohydrates (1 CU)

- approx. 125 ml fruit juice
- 12g of dextrose powder (2 tsp = approx. 1 CU)
- 2 dextrose slices

Slow-Acting Carbohydrates (1 CU)

- 1 slice of whole grain bread (30 g)
- ½ banana

Recommended procedure for hyperglycaemia

Possible causes

- Concomitant medication such as steroids, parenteral nutrition
- Insulin and/or diabetes medication omission/inadequacy
- Consider to check ketones
- BG-control already insufficient before admission, current A1c available?
- Hyperglycaemia as a result of hyperglycaemia

Possible procedure

1. Dose increased of oral medication?
2. Initiation of insulin therapy necessary?
3. Increase of existing overall insulin dose by 10-20%?

Possible procedure by correction scheme

1. Selection of dose suggestions based on total insulin dose or body weight (see table below)
2. Dose suggestions for correction are to be seen in dependence of preprandial BG-value
3. Be careful with corrections in postprandial condition or after glucose infusion/administration
4. Observe the minimum timespan to the last insulin injection
5. If the need for correction insulin continues, evaluate conversion to basal insulin

CORRECTION SCHEME for short-acting insulin

pre-existing insulin therapy (based on total daily insulin dose)

OR	< 25 IU	25-49 IU	50-80 IU	> 80 IU
No pre-existing insulin therapy (based on body weight)	< 50 kg	50-75 kg	76-100 kg	> 100 kg

preprandial BG-values (mg/dl) with suggested insulin doses	> 400	4 IU	6 IU	8 IU	12 IU
301-400	3 IU	4 IU	5 IU	8 IU	
201-300	2 IU	2 IU	3 IU	4 IU	

Discharge management

1. Clarify and cross-check BG medications before discharge
2. BG-therapy included in discharge letter
3. Devices for insulin therapy (insulin pen, glucometer)
4. Abilities to handle devices?
5. Ensure further follow up are scheduled by primary care physicians

Discharge management

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5. Ensure further follow up are scheduled by primary care physicians

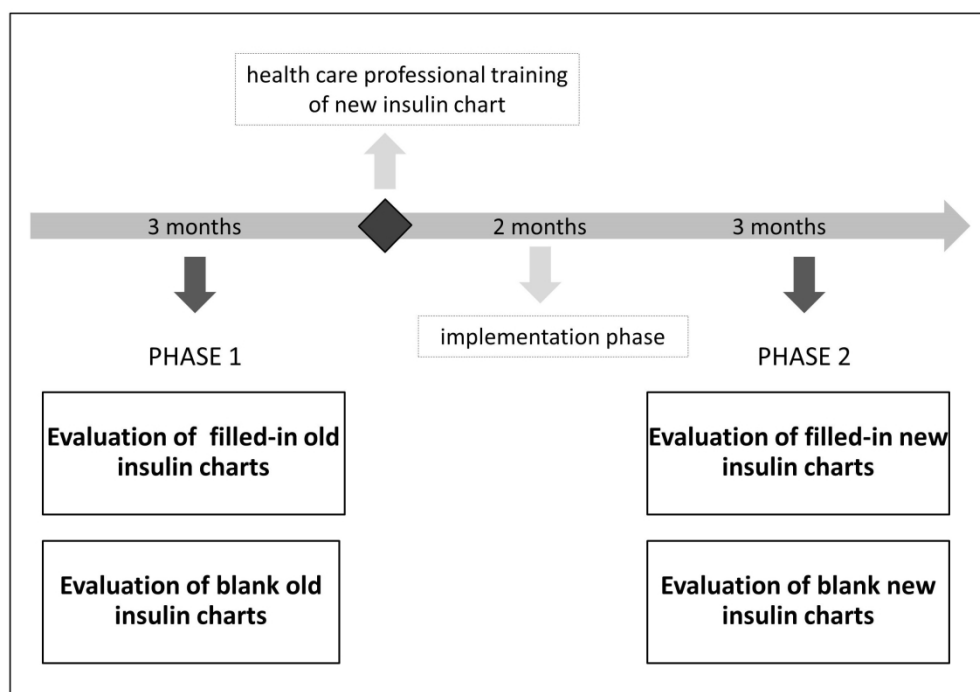


Figure 2: Timeline of study phases to identify structure, documentation and treatment quality

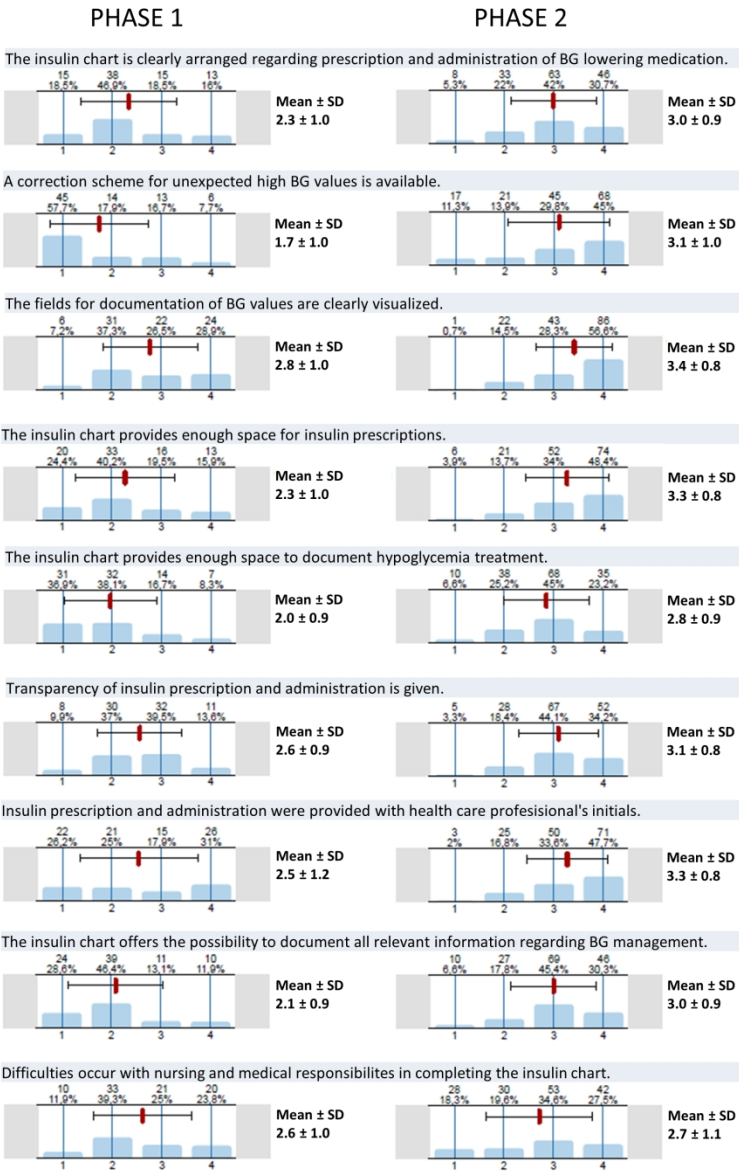


Figure 3: Structure quality of insulin charts assessed by physicians and nurses on a four-point Likert type response scale ("I disagree", "I agree to some extent", "I partially agree" and "I agree" coded as one-four)

190x274mm (284 x 284 DPI)

Diabetiker – Kurve																
Blatt Nr.:		Jahr:		Name:												
Blut-Glukose (mg/dl)	Zeit:	Datum:	Zeit:	Datum:	Zeit:	Datum:	Zeit:	Datum:	Zeit:	Datum:	Zeit:	Datum:	Zeit:	Datum:	Zeit:	Datum:
Insulin																
	Präparat:															
	Injektionszeitpunkt: Einheiten:															

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Barcode Etikett	Blatt Nr.:	Zi.Nr.:	Diät: 12BE 14BE	Medikation: ORAL INSULIN
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Anmerkung:				

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	F	M	A	F	M	A	F	M	A	F	M	A	F	M	A	F	M	A
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		X	X		X	X		X	X		X	X		X	X		X	X
	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
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SQUIRE 2.0 Checklist

Text Section and Item Name	Section or Item Description	Reported on page #
Title and Abstract		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	"improve quality and safety of diabetes care", title page 1
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	Abstract, page 2 (structure: objective, methods, results, conclusions)
Introduction		
3. Problem description	Nature and significance of the local problem	Introduction, page 3
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	Introduction, page 3-4
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	Introduction, page 3-4
6. Specific aims	Purpose of the project and of this report	Introduction, page 4
Methods		
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	Implementation of new insulin chart, methods, page 5
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	a. Methods, page 5-7, Figure 1 – the new insulin chart b. Interdisciplinary project team, methods page 5
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	a. and b. Methods, page 6-7
10. Measures	a. Measures chosen for studying processes and outcomes of the	a. Methods, page 6-7 b. Implementation of new

	intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	insulin chart, page 5 (no cost measures) c. Data management, methods, page 7
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	a. Statistical analysis, methods, page 8 b. Methods, page 6-7
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	Ethical approval, methods, page 5
Results	<i>What did you find?</i>	
13. Results	a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data	a. Figure 2 – timeline of study phases, no intervention modifications were needed b. Results, page 9-12 c. Results, page 9-10 d. Results, page 9-12 e. Results, page 9-12 (no cost evaluation) f. No missing data
Discussion	<i>What does it mean?</i>	
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project	a., b. Discussion, page 13-15
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs	a., b., c., d Discussion, page 13-16 e. Discussion and Conclusion, page 16

16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations	a., b, c Discussion, page 15
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps	a., b, c., d., e. Conclusion, page 16 b. Not given
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	Funding, page 17

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Evaluation of an implemented new insulin chart to improve quality and safety of diabetes care in a large University Hospital: a follow-up study

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Number of tables: 2

Number of figures: 3

Strengths and limitations of this study:

- A strength of the study is that improvements in documentation quality were connected with beneficial clinical outcome.
- The project was performed during regular working hours as an essential quality assurance project.
- A lesson learnt from the present work was that training of the nursing and medical staff is a real challenge in a typical hospital setting.
- When designing a new insulin chart an early review of the necessity of all fields on the new insulin chart should be done.
- It can be assumed that the more fields that need to be filled-in the less likely any of them will be charted.

Objectives: To evaluate structure, documentation, treatment quality of a new implemented standardized insulin chart in adult medical inpatient wards at a University Hospital.

Design: A before-after study (3-5 months after implementation) was used to compare the quality of old vs. new insulin charts

Setting: University Hospital Graz, Austria

Participants: Health-care-professionals (n=237) were questioned regarding structure quality of blank insulin charts.

Interventions: A new standardized insulin chart was implemented and health-care-professionals were trained regarding features of this chart. Data from insulinized inpatients were evaluated regarding documentation and treatment quality of filled-in insulin charts (n=108 old insulin charts vs. n=100 new insulin charts).

Main Outcomes and Measures: The primary endpoint was documentation error for insulin administration.

Results: Health-care-professionals reported an improved structure quality of the new insulin chart with a Likert-type-response-scale increase in all nine items. Documentation errors for insulin administration (primary endpoint) occurred more often on old than new insulin charts (77% vs. 5%, $p < 0.001$). Documentation errors for insulin prescription were more frequent on old insulin charts (100% vs. 42%) whereas documentation errors for insulin management rarely occurred in any group (10% vs. 8%). Patients of both chart evaluation groups (age: 71 ± 11 vs. 71 ± 12 years, 47% vs. 42% female, 75% vs. 87% type-2-diabetes for old vs. new charts, respectively) had a mean of 4 ± 2 good diabetes days. Overall, 26 vs. 18 hypoglycemic episodes (BG < 4.0

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mmol/L (72 mg/dL), $p=0.28$), including seven vs. two severe hypoglycemic episodes (BG <3.0mmol/L (54 mg/dL), $p=0.17$) were documented on old vs. new insulin charts.

Conclusions: The implementation of a structured documentation form together with training measures for health-care-professionals led to less documentation errors and safe management of glycemic control in hospitalized patients in a short time follow-up. A rollout at further medical wards is recommended, and sustainability in the long term has to be demonstrated.

Trial registration: The study has not been registered in any clinical trial registry.

Strengths and limitations of this study:

- A strength of the study is that improvements in documentation quality were connected with beneficial clinical outcome.
- The project was performed during regular working hours as an essential quality assurance project.
- A lesson learnt from the present work was that training of the nursing and medical staff is a real challenge in a typical hospital setting.
- When designing a new insulin chart an early review of the necessity of all fields on the new insulin chart should be done.
- It can be assumed that the more fields that need to be filled-in the less likely any of them will be charted.

INTRODUCTION

Up to 22-30% of hospitalized patients have diabetes and occurring hyperglycemia and hypoglycemia can lead to adverse outcomes and even to death (1–4).

To reduce high blood glucose (BG) values, insulin is often considered to be the first choice in the hospital setting (4,5). Despite good treatment effects, insulin is also listed as a high-alert medication by the Institute for Safe Medication Practices (6) because it can cause serious harm to patients when used incorrectly (4,5,7,8).

Errors in insulin prescription and administration are common (4,5,9) and include for example missed or wrongly administered insulin doses, incorrect prescription of insulin name, dose or type, abbreviations in insulin prescription, or illegible handwriting (4,5,7,9–13). The UK National Patient Safety Agency reported 3881 incidents with incorrect insulin doses from 2003 to 2009. Most commonly, abbreviations in insulin prescription and errors in using insulin syringes were identified that led to harm and in some cases even to death (9). In England and Wales, the National Diabetes Inpatient Audit (NaDIA) determined that in 31% of inpatients a medication error and in 18% an insulin error occurred during hospital stay (14).

In many hospital settings the main documentation tool for diabetes therapy is still a paper-based insulin chart. On this documentation sheet, insulin prescription, insulin administration, BG values, treatment for hypoglycemia and all other relevant information should be documented (4,5,11). The insulin chart is used by different health-care-professionals for documentation, interpretation and communication. Differences in the design of insulin charts could impact the quality of inpatient diabetes care (11). Therefore, international guidelines recommend a standardized documentation of diabetes management (4,5,15) and efforts are undertaken to identify safe and effective insulin charts (16). Previous studies reported improvements in

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inpatient diabetes care after implementation of a newly developed insulin chart (10,17–20).

At the University Hospital Graz, a new standardized paper-based insulin chart (Figure 1) was developed by an interdisciplinary project team including nurses, physicians, researchers and a quality manager due to previously identified quality deficits (e.g. missing transparency between insulin prescription and administration process, unclear patient identification, missing guidance for treatment of hypoglycemia) as well as international and local standards (4,5,10,11,21). In an iterative process pre-clinical piloting of the prototype was performed by health-care-professionals, who worked with insulin charts every day. All relevant features of the new insulin chart were discussed and feedback from health-care-professionals was integrated in the development until a consensus was found regarding design and content. The new insulin chart only relates to paper-based subcutaneous insulin prescription and comprises the following main components: patient identification, BG control, insulin prescription, insulin administration, integrated correction scheme, guidance for treatment of hypoglycemia and hyperglycemia. Electronic prescription systems and intravenous (iv) insulin prescription were not in the scope of this evaluation. We separated the documentation of insulin prescription and insulin administration to allow a transparent verification of clinical authorisation and notification of administration. The aim of the present investigation was to evaluate structure, documentation, and treatment quality when using the newly implemented paper-based insulin chart compared to the old insulin charts in patients receiving insulin therapy in adult medical wards.

METHODS

Ethics statement

This open monocentric retrospective study was approved by the ethical board of the Medical University of Graz (EK-No. 29-153 ex 16/17) and performed according to principles of good clinical practice.

Reporting

The research and reporting methodology was performed according the Squire 2.0 checklist.

Study design and setting

The evaluation of insulin charts was performed in nine adult medical wards at the Department of Internal Medicine at the University Hospital of Graz, Austria. At the time of this study the general wards were all using paper-based fever and insulin charts in routine patient care.

Implementation of new insulin chart

The rollout of the newly developed insulin chart (Figure 1) was conducted stepwise at the nine adult medical wards on behalf of the hospital management board. In general, the organizational readiness for lean management projects and patient safety topics is assured in our hospital (22). Therefore, the use of one standardized instead of several insulin charts was very well supported by hospital management.

Before the rollout took place in a ward, the head of the ward and the chief nurse were introduced to the new insulin chart by representatives of the developers. For the implementation, a training concept was developed by the interdisciplinary project team and training schedules were arranged together with each ward. The training regarding the use of the new insulin chart was done separately on each ward by the interdisciplinary team. Overall, 49% of physicians and nurses were trained together in group sessions during regular working hours by presenting them the main features of the new insulin chart using practical examples. Based on learning by doing, health-care-professionals themselves filled in the new insulin chart using practical examples. Further time for questions and ambiguities was provided. The training duration ranged from 45 to 60 minutes. The remaining health-care-professionals were trained individually or in small groups by an authorized representative on each ward, who was also responsible for implementation and available to answer any questions. Additional training material, such as a training manual, folder and poster, was generated to support the implementation process. In addition, a diabetes nurse specialist held courses regarding diabetes management with a focus on insulin therapy using the new insulin chart. All nine wards made use of this service.

Data collection

A before-after comparison regarding the quality of the old insulin charts (tested in phase 1) and the new insulin charts (tested in phase 2, 3-5 months after implementation of the new insulin chart) was conducted (Figure 2). Overall, there had been four different old insulin charts (see Supplement) in use at the nine evaluated wards vs. one new insulin chart after implementation. Regarding the four different old insulin charts, one insulin chart was used by five wards, one by two wards, and the

remaining two by one ward each. Blank and filled-in insulin charts were evaluated. Data on structure, documentation, and treatment quality of the insulin charts were collected.

Evaluation of blank insulin charts

In a before-after comparison the subjective perception of health-care-professionals regarding structure quality of blank old insulin charts (n=4) vs. blank new insulin charts was evaluated. A paper-based questionnaire was developed by the interdisciplinary team including relevant quality indicators identified in a previous study (23). To improve face validity and content, six nurses at the Division of Endocrinology and Diabetology completed the questionnaire individually in a pilot testing. The questionnaire was adapted based on their feedback regarding content, clarity, appropriateness, and design. Subsequently, physicians and nurses of all participating wards were asked to complete the adapted questionnaire by assessing the quality indicators. Each item was rated on a four-point Likert type response scale, with the four categories “I disagree”, “I partially disagree”, “I partially agree” and “I agree” coded as one to four.

Evaluation of filled-in insulin charts

Documentation and treatment quality were evaluated by reviewing filled-in old vs. new insulin charts based on methodological elements used by the National Diabetes Inpatient Audit (24,25) and, if needed for clarification, by referring to clinical notes for further explanations.

Paper-based insulin charts from adult inpatients who were treated with insulin and who were admitted at one of the nine wards for at least one day were evaluated for a maximum of seven days. A before-after comparison was conducted, in which the evaluation of the filled-in old insulin charts was compared to the evaluation of the filled-

in new insulin charts. For both evaluations a paper-based data entry form was developed including relevant quality indicators (10,11,17,24,25). The primary objective was to compare the number of documentation errors for insulin administration (primary endpoint). The following four items were generated for the definition of documentation errors for insulin administration:

- name of insulin was not written complete/legible/comprehensible,
- unclear dose,
- no initialing when insulin was administered,
- time of administration was not clearly documented.

Any chart with at least one documentation error for insulin administration in the seven-day audit period was counted as one documentation error for insulin administration. Secondary endpoints included documentation errors for insulin prescription, documentation errors for insulin management, clinical patient characteristics, good diabetes day (calculated according to NaDIA (24,25)), hypoglycemia management, patient identification as well as specific parameters of the new insulin chart. Documentation errors for insulin prescription (as defined by NaDIA (24,25) but excluding the item “insulin not signed as given” and adapting the item “insulin given/prescribed at the wrong time” to “insulin was prescribed at the wrong time”) and documentation errors for insulin management (as defined by NaDIA (24,25)) were counted as one error when any chart had at least one documentation error for insulin prescription or documentation error for insulin management in the seven-day audit period.

Data management

All patient-related data were pseudonymized with subject numbers following data protection guidelines. As data were collected by one scientist, a validation was

conducted to ensure data plausibility. Therefore, 20 old insulin charts and 20 new insulin charts were randomly chosen and evaluated regarding the primary endpoint “documentation errors for insulin administration” by two independent raters. A percent agreement of 90% (95% exact confidence interval: 76% - 97%) was observed. In order to check and ensure completeness, correctness and accuracy of data entry, an internal quality control was performed by two persons. All data relevant to the study are included in the article or uploaded as supplementary information.

Data sharing statement

No additional data available.

Patient and Public Involvement

Patients were not directly involved in the study.

Statistical analysis

For the primary endpoint comparison a sample size calculation was conducted. A Chi-square test was used to check for differences in the quality of old and new insulin charts. A total of 93 old insulin charts and 93 new insulin charts were needed to obtain a power of 80%. An absolute reduction of 20% in documentation errors for insulin administration, and an error rate of 70% for the old insulin charts, which was based on previous study results (23), were assumed. Depending on availability, in a first step up to 15 filled-in old insulin charts and in a second step up to 15 filled-in new insulin charts were collected per ward. Data on structure quality were analyzed by using EvaSys, a digital survey tool (26) and data on documentation and treatment quality were analyzed

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by using IBM SPSS Statistics 23 (27). Data were summarized with descriptive statistics. For numerical data – depending on distribution – mean, standard deviation, median, minimum and maximum were calculated. Categorical data are presented as relative and absolute frequency. Number of old insulin charts and new insulin charts with documentation errors for insulin administration and number of hypoglycemic episodes were compared using a Chi-square test or Fishers exact test. A two-sided significance level of 5% indicates statistical significance.

RESULTS

Structure quality of blank old vs. new insulin charts

In phase 1 a total of 84 health-care-professionals (51 physicians, 32 nurses, and one not specified) completed the questionnaire regarding structure quality of blank old insulin charts and in phase 2 a total of 153 health-care-professionals (28 physicians, 123 nurses, and two not specified) completed the same questionnaire for blank new insulin charts. The Likert type response scale indicated a shift towards agreeing answers (code 3 and 4) by health-care-professionals for improved structure quality of the new insulin chart for all nine items (Figure 3). Comparing the blank old vs. new insulin charts, health-care-professionals indicated that the documentation of prescription and administration of BG lowering medication was more clearly arranged (2.3 ± 1.0 vs. 3.0 ± 0.9), the correction scheme was better integrated (1.7 ± 1.0 vs. 3.1 ± 1.0), boxes for documentation of measured BG values were more clearly visualized (2.8 ± 1.0 vs. 3.4 ± 0.8), there was more space for insulin prescriptions (2.3 ± 1.0 vs. 3.3 ± 0.8) and for documentation of hypoglycemia treatment (2.0 ± 0.9 vs. 2.8 ± 0.9) on new insulin charts. Transparency of insulin prescription and insulin administration (2.6 ± 0.9 vs. 3.1 ± 0.8), as well as support of confirmation of both processes with initials was increased (2.5 ± 1.2 vs. 3.3 ± 0.8), and documentation of all relevant information regarding BG management was easier (2.1 ± 0.9 vs. 3.0 ± 0.9) on new insulin charts. As a single item, difficulties with nursing and medical responsibilities in completing the insulin chart were found to be almost constant (2.6 ± 1.0 vs. 2.7 ± 1.1).

Documentation and treatment quality of filled-in old vs. new insulin charts

A total of 108 filled-in old insulin charts and 100 filled-in new paper-based insulin charts of inpatients receiving insulin were evaluated (phase 1 vs. phase 2). Patient characteristics and treatment modalities of both groups are given in Table 1.

Table 1: Patient characteristics and treatment modalities of 208 inpatients treated with insulin

	Patients with old insulin charts (n=108)	Patients with new insulin charts (n=100)
Age, years (mean ± SD)	71±11	71±12
Female (n (%))	51 (47)	42 (42)
Admission type: emergency (n (%))	63 (58)	66 (66)
Reasons for admission (n (%))		
Medical non diabetes specific reasons (e.g. respiratory, cardiovascular)	89 (82)	81 (81)
Diabetes specific reasons for admission	19 (18)	19 (19)
Nights in the hospital (median (min-max))	8 (1-86)	7 (1-66)
Foot disease (previous ulcer, amputation, Charcot) (n (%))	17 (16)	18 (18)
Renal replacement therapy (n (%))	10 (9)	7 (7)
Diabetes type (n (%))		
Diabetes type 1	6 (6)	2 (2)
Diabetes type 2	81 (75)	87 (87)
Other diabetes type	6 (6)	9 (9)
Not documented	15 (14)	2 (2)
HbA1c (mmol/mol) (mean ± SD)	62±14	67±21
BG per patient		
mmol/L (mean ± SD)	10.3±2.8	10.3±2.4
mg/dL (mean ± SD)	186±50	186±44
BG measurement frequency per day (mean ± SD)	3±1	3±1
Treatment modalities (n (%))		
Premixed insulin	43 (40)	42 (42)
Basal insulin	28 (26)	26 (26)
Basal-bolus insulin	12 (11)	13 (13)
Prandial insulin	4 (4)	2 (2)
Correctional bolus insulin	57 (53)	51 (51)
DPP-4 inhibitor	31 (29)	25 (25)

Metformin	14 (13)	15 (15)
Sulfonylurea	4 (4)	6 (6)

SD standard deviation, BG blood glucose

The number of documentation errors for insulin administration (primary endpoint) was significantly higher for the old insulin charts compared to the new insulin charts (83 (77%) vs. 5 (5%)) ($p < 0.001$). Each parameter of documentation errors for insulin administration was distinctly higher on old insulin charts than on new insulin charts. Documentation errors for insulin prescription were more frequent on old insulin charts (108 (100%) vs. 42 (42%)), whereas documentation errors for insulin management rarely occurred in any group (11 (10%) vs. 8 (8%)). A detailed breakdown of listed parameters for documentation errors is shown in Table 2.

Table 2: Documentation errors for insulin administration, prescription and management with detailed listed parameters for seven days of inpatient stay

Documentation error type	Old insulin charts (n=108)	New insulin charts (n=100)
Documentation error for insulin administration (n (%))	83 (77)	5 (5)
Name of insulin was not written complete/legible/comprehensible	17 (16)	3 (3)
Unclear dose	25 (23)	1 (1)
No initialing when insulin was administered	55 (51)	3 (3)
Time of administration was not clearly documented	46 (43)	0
Documentation error for insulin prescription (n (%))	108 (100)	42 (42)
Insulin was not written up	27 (25,0)	0
Name of insulin was not written complete/legible/comprehensible	19 (18)	0
Unclear dose	32 (30)	1 (1)
Unit was written unclear	30 (28)	0
No initialing when insulin was prescribed	108 (100)	42 (42)
Insulin was prescribed at the wrong time	0	0

Documentation error for insulin management (n (%))	11 (10)	8 (8)
Insulin not increased when BG persistent >11.0 mmol/L (198 mg/dL) and a better control was appropriate for patient	10 (9)	7 (7)
Insulin was not reduced when unexplained BG <4.0 mmol/L (72 mg/dL)	1 (1)	1 (1)
Inappropriate omission of insulin after hypoglycemic episode	0	0

Both groups had a mean of 4±2 good diabetes days scaled to hospital stay days. Most frequently BG values >11.0 mmol/L (198 mg/dL) were responsible for not achieving good diabetes day criteria, whereas BG values <4.0 mmol/L (72 mg/dL) and inappropriate BG measurement frequency occurred less. Overall, 26 vs. 18 hypoglycemic episodes (BG <4.0 mmol/L (72 mg/dL), p=0.28), including seven vs. two severe hypoglycemic episodes (BG <3.0 mmol/L (54 mg/dL), p=0.17) were documented on old vs. new insulin charts, respectively. Treatment of severe hypoglycemia was documented in six out of seven cases on old charts vs. in both cases on new charts, respectively. Documented treatment modalities included four times infusion of iv dextrose on old charts, whereas in all remaining cases oral carbohydrates were given.

Moreover, 12% absolute improvement in documentation of patient identification (78% vs. 90%) was achieved by implementing the new insulin chart. Documentation of HbA1c value on insulin charts was rare in both groups (1% vs. 7%). Additionally, diabetes type was documented on 47%, pre-diabetes therapy on 17%, correction scheme on 28% and glomerular filtration rate on 6% of the filled-in new insulin charts.

DISCUSSION

The results of this study indicate that improved inpatient diabetes care was achieved by implementing a new insulin chart.

Erroneous documentation of insulin administration was significantly lower in new compared to old insulin charts. The design of the new chart was found suitable to improve all parameters of documentation errors for insulin administration. For example, errors regarding initialing of insulin administration by nurses were distinctly lower on new insulin charts compared to the previously used insulin charts. Our finding (3%) is similar to a rate of 4% not signed as given on audited drug charts at the NaDIA (14). Thus, a comprehensible documentation of mandatory administration data for effective and safe glucose management was guaranteed by implementation of this new insulin chart. A Scottish study, which identified evidence-based subcutaneous insulin care clusters to develop a new insulin chart showed similar improvements in the correct documentation of insulin administration after implementing a new insulin chart (10).

Regarding documentation errors for insulin prescription, we identified half as many errors on the new insulin charts. The detailed analysis of documentation errors for insulin prescription indicated that all but one parameter, the initialization of the prescription, were sufficiently improved on new insulin charts and comparable to recent data of the NaDIA (14). None of the previously used insulin charts at our institution had provided a dedicated area for the initialing of therapy which is reflected in 100% documentation error rate in the baseline evaluation. Although the new design supports this legal prerequisite of documentation, a sufficient practice change among physicians has not yet been achieved. Similarly, the Scottish study did not report a significant change in insulin prescription by implementing a new insulin chart. The authors argued, that this may arise from longstanding practice on the wards which is not easily changed

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(10). The same challenge may also apply to our hospital and hence further training should be offered to health-care-professionals to improve initialing of prescription. Additionally, pharmacists should be involved in the insulin prescription process when possible to review charts and to indicate any concerns to physicians and nurses to improve insulin error reduction strategies (28–30).

Documentation errors for insulin management were rare in both groups and remained lower than the average error rate reported in a recent NaDIA report (14). The number of good diabetes days, an indicator for established glycemic control without the occurrence of hypoglycemia, remained at a higher level compared to the benchmark of insulin treated patients in the NaDIA audit (14). Of note, the number of hypoglycemic events, including severe episodes, was, although non-significantly, lower in new insulin charts and treatment of severe hypoglycemia was documented in all cases on new insulin charts. Thus, regarding overall treatment quality, the use of the new insulin chart seems to be clinically safe and beneficial to hospitalized patients that need insulin therapy to control glycemia.

Our evaluation of structural quality features showed a shift towards agreeing answers by nurses and physicians for improved structure quality of the new insulin chart for all nine items. Most of the structural improvements led to the desired positive changes in documentation quality. However, not all offered documentation possibilities were used to the same extent in clinical routine. As discussed above, there was a distinct difference in the authorization of prescription or confirmation of administration through initializing on the new insulin chart by physicians and nurses, respectively.

In this regard it is important to emphasize the potential limitation that the evaluation of filled-in insulin charts may not reflect the entire actual care at the wards. Similar to the

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3 Scottish study it can be assumed that there is a potential gap between the actual quality
4 of care and the documentation (10). The implementation report of a national
5 subcutaneous insulin chart in the Australian project observed a decrease in the
6 proportion of doses initialed as having been administered and orders where the
7 prescriber had signed. The authors argued, that this does not necessarily mean that
8 the insulin doses were not given, as otherwise this would be seen in increasing BG
9 values (17). Of note, an appropriately documented insulin dosing on an insulin chart
10 solely does not guarantee that all system and human factors have been adequately
11 respected when the insulin dosing has been performed (28,31). The preparation and
12 administration process is complex, errors are multifaceted and may be related to e.g.
13 missed resuspension of NPH insulin, inappropriate mixtures of different insulins when
14 using a syringe, overdosing due to use of wrong insulin concentration, use of an
15 improper injection site, injection of a prandial insulin despite omission of nutritional
16 intake or delayed injection due to excessive workload of the nursing staff. Education
17 and resource availability have been claimed as important interventions by health-care-
18 professionals to administer insulin in a timely and safe way for every patient (29). To
19 reduce the workload of the nursing staff a policy regarding self-administration and self-
20 management and it's standardized documentation on the new chart has been
21 developed.

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23 Furthermore, the observed beneficial effects in the current investigation may not be
24 solely attributed to the use of the new insulin chart as the implementation was
25 accompanied by extensive training measures to improve compliance of medical and
26 nursing staff. The limitation of a missing control group, which has undergone
27 comparable training measures with the previous insulin charts in order to assess the
28 impact of the new form on its own is acknowledged. Usefulness of a control group can
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be limited when evaluating a complex intervention in an open system such as a ward area in a hospital, where it is challenging to control for multiple confounders.

To ensure that our new insulin chart is empirically and theoretically well founded for our institutional setting we integrated results of previous audit data, followed international and local standards when developing the new insulin chart and performed pre-clinical piloting of the prototype (23). However, we acknowledge that using the concise methodology of the Medical Research Council framework (32) could have further improved several phases of our complex intervention e.g. the phase of assessing feasibility and piloting by performing clinical testing of the new chart or the phase of evaluation by using focus groups and in-depth interviews to explore the implementation of the intervention, contextual factors and potential mechanisms of action. Additionally, the implementation of one standardized insulin chart per se in our institution may have contributed to a reduction of documentation errors, as junior doctors rotating between wards have to deal with one insulin chart instead of four. It can be expected that similar to observational charts, variations in prescription chart design are related to different prescription error frequency and through chart standardization prescription error rates can be reduced in insulin charts as well (33).

Moreover, the implementation and subsequent effects of the new insulin chart to other, e.g. surgical disciplines may be different. However, insulin prescription and administration should not differ between conservative and surgical disciplines and accompanying training measures should allow a safe and effective implementation. When implementing any type of insulin chart, the integration within the standard prescription chart process needs to be secured. In particular, the process of documentation and administration of iv insulin necessitate cautiousness (34). The use

of electronic prescription systems with integrated insulin charts may help to reduce interface errors between different prescription systems. International guidelines recommend electronic diabetes documentation as necessary for optimizing diabetes inpatient care (4,15). This is also confirmed by NaDIA, where hospitals that were prescribing diabetes medication electronically were less likely to have prescription errors (14). Electronic systems with clinical decision support have the potential to reduce errors and to increase treatment quality (35).

A strength of the study is that improvements in documentation quality were connected with beneficial clinical outcome. Moreover, the project was performed in daily clinical routine work as an essential quality assurance project. The hours spent for implementation were covered out of general employment and, thus, feasibility of a rollout in comparable hospital institutions can be assumed.

Nevertheless, a lesson learnt from the present work was that training of the nursing and medical staff is a real challenge in a typical hospital shift rotation system.

Another critical aspect when designing a new insulin chart is an early review of the necessity of all fields on the new insulin chart. It can be assumed that, similar to the Scottish study, the more fields that need to be filled-in the less likely any of them will be charted (10). In our case the item glomerular filtration rate will be removed from the chart as the degree of filling-in was low and importance for the actual treatment process in daily routine care has been scrutinized.

Finally, we agree with the conclusion of the Australian Quality Initiative that further optimization of specific endpoints, such as initialing of physician's prescription or documentation of hypoglycemia treatment should be addressed through effective change management processes and more explicit training and education for health-

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care-professionals, rather than further modification of chart design (17). The insulin chart, as a standardized documentation of diabetes management, is only one component for good diabetes inpatient care. It is also important to address the knowledge gaps regarding insulin therapy and insulin use among health-care-professionals (4,5,9,28,29).

CONCLUSION

Inpatient diabetes care was optimized through implementation of the new insulin chart. Structural changes on the new insulin chart along with accompanying training measures throughout the implementation process, not only led to better quality of insulin chart structure, but also improved documentation quality of filled-in new insulin charts and supported safe management of glycemic control. The present work supports a rollout of the new insulin chart at further departments, and sustainability of the beneficial effects in the long term has to be demonstrated in further investigations.

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Competing interest

None declared.

Author contributions

JK, GS, KML, BS, TRP and JP designed and performed the study, interpreted data and contributed to discussions, RR performed statistical analysis, JP, GB, CT and TRP supervised the project and JP is the guarantor of this work.

Prior presentation of data

Prior presentations of the data include the 6th Grazer Risk Day 2018, Austria, the Annual Meeting of the ÖDG 2017 and 2018 Salzburg, Austria and as abstract (published only) at Diabetes 2019 from the American Diabetes Association.

Reference List

1. Umpierrez GE, Isaacs SD, Bazargan N, et al. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. *J Clin Endocrinol Metab* 2002;87:978–82.
2. Draznin B, Gilden J, Golden SH, et al. Pathways to quality inpatient management of hyperglycemia and diabetes: A call to action. *Diabetes Care* 2013;36:1807–14.
3. Fritsche A. Diabetes Mellitus in der Klinik - Mehr Strukturen schaffen - Die Anforderungen an die stationäre Behandlung von Diabetespatienten wird unterschätzt. *Dtsch Arztebl* 2017;114:16–9.
4. ADA. 15. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes-2020. *Diabetes Care* 2020;43:193–202. Available from: https://care.diabetesjournals.org/content/43/Supplement_1/S193. Accessed September 01, 2020.
5. JBDS-IP. A good inpatient diabetes service. 2019. Available from: https://abcd.care/sites/abcd.care/files/site_uploads/JBDS_A_Good_Inpatient_Service_Updated_060720.pdf. Accessed September 01, 2020.
6. ISMP. ISMP List of High-Alert Medications in Acute Care Settings. *Inst Safe Medicat Pract* 2018; Available from: <https://www.ismp.org/sites/default/files/attachments/2018-08/highAlert2018-Acute-Final.pdf>. Accessed September 01, 2020.
7. Cox AR, Ferner RE. Prescribing errors in diabetes. *Br J Diabetes Vasc Dis* 2009;9:84–8. Available from:

- <http://dvd.sagepub.com/cgi/doi/10.1177/1474651409103902>. Accessed September 01, 2020.
8. Kolanczyk DM, Dobersztyn RC. Challenges with insulin in the inpatient setting. *Diabetes Spectr* 2016;29:146–52.
 9. Lamont T, Cousins D, Hillson R, et al. Safer administration of insulin: summary of a safety report from the National Patient Safety Agency. *BMJ* 2010;341:882–7.
 10. Rushmer R, Voigt D. Measure it, improve it: the safer patients initiative and quality improvement in subcutaneous insulin therapy for hospital in-patients. *Diabet Med* 2008;25:960–7.
 11. Christofidis MJ, Horswill MS, Hill A, et al. Task analysis and heuristic analysis of insulin charts: final report for the Australian Commission on Safety and Quality in Health Care. Sydney; 2012. Available from: <https://safetyandquality.gov.au/wp-content/uploads/2012/06/56679-Insulin-charts-heuristic-analysis-2-Feb-2011-Final-Report.pdf>. Accessed September 01, 2020.
 12. Cobaugh DJ, Maynard G, Cooper L, et al. Enhancing insulin-use safety in hospitals: Practical recommendations from an ASHP Foundation expert consensus panel. *Am J Heal Pharm* 2013;70:1404–13.
 13. Cousins D, Rosario C, Scarpello J. Insulin, hospitals and harm: a review of patient safety incidents reported to the National Patient Safety Agency. *Clin Med (Northfield Il)* 2011;11:28–30. Available from: <http://www.clinmed.rcpjournals.org/content/11/1/28.full.pdf>. Accessed September 01, 2020.

14. NDIA. National Diabetes Inpatient Audit 2017. Full report. England and Wales 2018. Available from: <http://www.hscic.gov.uk/catalogue/PUB06279/nati-diab-inp-audi-11-nat-rep.pdf>. Accessed September 01, 2020.
15. Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of hyperglycemia in hospitalized patients in non-critical care setting: An endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 2012;97:16–38.
16. Dashora U, Sampson M, Castro E, et al. Rowan Hillson Insulin Safety Award 'best in class' insulin prescription chart competition. *Br J Diabetes Vasc Dis* 2015;15:135–8. Available from: <http://bjdvd.co.uk/index.php/bjdvd/article/view/87/187>. Accessed September 01, 2020.
17. Australian Commission on Safety and Quality in Health Care. Development and evaluation of a new chart for subcutaneous insulin administration in acute care settings. 2017.
18. Bain A, Hasan SS, Babar ZUD. Interventions to improve insulin prescribing practice for people with diabetes in hospital: a systematic review. *Diabet Med* 2019;36:948–60.
19. Hamilton P, Nation M, Penfold S, et al. Reducing insulin prescription errors in hospital: more stick than carrot? *Pract Diabetes* 2013;30:370–3.
20. McIver FB, Mitchell CA, Finn CP, et al. Standardising practices through form design and education improves insulin management. *Aust Health Rev* 2009;33:434–41. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/20128759>. Accessed September 01, 2020.

21. Horswill MS, Hill A, Christofidis M, et al. Development and initial evaluation of a new subcutaneous insulin form: final report. Australia 2015. Available from: <http://www.safetyandquality.gov.au/wp-content/uploads/2015/08/Development-and-initial-evaluation-of-a-new-subcutaneous-insulin-form-Final-Report.pdf>. Accessed September 01, 2020.
22. Sendlhofer G, Brunner G, Tax C, et al. Systematic implementation of clinical risk management in a large university hospital: the impact of risk managers. *Wien Klin Wochenschr* 2015;127:1–11.
23. Kopanz J, Lichtenegger KM, Sendlhofer G, et al. Limited Documentation and Treatment Quality of Glycemic Inpatient Care in Relation to Structural Deficits of Heterogeneous Insulin Charts at a Large University Hospital. *J Patient Saf* 2018.
24. NDIA. National Diabetes Inpatient Audit 2013. National Summary. England and Wales 2013. Available from: <http://content.digital.nhs.uk/catalogue/PUB13662/nati-diab-inp-audi-13-nat-rep.pdf>. Accessed September 01, 2020.
25. NDIA. National Diabetes Inpatient Audit 2015. National Report. England and Wales 2016. Available from: <http://www.hscic.gov.uk/catalogue/PUB06279/nati-diab-inp-audi-11-nat-rep.pdf>. Accessed September 01, 2020.
26. Electric Paper. EvaSys 6.0 - Electric Paper Evaluationssysteme GmbH. Lüneburg Deutschland 2013. Available from: <https://www.evasys.de>. Accessed September 01, 2020.
27. IBM Analytics. IBM SPSS-Statistics Version 23. 2018. Available from: <https://www.ibm.com/analytics/at/de/technology/spss/>. Accessed September

- 01, 2020.
28. Lee MKS, Liu Z, Quek TPL, et al. Insulin-related knowledge among health care professionals at a tertiary hospital. *Diabetes Spectr* 2013;26:187–93.
29. Bain A, Kavanagh S, McCarthy S, et al. Assessment of Insulin-related Knowledge among Healthcare Professionals in a Large Teaching Hospital in the United Kingdom. *Pharmacy* 2019;7:16.
30. Bain A, Hasan SS, Kavanagh S, et al. Strategies to reduce insulin prescribing errors in UK hospitals: results from a national survey. *Diabet Med* 2020;37:1176–84.
31. Robb A, Reid B, Laird EA. Insulin knowledge and practice: a survey of district nurses in Northern Ireland. *Br J Community Nurs* 2017;22:138–45.
32. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: Following considerable development in the field since 2006, MRC and NIHR have jointly commissioned an update of this guidance to be published in 2019. 2019. Available from: <https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/>. Accessed September 01, 2020.
33. Horswill MS, Preece MH. W, Hill A, et al. Human factors research regarding observation charts: Research project overview. Sydney Australia 2010. Available from: <https://www.safetyandquality.gov.au/wp-content/uploads/2012/01/35986-HumanFactors.pdf>. Accessed September 01, 2020.
34. JBDS-IP. The use of variable rate intravenous insulin infusion (VRIII) in medical

inpatients. 2014. Available from:

https://abcd.care/sites/abcd.care/files/resources/JBDS_IP_VR111.pdf. Accessed September 01, 2020.

35. Neubauer KM, Mader JK, Höll B, et al. Standardized Glycemic Management with a Computerized Workflow and Decision Support System for Hospitalized Patients with Type 2 Diabetes on Different Wards. *Diabetes Technol Ther* 2015 Oct;17:685–92. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26355756>. Accessed September 01, 2020.

Figure Legend

Figure 1: The newly designed standardized insulin chart

Figure 2: Timeline of study phases to identify structure, documentation and treatment quality

Figure 3: Structure quality of insulin charts assessed by physicians and nurses on a four-point Likert type response scale (“I disagree”, “I partially disagree”, “I partially agree” and “I agree” coded as one-four)

Supplement

Supplement: Different insulin charts in use at the nine wards before implementation of the new insulin chart

a) front

patient identification label

medication chart marked ☐
 diabetes: type1 ☐ type2 ☐ other ☐

Insulin Chart No.: _____

Year: 20__

Correx Summ. Insulin

doesn't replace routine insulin

doesn't count

MD **MD**

pre-every 4h

Name of correction insulin

addition insulin

insulin

Time	pre-meal		fasting BG		pre-meal		fasting BG		pre-meal		fasting BG		pre-meal		fasting BG		pre-meal		fasting BG	
	12-00h	Other	12-00h	Other	12-00h	Other	12-00h	Other	12-00h	Other	12-00h	Other	12-00h	Other	12-00h	Other	12-00h	Other		
	BG frequency		BG frequency		BG frequency		BG frequency		BG frequency		BG frequency		BG frequency		BG frequency		BG frequency			
Time	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:	:
>400																				
301-400																				
201-300																				
141-200																				
71-140																				
<70																				

b) back

Recommended procedure for hypoglycaemia (<70 mg/dl)

If the patient is **conscious** and **p.o. administration possible**:

- Administration of 2 Carbohydrate Units (CU) of Fast-Acting Carbohydrates and BG-control after 15 min.
- Repeat the procedure if BG persists <70 mg/dl

If the patient is **conscious** and **no p.o. administration possible**:

- Administration of 100 ml of 20% glucose IV access
- Recheck BG after 15 min.
- If BG persists <70 mg/dl, re-administration of 100 ml of 20% glucose IV

If the patient is **unconscious/drowsy**:

- Ensure vital functions
- Immediate notification of the responsible medical personnel
- Administration of 100 ml of 20% glucose IV
- Recheck BG after 5 min., if still conscious/drowsy, or after 15 min., if conscious
- If BG persists <70 mg/dl, ensuring an IV access and re-administration of 100 ml of 20% glucose IV
- Continuous monitoring of patient until consciousness regained

Further procedure:

- Administration of 1U long-acting Carbohydrates, if BG >70 mg/dl increased and patient became conscious
- Evaluation of the cause
- Documentation of hypoglycaemia-treatment
- Medical planning of further BG-monitoring
- Recheck BG after 1 hour
- In case of a causative long-acting blood glucose lowering medication (e.g. sulfonylureas, basal insulin) ensure a longer control period

Fast-Acting Carbohydrates (1 CU)

- approx. 125 ml fruit juice
- 12g of dextrose powder (2 tsp = approx. 1 CU)
- 2 dextrose slices

Slow-Acting Carbohydrates (1 CU)

- 1 slice of whole grain bread (30 g)
- ½ banana

Recommended procedure for hyperglycaemia

Possible causes

- Concomitant medication such as steroids, parenteral nutrition
- Insulin and/or diabetes medication omission/adequacy
- Consider to check ketones
- BG-control already insufficient before admission, current A1c available?
- Hyperglycaemia as a result of hyperglycaemia

Possible procedure

- Dose increased of oral medication?
- Initiation of insulin therapy necessary?
- Increase of existing overall insulin dose by 10-20%?

Possible procedure by correction scheme

- Selection of dose suggestions based on total insulin dose or body weight (see table below)
- Dose suggestions for correction are to be seen in dependence of preprandial BG-value
- Be careful with corrections in postprandial condition or after glucose infusion/administration
- Observe the minimum timespan to the last insulin injection
- If the need for correction insulin continues, evaluate conversion to basal insulin

Fast-Acting Carbohydrates (1 CU)

- approx. 125 ml fruit juice
- 12g of dextrose powder (2 tsp = approx. 1 CU)
- 2 dextrose slices

Slow-Acting Carbohydrates (1 CU)

- 1 slice of whole grain bread (30 g)
- ½ banana

Correction Scheme for short-acting insulin

OR	pre-existing insulin therapy (based on total daily insulin dose)			
	< 25 IU	25-49 IU	50-80 IU	> 80 IU
No pre-existing insulin therapy (based on body weight)	< 50 kg	50-75 kg	76-100 kg	> 100 kg

preprandial BG-values (mg/dl) with suggested insulin doses	> 400			
	4 IU	6 IU	8 IU	12 IU
301-400	3 IU	4 IU	5 IU	8 IU
201-300	2 IU	2 IU	3 IU	4 IU

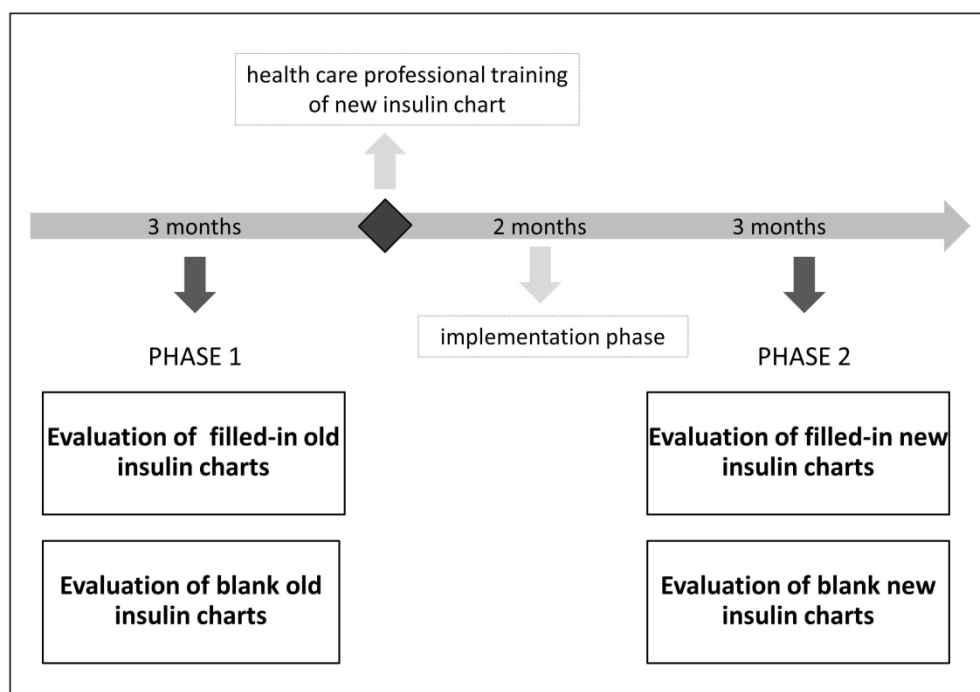


Figure 2: Timeline of study phases to identify structure, documentation and treatment quality

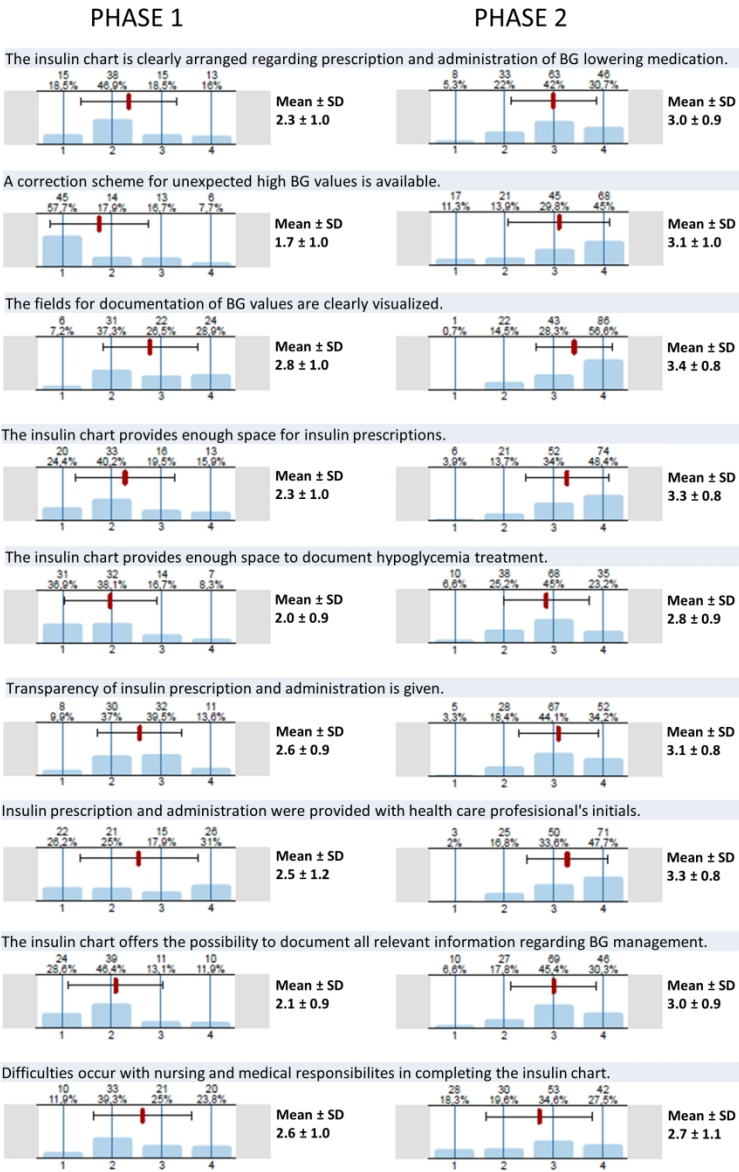


Figure 3: Structure quality of insulin charts assessed by physicians and nurses on a four-point Likert type response scale ("I disagree", "I agree to some extent", "I partially agree" and "I agree" coded as one-four)

190x274mm (284 x 284 DPI)

Diabetiker – Kurve														
Blatt Nr.:	Jahr:	Name:												
	Zeit:	Datum:	Zeit:	Datum:	Zeit:	Datum:	Zeit:	Datum:	Zeit:	Datum:	Zeit:	Datum:	Zeit:	Datum:
Blut-Glukose (mg/dl)														
Insulin														
Präparat: Injektionszeitpunkt: Einheiten:														

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Barcode Etikett	Blatt Nr.:	Zi.Nr.:	Diät:	Medikation:
	Jahr:		12BE ○ 14BE ○	ORAL ○ INSULIN ○
	Anmerkung:			

	Mo:	Di:	Mi:	Do:	Fr:	Sa:	So:
Nüchtern:							
Mittag:							
Abend:							
Nacht:							
Präparat:	F M A	F M A	F M A	F M A	F M A	F M A	F M A
	X / X	X / X	X / X	X / X	X / X	X / X	X / X
	X / X	X / X	X / X	X / X	X / X	X / X	X / X
	X / X	X / X	X / X	X / X	X / X	X / X	X / X
Sonstiges:							
orale Therapie:							

ANGIOLOGIE

DIABETES – Kurve

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SQUIRE 2.0 Checklist

Text Section and Item Name	Section or Item Description	Reported on page #
Title and Abstract		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	"improve quality and safety of diabetes care", title page 1
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	Abstract, page 2 (structure: objective, methods, results, conclusions)
Introduction		
3. Problem description	Nature and significance of the local problem	Introduction, page 3
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	Introduction, page 3-4
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	Introduction, page 3-4
6. Specific aims	Purpose of the project and of this report	Introduction, page 4
Methods		
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	Implementation of new insulin chart, methods, page 5
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	a. Methods, page 5-7, Figure 1 – the new insulin chart b. Interdisciplinary project team, methods page 5
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	a. and b. Methods, page 6-7
10. Measures	a. Measures chosen for studying processes and outcomes of the	a. Methods, page 6-7 b. Implementation of new

	intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	insulin chart, page 5 (no cost measures) c. Data management, methods, page 7
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	a. Statistical analysis, methods, page 8 b. Methods, page 6-7
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	Ethical approval, methods, page 5
Results	<i>What did you find?</i>	
13. Results	a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data	a. Figure 2 – timeline of study phases, no intervention modifications were needed b. Results, page 9-12 c. Results, page 9-10 d. Results, page 9-12 e. Results, page 9-12 (no cost evaluation) f. No missing data
Discussion	<i>What does it mean?</i>	
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project	a., b. Discussion, page 13-15
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs	a., b., c., d Discussion, page 13-16 e. Discussion and Conclusion, page 16

16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations	a., b, c Discussion, page 15
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps	a., b, c., d., e. Conclusion, page 16 b. Not given
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	Funding, page 17