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Glucosafe 2

de Watteville, Aude; Pielmeier, Ulrike; Graf, Séverine; Siegenthaler, Nils; Plockyn, Bernard; Andreassen, Steen; Heidegger, Claudia-Paula

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ORIGINAL RESEARCH

Usability study of a new tool for nutritional and glycemic management in adult intensive care: Glucosafe 2

Aude de Watteville[1,2] · Ulrike Pielmeier[3] · Séverine Graf[2] · Nils Siegenthaler[1] · Bernard Plockyn[1] · Steen Andreassen[3] · Claudia-Paula Heidegger[1]

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Abstract
The new decision support tool Glucosafe 2 (GS2) is based on a mathematical model of glucose and insulin dynamics, designed to assist caregivers in blood glucose control and nutrition. This study aims to assess end-user acceptance and usability of this bedside decision support tool in an adult intensive care setting. Caregivers were first trained and then invited to trial GS2 prototype on bedside computers. Data for qualitative analysis were collected through semi-structured interviews from twenty users after minimum three trial days. Most caregivers (70%) rated GS2 as convenient and believed it would help improving adherence to current guidelines (85%). Moreover, most nurses (80%) believed that GS2 would be timesaving. Nurses' risk perceptions and manual data entry emerged as central barriers to use GS2 in routine practice. Issues emerged from the caregivers were compiled into a list of 12 modifications of the GS2 prototype to increase end-user acceptance and usability. This usability study showed that GS2 was considered by ICU caregivers as helpful in daily clinical practice, allowing time-saving and better standardization of ICU patient's care. Important issues were raised by the users with implications for the development and deployment of GS2. Integrating the technology into existing IT infrastructure may facilitate caregivers' acceptance. Further clinical studies of the performance and potential health outcomes are warranted.

Keywords Nutrition · Glycemic control · ICU · Critically ill · Computer-assisted decision support system · Quality improvement

Abbreviations

BG	Blood glucose
EE	Energy expenditure
EN	Enteral nutrition
GS2	Glucosafe 2
PN	Parenteral nutrition
ICU	Intensive care unit

1 Introduction

Survival and outcome of intensive care unit (ICU) patients correlate with the management of insulin therapy and nutritional support during critical illness [1–3]. Hypo- or hyperglycemia is related to higher mortality, especially in non-diabetic patients [4, 5]. There is an association between high blood glucose (BG) variability and increased infection rates and mortality [6, 7]. Inadequate nutritional support contributes to protein loss and muscle wasting, which may lead to post-ICU weakness [3, 8, 9] and further increase of the ICU and post-ICU morbi-mortality [10–12].

International professional societies have published evidence-based guidelines for BG control and nutritional support for ICU patients [13–15], but implementation and adherence to local protocols remain challenging. Implementation of BG control according to local guidelines showed a low 50% adherence [16, 17] and even increased the frequency of hypoglycemic events [18]. Most issues impacting adherence to BG control protocols are unrelated to the perceived risk for the patient; instead, it appears that adherence to some extent

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✉ Claudia-Paula Heidegger
claudia.heidegger@hcuge.ch

[1] Division of Intensive Care, Department of Acute Medicine (DMA), Geneva University Hospital, Geneva, Switzerland

[2] Nutrition Unit, Geneva University Hospital, Geneva, Switzerland

[3] Respiratory and Critical Care Group (Rcare), Aalborg University, Aalborg, Denmark

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depends on how compatible the protocol-specified workflow is with the user's other clinical tasks [18, 19].

Recent nutritional guidelines suggest initiating enteral nutrition (EN) for all patients with a functional digestive tract and who cannot eat orally within 48 h after admission. Nutritional therapy (EN and/or parenteral nutrition (PN)) should be progressively increased during the early phase of the critical illness in order to achieve 80–100% of the measured energy expenditure from day 4 [13–15]. Despite these recommendations, a multi-centre prospective observational study observed that patients who stayed longer than 72 h in the ICU received on average less than 60% of their caloric needs as estimated by energy expenditure (EE) as well as less than 60% of the protein needs [20].

Meeting these challenges becomes even more difficult since the most recent guidelines recommend a personalized approach to patient care, including optimized nutrition therapy and glycemic control [13–15]. In particular, in critically ill patients with severely reduced insulin sensitivity, it may not be possible to achieve BG within the target range without temporarily adjusting nutrition support [13].

Glucosafe 2 (GS2) is a decision support system, intended to assist caregivers in achieving optimised BG control coupled to nutritional support. GS2 is based on a physiological model of insulin pharmacodynamics and of glucose metabolism, including absorption of nutrients [21, 22]. Its predecessor, Glucosafe, has been evaluated in three small clinical pilot studies [21–23], which, like other model-based systems [24–28], has shown promise by providing tight glucose control, while keeping the risk of hypoglycemia minimal.

GS2 offers built-in mechanisms to make adaptions to international and local guidelines which can be transposed into personalized advice for each patient. The use of GS2 software requires substantial interaction with the clinical user at the patient bedside. In this context, low user acceptance could inhibit the effective use of decision support tools in clinical practice.

Measuring and evaluating usability can be very difficult, especially if the tool or device is still under development [29]. This study marks the first step of the "usability engineering process" suggested by Hallbeck et al. [29] in which we evaluated the GS2 prototype with qualitative methods in the intended clinical environment according to the user-centered design principles [29]. The aim of the study was to identify potential barriers to the end-user acceptance of GS2 and to assess how these could be overcome in a revised version of GS2.

2 Methods and materials

2.1 Setting

This single-center usability study was conducted from December 2017 to February 2018 in the 36-bed mixed ICU of Geneva University Hospitals (HUG) in collaboration with Aalborg University, where the GS2 algorithm and the user interface of the GS2 prototype for this study was developed. The ICU department used the Centricity™ Critical Care patient data management system. The GS2 prototype version was installed on the bedside computers, accompanied by an instruction manual.

2.2 Description of GS2 prototype version

GS2 is a decision support software tool intended for use in adult ICU patients who are fasting or on EN and/or PN. The GS2 algorithm models insulin pharmacodynamics and glucose metabolism. The patient's anthropometric data, history of BG measurements, nutrition and insulin therapy are used to calculate the patient's current insulin sensitivity, providing the basis for predicting the patient's BG levels for the next four hours. Furthermore, based on insulin sensitivity and the patient's nutritional targets, the system can be prompted to give patient-specific personalized advice on insulin and nutrition therapy (EN and/or PN). GS2 was set to have a BG target range from 4 to 8 mmol/l. According to the local nutritional guidelines GS2 advised progressive feeding starting with 30% of the EE and protein target on day one and increasing the goals by 30% per day until reaching 100% of EE and protein targets on day four.

The intended users of GS2 are ICU physicians and nurses. Physicians interact with GS2 to specify the patient's EE and daily nutritional caloric and protein intake targets, while nurses interact mainly with GS2 to monitor progress and to elicit advice on nutrition and BG control.

The GS2 advice page, as used during the usability study is shown in Fig. 1 (in French).

2.3 Design of the study

At the beginning of the study, 14 caregivers (nurses and physicians) received intensive group training by the investigators and were appointed in charge of the software. Ten additional caregivers received bedside training by the investigators assisted by already trained caregivers. The objective of the training was to ensure, at least one trained caregiver was available at all shifts to guide and help new users.

Over 2-months the investigators screened all ICU patients, who were fasting or receiving EN and/or PN. All

Fig. 1 GS2 prototype advice page. Top left panel: insulin infusion (blue) and BG measurements (red), prediction of future BG concentration (black) and insulin sensitivity calculation (dark blue). Bottom left panel: nutrition therapy (ml/h) and total intake (kcal/day). Below: key to enter data and to ask for advice. Right panel from top: To Do list with prompts for the user; list of nutritional products that the patient is receiving and pump rate; Caloric and protein status from current day

caregivers in charge of those patients were asked to use GS2 to elicit advice from the tool, but they were for regulatory reasons not allowed to use the advice. All ratings of the usefulness of the given advice was therefore subjectively given by the GS2 users. The minimum time duration to use GS2 was 3 days. We considered this to be sufficiently long for users to familiarize with the GS2 graphical user interface and to recognize its strengths and weaknesses. Users who used GS2 for 3 days activated the advice function on average 24 times, considering that BG is measured in regular intervals, on average every 3 h. A total of 55 caregivers used GS2 at least once. The first 20 caregivers who used GS2 for at least 3 days were interviewed, using a semi-structured questionnaire.

2.4 Semi-structured questionnaire

The objective of semi-structured questionnaire was to guide the interviews and to assess in depth the perceived barriers to the use of GS2 and to collect qualitative feedback following the user-centered design dimensions according to Hallbeck et al. [29]: (1) *Ease of learning and use* –users who have never seen the tool before should be able to learn to use it quickly, (2) *Efficiency of use*—the tool needs to be designed to allow rapid accomplishment of tasks, (3) *Error minimization*—the tool should be designed to minimize the number and severity of errors, (4) *Subjective satisfaction*—the experience of using the tool should be pleasant and comfortable, and (5) *Accommodation*—the tool needs to be fit or adjustable to as wide a group of users as possible. The semi-structured questionnaire was developed by a multidisciplinary team including dieticians, ICU physicians and biomedical engineers, with two team members with previous experience in the development of questionnaires [30]. It was then pre-tested by three investigators, not involved in the development of the questionnaire, to ensure that the questions were clearly stated and did not induce biased answers. The structured part had 45 questions under these topics: General information and computer literacy, user-friendliness and ergonomics, navigation, error handling, help and support, time-saving and overall impression. Answers were given as scores on scales with either numeric (e.g. "1–10″) or categorical (e.g. "very useful"…"not useful at all") values. In addition, users could add free text comments to their answers.

2.5 Data collection and analysis

Results from the interviews were collected through one-to-one interviews, based on a semi-structured questionnaire. Each interview lasted 20–30 min and was conducted by the same investigator (ICU research dietitian).

All answers, including interview transcripts and field notes were written down by the interviewer and were confirmed by the person who was interviewed.

Results from the interviews were entered into an Excel data sheet. The average scores ± standard deviations (SD) were calculated for answers given on a numeric scale, and otherwise the percentage of answers in each category was calculated. Where appropriate, Fisher's test and t-test were used to detect statistically significant differences ($p = 0.05$). Comments and recommendations from users for improvement were codified and categorized [31]. We identified emergent themes corresponding to the core constructs of usability engineering [29], based on which we compiled a list of issues and possible solutions for future development and deployment.

3 Results

The results section is ordered according to the two purposes of the study: (1) results relating to the assessment of usability; (2) results relating to the solution of issues identified during the study.

4 Assessment of usability

The results from the user interviews are summarized below. The full report of the study results (in French) is given in Appendix A (App. A).

4.1 Study participants (App. A, Sect. 1.1.1)

The characteristics of the 20 interviewed users are described in Table 1.

5 The questionnaire topics are summarized below:

5.1 General information and computer literacy (App. A, Sect. 1.1.2–1.1.5)

The objectives of GS2 were clear to all users. Most users (55%) were fully satisfied with the objectives, 40% were partially satisfied.

5.2 User friendliness, ergonomics and navigation (App. A, Sect. 1.1.7–1.1.20)

The majority of users (75%) did not find the graphical user interface overloaded. On a one to ten scale, the graphics components (pictograms, use of colours, graphics layout) received high average scores (8.1 ± 1.8, 8.4 ± 1.2, and 7.6 ± 1.9, respectively). The interface was described as easy or fairly easy to use by the majority of the users (80%). The instructions by GS2 were clear for nearly all users (85%) and there was no doubt about when asking for an advice (95%) or about its interpretation (70%). Almost half (40%) of the users had to use the program four or five times, in the beginning, to get acquainted with it. Some navigation problems seem to be due to the use of abbreviations that users were not familiar with and in part to some terms not translated into French. Users also complained of differences in use between GS2 and the Centricity™ Data Management System used in their clinical routine. (Table 2, Issue4).

5.3 Error handling, help and support (App. A, Sect. 1.1.21–1.1.31)

No technical problems appeared during the use of GS2 for a large majority of users (85%) and data entry was easy to perform for most of them (70%). Half of the users needed to refer to the initial instructions when trying to correct data entry mistake (Table 2, Issues 2 and 3) and 68% reported

Table 1 Description of users

	Users (n = 20)		Nurses (n = 17)		Physicians (n = 3)	
	n	%	n	%	n	%
Men	12	(60)	9	(53)	3	(100)
Women	8	(40)	8	(47)	0	(0)
	Mean	(SD)	Mean	(SD)	Mean	(SD)
Age	39.2	(8.43)	39.06	(9.13)	40	(3)
ICU years of experience	11.11	(6.40)	11.31	(6.87)	10	(2.45)
% of work	88.45	(11.36)	86.41	(11.13)	100	(0)
Software use (days)	5.77	(2.31)	5	(1.55)	10	(0)

Table 2 Issues compiled from the user interviews and proposed solutions

	Dimension according to Hallbeck et al. [29]	Issues	Proposed solutions	Example(s) from the interviews
1	Efficiency of use/error minimization	Manual data entry is time-consuming and error prone	In addition to manual data entry, all data are automatically imported from Centricity™ Critical Care	"Connect with Centricity™" software for automated data extraction"
2	Ease of learning and use	Date and time formats differ from Centricity™ Critical Care	The date and time formats can be set by a user with "Administrator" rights	"Difficulty to enter the time of measurements"
3	Ease of learning and use	Correction of erroneous data is difficult	Erroneous data can be selected and deleted with single mouse-click	"Difficult to find where to go to add/edit data: advice? Edit data?"
4	Ease of learning and use	Unfamiliar labelling and abbreviations	Detailed information is provided in the form of pop-up help texts in local language	"Abbreviations are not clear" "The abbreviations are to be unified with those used in Centricity™"
5	Ease of learning and use	Provide more guidance on the nutritional targets page	Specific buttons have been made to choose the EE source. Highlighting of labels guides the user through nutritional target calculations	"Visualization of the menus and parameters need to be cleaner in the nutritional target page."
6	Subjective satisfaction	Show all information on one page	The page to display data has a scrollable time axis to view all data over the entire ICU patient's stay	"Simplify the interface: if you want to document several items at once, moving from one to the other is complicated."
7	Error minimization/efficiency of use	Make user aware of hyperglycaemic events	Glycaemic excursions (hypo- and hyperglycaemia) are highlighted and labelled	"It would be more visual to have numerical values on the graph and to be able to see them in the graph also when the blood glucose is greater than 12 mmol/l."
8	Accommodation	Adjust the BG target range to 5.0 mmol/l to 8.5 mmol/l to be in line with departmental clinical practice	The BG target range (4 to 8 mmol/l) is changed to range from 5 mmol/l to 8.5 mmol/l to fit local guidelines	"Difference with the current local protocol: range too low." "Readjust the glycemic targets upwards"
9	Accommodation	Advice on insulin from GS2 may be too high and can differ from departmental guidelines	The maximum allowed increase in insulin can be set by an "Administrator"	"It's more reassuring to do it by ourselves. The advices are very different from the current practice with much higher doses of insulin. Impression: by following the advice all patients will have an insulin therapy at the end."
10	Efficiency of use	Advice with only small insulin or nutrition adjustments unduly increases the workload for the nurse	GS2 ignores adjustments below certain thresholds, which can be set by an "Administrator"	"Frequency of the nutritional advices is too important."
11	Accommodation	Advice from GS2 is not adapted to the pathology of all patients	GS2 advice on nutrition can be individualized to "acuteness" off illness and to ongoing dialysis	"The objectives are clear but the use is not necessarily adapted to the pathologies and not necessarily usable in all patients (in about 50% of cases)."
12	Error minimization	Configure alerts to measure BG	GS2 prompts the user when a BG measurement is due. The measurement interval can be set independently for stable and unstable patients	"A reminder alert message is missing to measure blood glucose after insulin flow is introduced or changed."

Table 2 (continued)

Dimension according to Hallbeck et al. [29]	Issues	Proposed solutions	Example(s) from the interviews
13 Accommodation	Do not reduce nutrition in response to high BG	Change of advice settings to give priority to prescribed calories	"Giving insulin adaptation advices is more logical than nutrition adaptation. Decreasing nutrition debit to correct blood sugar is the opposite of their usual practices."

that they often detected data omission by the previous GS2 user (Table 2, Issue 1). Nine of the caregivers (45%) never used the paper instruction manual at the bedside, because they considered group and individual bedside training as more useful and sufficient.

5.4 Time-saving and overall impression (App. A, Sect. 1.1.32–1.1.50)

The time spent for entering data into GS2 was estimated short or suitable by the majority of the users (30% and 35% respectively) while 20% of users considered it long and 15% too long. Most users (70%) did not feel that their daily workload was interrupted by GS2 and believed (67%) GS2 would allow them to save time in the medium and long run. On this point the opinions differed between nurses and physicians. A large majority (80%) of the nurses believed it would save time, whereas none of the physicians did.

Most of the caregivers (70%) expressed that the software will be useful for their clinical routine, and believed (85%) that it can help to standardize care and to improve adherence to best practice guidelines for ICU patients. The GS2 prototype version performed as expected in the opinion of 55% of the caregivers, and another 20% felt overall satisfied with the performance. Three users (15%) were not satisfied with the prototype version and would not use it without improvement (Table 2, Issues 8, 9, 10 and 11).

6 Compilation of issues and proposed solutions

Issues identified by users' feedback and improvements to the software decision support system prior to its deployment in further clinical studies are summarized in Table 2.

The investigators decided to implement all proposed solutions, except for n°13. It was not implemented because a temporary reduction of nutrition can be necessary for patients with high insulin resistance, as underlined in the recent German nutrition guidelines for intensive care patients [13].

7 Adaptation of GS2 to local guidelines and clinical workflow

Following the implementation of the 12 solutions, GS2 was adapted to local guidelines and clinical workflow. This process is exemplified by the screenshots below (Figs. 2 and 3, in English).

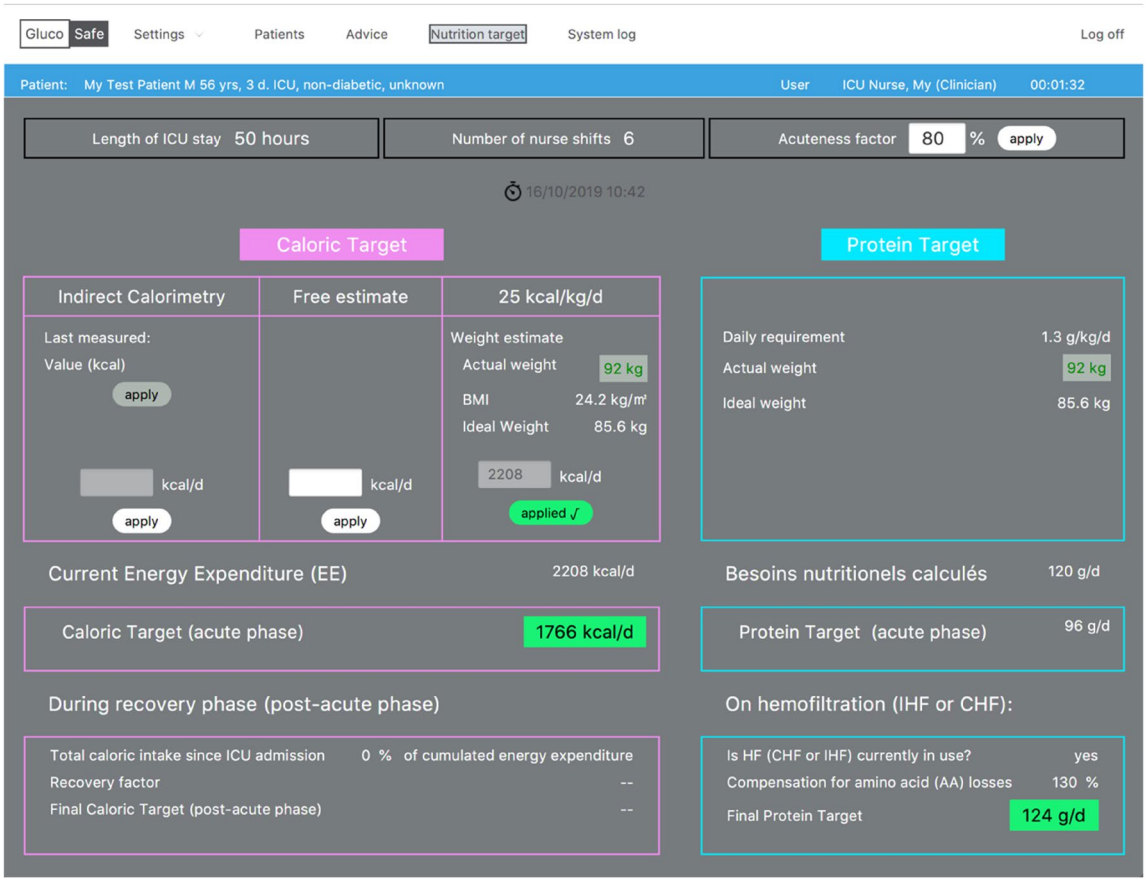

Fig. 2 GS2 Nutrition target page. Caloric and protein goals. The left panel describes the assessment of energy expenditure and the determination of a caloric target. The right panel describes how the protein target is determined

7.1 Nutrition targets page of GS2

Figure 2 illustrates how the issues 5 and 11 were handled. Patients' nutrition targets are adapted daily according to the local protocol (App. B). Nutrition therapy is started by EN from day one whenever possible, and increased gradually during the "acute phase" to reach isocaloric feeding on day four.

GS2 implements these recommendations by calculating the caloric target from the most recent EE estimate and an "acuteness factor". This factor is set to 20% at ICU admission and subsequently incremented by 10% at the beginning of each nurse shift (every 8 h).

A similar approach is adopted to calculate the recommended protein target from daily protein requirements of 1.3 g/kg/d [15] with an adaptation to the acuteness factor in the same way as for the caloric target. Furthermore, a dialysis factor is added to account for protein loss if the patient is on renal replacement therapy.

7.2 Advice page of GS2

Figure 3 illustrates how issues 4, 6 and 8 were handled. The new version of the advice page can be compared with the prototype version of GS2 (Fig. 1). The main improvements are summarized below:

- BG target range has been changed to 5.0–8.5 mmol/l.
- Insulin sensitivity calculation can be seen for each BG measurement.
- A slider has been made to shift the display window to see older data.
- Status of caloric and protein intake can be seen for the entire ICU stay and for each nurse shift.

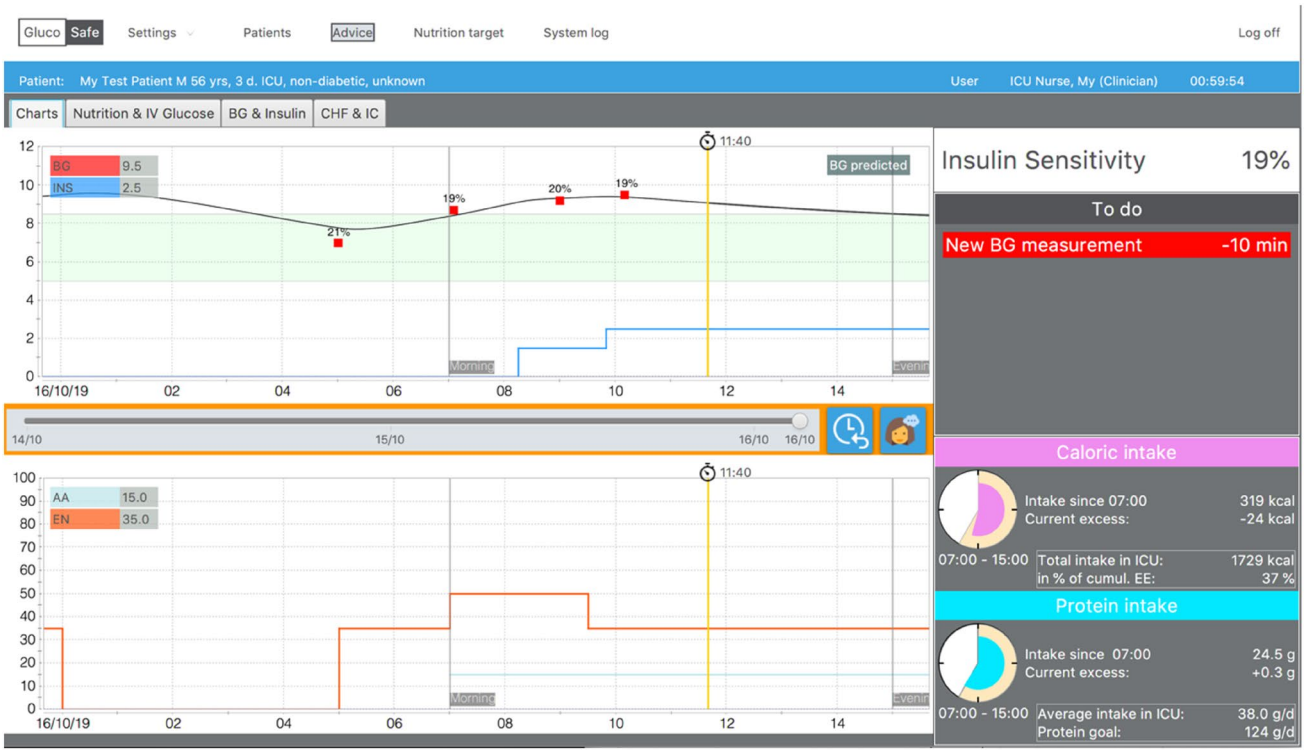

Fig. 3 GS2 Advice page. The Advice page. Top left panel: Plots of insulin infusion (blue) and BG measurements (red). BG measurements are labelled with the Insulin Sensitivity (%) calculated at the time of the measurement. Middle left panel: Slider to shift the display window to show older data; an icon to reset the display window to current time and an icon to request advice. Bottom left panel: Plots of nutrition rate. Right panel from top: Insulin Sensitivity at the time of the last BG measurement; the "To do" list with prompts for the user; Caloric and protein status from time of admission and from the beginning of the current nurse shift

8 Discussion

The objectives of this study were to assess the end-user acceptance and usability of GS2 and, based on users' feedback, to identify and remove potential barriers to the use of this new tool in the intended clinical environment. The qualitative data analysis showed that the majority of the users found GS2 useful (70%), time-saving (67%), and easy or fairly easy to use (80%). Moreover, they believe that GS2 could help to standardise care and could improve adherence to guidelines (85%).

Comments and potential barriers were raised by the users and were compiled into a list of 13 issues with corresponding solutions, out of which 12 were implemented in the software. With these changes in the software, the new version of GS2 has been better adapted to local guidelines and clinical workflow. The implementation of solutions marks only the first step of a "user-centered design" process which must be followed by an objective assessment of usability involving quantitative methods. Two major issues emerged from the qualitative analysis of this study, i.e. problems with manual data entry and that the integration of GS2 into the existing IT infrastructure would be preferable. In fact, the usability of GS2 adapted according to the solutions found should be further tested in a randomized study measuring the real time of use of GS2 and the data error frequencies.

As mentioned before, the implementation of the recent international guidelines on BG control and nutrition therapy [13–15] in local protocols remains a challenge and the adherence to these guidelines was shown to be low [16, 17]. Also, a study on evaluation of nursing work showed that two hours of direct nursing time per day were needed for patients with hourly controls [32]. These different points underline the importance of a decision support system, such as GS2, which help to standardise local protocols and to save time.

Previously, a few other decision support systems for BG control or nutrition in the ICU have been studied. A randomised control trial of the Space GlucoseControl system with an integrated predictive glucose control algorithm showed BG could be maintained in the defined target range 83% of the time, with a very low rate of hypoglycemia episodes [33]. Another randomised controlled trial comparing the LOGIC-2 Insulin BG control algorithm to standard practice in ICU patients showed that the use of LOGIC-2 algorithm improved the quality of BG control without increasing hypoglycemia episodes [27]. In the same way

some studies concerning nutrition therapy, showed a better standardization of the care and an increased nutrients delivery closer to target with computerized monitoring systems [34–36].

However, to the best of our knowledge, GS2 is the first system to perform a simultaneous optimization of BG control and nutrition therapy, and to deliver personalized advice in the form of calculated pump rates for the insulin and nutrition pumps. This new tool could help caregivers to individualise patient care and to create a coupling between BG control and nutrition, as these two aspects of care must be optimised simultaneously [13].

Despite this, these systems have not been widely accepted clinically and to our knowledge, only one system for glucose control is commercially available [33]. An explanation could be that commercial developments require a sizable amount of resources and are slowed by an extensive body of regulatory work. Besides, low user-acceptance is an often neglected but important aspect that can inhibit the effective use of decision support tools in clinical practice. For example, a systematic review indicated that between 49 and 96% of computer-generated medication safety alerts were overridden by clinicians [37]. Low user acceptance may be due to technological, behavioural, social, and organizational barriers and unintended (e.g., technology-introduced) adverse events could result from unidentified or unaddressed barriers prior to implementing a new technology [38–41].

We are unaware of other usability studies of decision support tools for BG control and/or nutrition in the ICU setting. This study is unusual in the sense that it was performed at an early stage of development. We feel that this type of study has been valuable for the development and deployment of GS2, because we could use the comments raised by the users to improve GS2.

It's noteworthy to mention that this usability study has been performed as defined by the International Organization for Standardization on Medical Devices (IEC 62366-1:2015) as *"A test of either an actual device or an advanced prototype with a fully functional interface whereby data obtained includes user performance …. and subjective responses of test participants…"*. The major strength of this study is that it was performed in the same setting as GS2 is intended to function in clinical practice. The participating staff had on average more than10 years of clinical experience. Moreover GS2 was used extensively during the study with a mean duration use of 5.7 (±2.31) days. It is difficult to say if the number of participants in this study can be considered as "large" in the sense that we had interviewed 20 users. However, current EU regulations demand between 5 and 15 participants (IEC 62,366–1:2015). Also, the number of participants is similar to other usability studies with, for example, 20 ICU nurses [42], 15 ICU doctors, or 2 ICU pharmacists [43]. Finally, the investigators consider that it is unlikely that a larger number of participants would have identified many other new issues.

This usability study has some limitations. Firstly, only a limited set of questions could be addressed. Indeed aspects as user friendliness, integration into local guidelines and workflow and potential for time saving were evaluated, while other aspects as efficiency and safety could not be quantitatively addressed. Secondly, bedside teaching was not standardized but was adapted individually to each user needs. One possible selection bias could have been that the caregivers were highly experience with a mean ICU experience of 11 years (SD ± 6.40 years). However, the range was large with a minimum of 0.5 and a maximum experience of 23 years. Finally, another limiting factor may be that this usability study has only been conducted in a single ICU, and that the same usability study performed in another ICU with different local guidelines and workflow may reveal other problems. However, due to the extensive amount of modifiable settings, the investigators believe that GS2 offers sufficient flexibility to make appropriate adaptations to most local guidelines as well as changes over time. Further clinical studies with the GS2 software are warranted, with the aim to evaluate the safety and efficiency of this new tool and to confirm findings from this study.

9 Conclusion

This usability study showed that GS2 was considered by ICU caregivers as helpful in daily clinical practice, allowing time-saving and better standardization of ICU patient's care. Some important issues were raised and allowed substantial improvements of the usability of GS2. Efficacy and safety issues should be evaluated in a randomized controlled trial, with a focus on achieving optimised blood glucose control and better adherence to nutritional guidelines.

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Author contributions AW participated in the study design, trained the caregivers, screened and included the patients, collected, analysed and interpreted the data, and drafted the manuscript. UP participated in the study design, protocol and questionnaire, trained caregivers, participated in the setting up of the study, developed the software and drafted the manuscript. SG conceived the study protocol, design and questionnaire, participated to the setting up of the study and drafted the manuscript. NS contributed to the study design, protocol, and questionnaire and to setting up the study and revising the manuscript. BP implemented the software, was responsible for the IT support and participated to setting up the study. SA conceived the study protocol, design and questionnaire, contributed to the software development and revised the manuscript. CPH, as responsible part, conceived the study protocol, design and questionnaire, trained the caregivers, obtained funding, analysed and interpreted the data, and drafted the manuscript.

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Compliance with ethical standards

Conflict of interest A de Watteville (AW), U Pielmeier (UP), S Graf (SG), N Siegenthaler (NS) and B Plockyn (BP) declare that they have no conflict of interest. S Andreassen (SA): board member of Judex Datasystems AS, Treat Systems ApS, OBI Medical AS and Amphi Systems, none being related to the present study. CP Heidegger (CPH): received restricted research Grants from Fresenius Kabi and Nestlé, none being related to the present study.

Ethical approval The Ethics Committee of Geneva University Hospital decided that there was no need for approval for this project according to the art. 2 of the law on research on the human being ("Loi relative à la recherché sur l'être humain").

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