Interface Design and Human Factors Considerations for Model-Based Tight Glycemic Control in Critical Care

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List of Abbreviations / Acronyms:

- Blood Glucose (BG)
- Graphical User Interface (GUI)
- Human Computer Interaction (HCI)
- Intensive Care Unit (ICU)
- Specialised Relative Insulin Nutrition Titration (SPRINT)
- Stochastic Targeted (STAR)
- Tight Glycemic Control (TGC)

ABSTRACT:

Introduction: Tight glycemic control (TGC) has shown benefits, but been difficult to implement. Model-based methods and computerized protocols offer the opportunity to improve TGC quality and compliance. This research presents an interface design to maximize compliance, minimize real and perceived clinical effort, and minimize error based on simple human factors and end-user input.

Method: The graphical user interface (GUI) design is presented by construction based on a series of simple, short design criteria based on fundamental human factors engineering, and included the use of user feedback and focus groups comprising nursing staff at Christchurch Hospital. The overall design maximizes ease of use and minimizes (unnecessary) interaction and use. It is coupled to a protocol that allows nursing staff to select measurement intervals and thus self manage workload.

Results: The overall GUI design is presented and requires only 1 data entry point per intervention cycle. The design and main interface are heavily focused on the nursing end-users who are the predominant users, while additional detailed and longitudinal data of interest to doctors guiding overall patient care are available via tabs. This dichotomy of needs and interests based on the end-users immediate focus and goals shows how interfaces must adapt to offer different information to multiple types of users.

Conclusion: The interface is designed to minimize real and perceived clinical effort, and ongoing pilot trials have reported high levels of acceptance. The overall design principles, approach and testing methods are based on fundamental human factors principles designed to reduce user effort and error, and are readily generalisable.

1.0 Introduction

Hyperglycaemia and glycaemic variability increase the risk of negative outcomes [1-3], as well as cost [4, 5], in critical care. Tight glycaemic control (TGC) can mitigate these issues [6-9]. While consistent, effective TGC is elusive [10], computerized and model-based methods [11-13] have the potential to provide significant improvements. However, a computer-based system may also introduce added sources of error, as well as increasing workload through unnecessary or repetitive interactions with computer software.

This case study explores several aspects of user interface design in the clinical context of TGC. The goal is to maximize the potential benefits of a more complex, patient-specific system by minimising the effort and error of interacting with the computer. The advantages of model-based systems to offer patient-specific therapy [14-16] can potentially be offset by data entry or non-compliance errors that increase resistance to adoption despite promising pilot trial results. Good interface design and ergonomics can minimize effort and error, thus improving the potential adoption and efficacy of the underlying protocol.

The current "human in the loop" approach for computerized protocols ensures safety and reduces regulatory issues. There is thus a range of interaction between the technology, the protocol and human behaviour. These human factors can lead to problems including:

- Poor/mis-entry of data or/and transcription errors
- Poor/mis-entry of the control input suggested to insulin or nutrition pumps
- Incomplete data entered or available

- Non-compliance with protocol interventions or measurement frequency

All of these errors can influence the performance of a computer-based TGC protocol.

Human computer interaction (HCI) is well studied in other fields and industries, but is an emerging topic in medicine, which has its own unique application-specific features. Studies have described a link between real and perceived clinical effort and user interface [17]. In TGC, the issues that most affect compliance are quite often unrelated to the specific patient or treatment, but are a function of the protocol design and its ability to integrate into a given clinical setting [18, 19]. Hence, compliance has been problematic in TGC and can significantly affect results [11, 20, 21]. Other human factors and the objective feedback from protocol success or failure have also been noted [17, 22-24]. Thus, the specific interface design and ergonomics of data entry and management are equally critical aspects of TGC protocol development.

This case study presents the design of a graphical user interface (GUI) for a new model-based and computerised TGC protocol (STAR) being designed to replace a paper-based protocol (SPRINT). The design presented is based on significant end-user (nursing) input and feedback, and thus focuses on minimizing unnecessary inputs and clinical effort to maximize ease of use and compliance.

2.0 Methods

2.1 STAR TGC system:

This GUI is designed for use with the glycaemic control protocol STAR (Stochastic TARgeted), a model-based and computerized control protocol that uses probabilistic methods [14, 15, 25] to determine the optimum combination of dextrose (nutrition) and insulin administration to ensure tight control and safety from hypoglycaemia in the presence of significant, clinically observed intra- and inter- patient variability [26, 27]. A version of STAR is currently in use in Liege, Belgium [25]. Nurses measure BG manually at the bedside every 1-3 hours (per the protocol) using a hand-held glucometer and input this measurement into a computer. The model-based treatment suggests an insulin and nutrition intervention to maximize time in clinically specified glycaemic bounds and a specified 5% or lower hypoglycemic risk (BG < 4.4 mmol/L). Nurses select the measurement interval to self-manage workload within the protocol.

2.2 Implementation system:

A touch-screen tablet was selected as the implementation platform for STAR, primarily for size, portability and hygiene reasons. The main design goals were minimal touches, minimal screens and maximal default entry. The overall intent is to minimize user error and effort via a system that safely minimizes unnecessary inputs, which was also part of end-user feedback. These goals are designed to reduce risk of both entry error that can lead to inappropriate recommendations, as well as the risk of mis-use or non-compliance. Importantly, STAR itself limits the rate of change, as well as the maximum and minimum rates of insulin and nutrition administration, providing a significant level of safety from

extreme recommendations [15, 25]. Thus, data entry methods (described elsewhere) and easy functional use by nursing staff were critical design elements.

Blood glucose data entry is done using a Cash Register method that avoids having to explicitly use the decimal button. This approach reduced uncorrected entry errors from 5-7% reported to less than 1%. All uncorrected errors resulted in extreme values that automated data entry checking (e.g BG < 2.0 mmol/L or BG > 15.0-20.0 mmol/L) would catch these entries and ask for confirmation.

2.3 GUI Design and Operation:

The final user interface design and basic operation were done using the results of several nursing and doctor focus groups that were held as open discussions during the break periods of each shift at the Christchurch ICU. The actual design was based on these interviews and the testing of intermediate designs from which further input and feedback was obtained. Specific attention and input was obtained from the unit's three nurse trainers and the senior nurses on each shift, as well as the senior consulting doctors.

Based on this feedback the design goal was to minimize touches and unnecessary entry that increase the risk of error or unnecessary confirmation that increases (perceived) effort and can lead to potential non-compliance. A fast, easily used interface will encourage users not to "work around" the system. The resulting interface is presented "as constructed" along with initial nursing feedback.

3.0 Results and GUI Interface Design

The GUI design is presented by construction. The overall workflow and number of touches for typical use are presented graphically.

The GUI is designed so that the most important information is presented as clearly and unambiguously as possible. Screens display minimal wording to avoid clutter and ensure information is easy to find, as well as to avoid misreading. Infrequently used screens present detailed information for review (e.g. history) or give access to infrequent options. These screens are only available via tabs so only interested users need see or use them.

This latter choice was made based on direct nursing input that focused on running the protocol with minimal interruption or distraction. It ran counter to the doctors desire to see more detailed long term data to help them guide care. This dichotomy is critical to the design and indicates the significant differences between the end-user (nurses) who apply the therapy, and the end-users (doctors) who guide the overall patient care. Thus, the interface design focuses on the nursing end-user who has the vast majority of contact with the system, while providing different, more comprehensive information for the doctor end-user.

The three main screens that the user interacts with are the main screen, the blood glucose entry screen, and treatment recommendation screen. They are shown in Figures 1-3.

The centre of the main screen is a large display of the current (ongoing) treatment options making it easy to read and interpret and check against pumps connected to the patient. The tabs at the bottom can be used to get to more detailed information or treatment

history. The buttons are large for easy use and minimal error on a touch-screen. The upper right-hand corner has a counter (minutes) until the next scheduled measurement and intervention based on the nurses selection of intervention interval at the prior intervention. It thus provides the critical data of current therapy and time until next action. Further longitudinal data and data detail are available via the tabs. Equally, for specific changes in therapy, the tabs offer access to customise care.

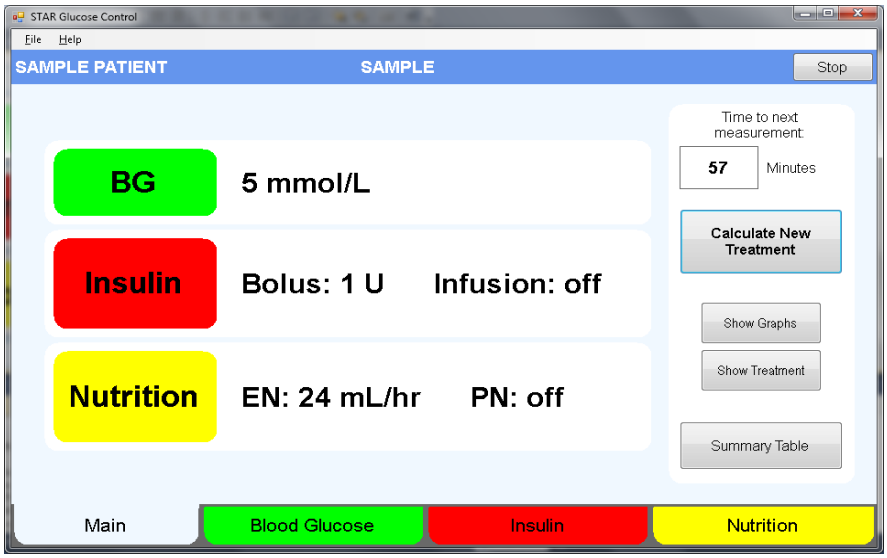

Figure 1: GUI main screen. The information displayed reflects the most recent set of BG control treatment data

The blood glucose entry screen has the Cash Register entry method. The buttons are large (Figure 2) for ease of use and to reduce errors and perceived effort. It is typically the only data entry required per intervention cycle. Hence, once patient data is input at beginning of protocol use, effectively all data entry occurs only in this screen, unless unplanned changes are made to the treatment.

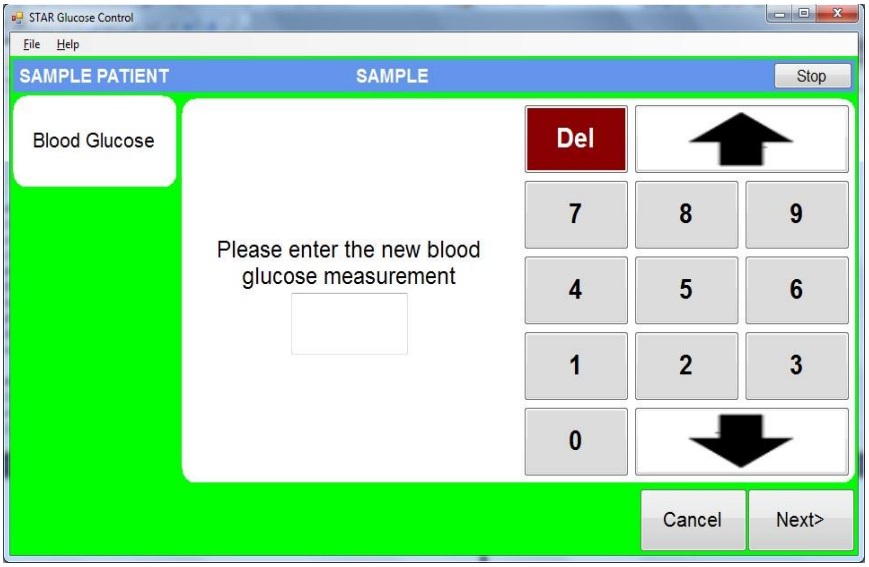

Figure 2: Blood glucose entry screen. Number entry is via the Cash Register (B) method with automatic insertion of a decimal point. The user reads the measurement from the glucometer or blood gas analyzer and enters it, then presses "Next".

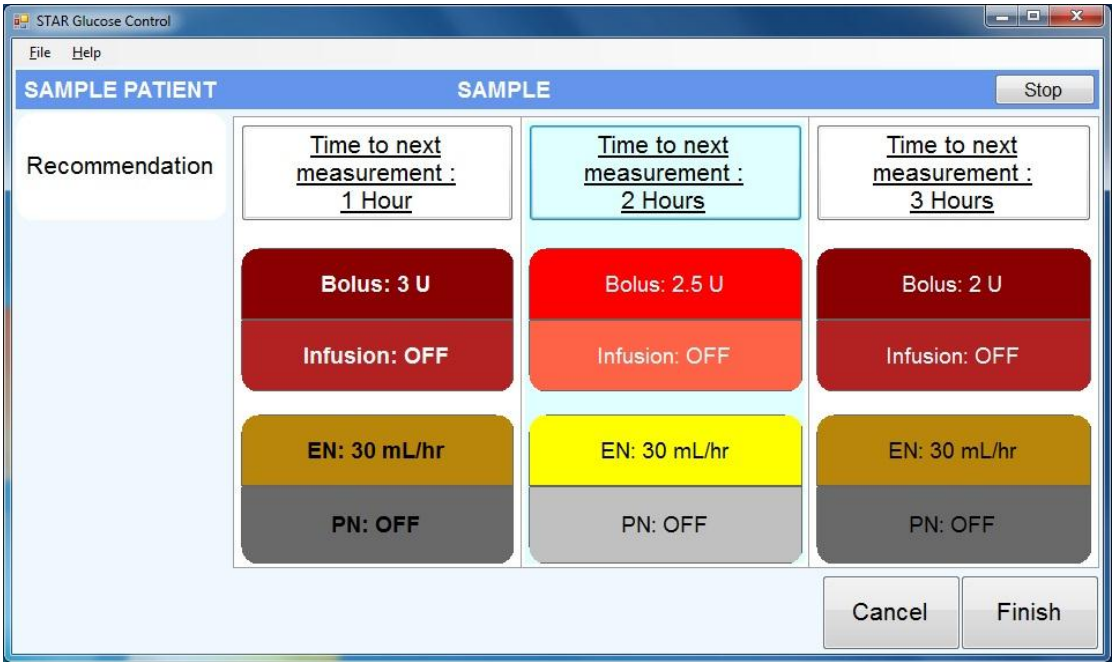

Figure 3: Treatment recommendation screen, specific to STAR it offers 1-3 hour treatment intervals if possible. The nurse freely selects the interval to self manage that aspect of clinical effort. If a certain interval is not available it is not shown as an option. Colors match chart colors and syringe sticker colors used in the Christchurch ICU. Column 2 is highlighted as the selected option here.

The treatment recommendation screen is specific to the STAR protocol and presents a comparative summary of possible treatment options for 1, 2 and 3 hour intervals, all of which meet clinically set overall protocol targets. The information is in large text and colour coded to aid in association with the same information on ICU charts and syringe labelling, which use similar colours. Large buttons allow the user to easily select the treatment option with minimal possibility of error. The user selects their desired option by touching the relevant "column" to select it and then pressing "Finish".

Regular Use:

The flow of regular use in TGC is show in Figure 4. Each regular interaction requires two main steps: **1**) input the latest BG value; and **2**) choose a recommended treatment. The GUI automatically reminds the user when a BG measurement is required, as shown in Figure 4 (Step 2). Step 3 is the BG input. Up to three treatment options will be calculated by the STAR algorithm, depending on the safety of longer measurement intervals [14, 15, 25], and are displayed in Step 4. The user will be asked to confirm the selected treatment (Step 5), before returning to the main screen (shown as Step 6).

Each of Steps 1-5 in Figure 4 requires a single touch. Steps 2 and 5 are confirmatory entries and are the minimum number of confirmatory entries that was felt safe, based on consultation with clinicians and nursing staff. In particular, Step 2 is a brightly coloured visual (audible was not desired by nurses) alarm noting when a measurement was due. Note that the protocol accounts for any timing delay by noting the exact time of glucose entry in Step 3, which starts the calculation process. Finally, the confirmation of Step 5 offers the option to alter the (chosen) recommendation if desired.

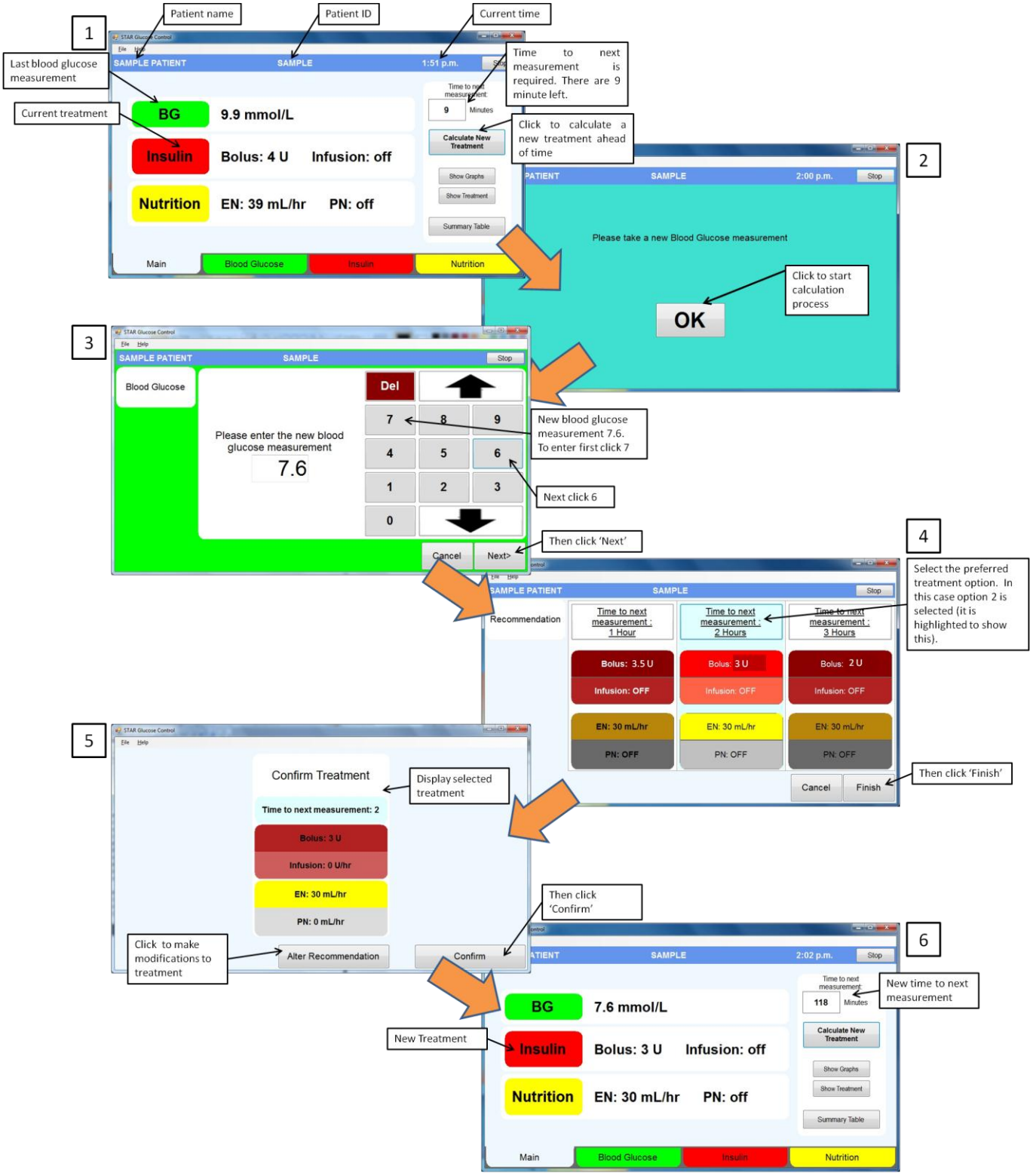

Figure 4: Screen flow for a typical interaction to input a new measurement and calculate a new intervention.

In this GUI EN and PN refer to parenteral and enteral nutrition, each of which has its own specific formulation. Equally, while STAR can vary nutrition as part of controlling glycemia, it may also be held at a constant value or shut off if clinically desired. The type of nutrition is specified on the nutrition tab and is part of starting a patient on STAR. Nutrition formulation and carbohydrate content are part of a drop down menu showing all possible choices available in this ICU. It also includes formulation for 5% dextrose solutions and other common infusions.

Turning the Feed off:

Occasionally, the details of insulin and/or nutrition administration will need to be altered mid-treatment interval due to unforeseen circumstances. As an example, Figure 5 shows the process when altering nutrition inputs, which is only used if all clinical recommendations are over ridden or if nutrition is changed/stopped for clinical reasons between measurements.

To make changes to the current treatment, the user must first navigate to the relevant tab, in this case the nutrition tab, shown in Figure 5 (Step 1). Feed can then be switched off (for this example) using the button highlighted in Step 2. After informing the GUI whether feed must remain off (Step 3), the user will input approximately how long ago the change occurred, which allows necessary changes to happen without any need to rush and update the controller, minimising stress on staff and both real and perceived clinical burden [17, 19]. The model-based STAR controller will then account for this change in the next intervention.

It is important to note that if the change is significant and might lead to risk, the nurse has the choice to make a measurement and calculate a new intervention immediately. This is

specified for STAR, for example, when stopping feed. However, it is not explicitly part of the GUI as it was a clinical choice left to local practice and culture. Equally, one might choose only to use 2-hourly intervention periods despite being offered longer intervals, based on patient condition or local approach. Hence, this approach still maintains overall safety, but that these choices are left to the local clinical staff and approach, rather than creating an over prescriptive approach. This choice was made, as with others, based on clinician and nursing feedback. Equally, further such advisories could also be added.

An entirely similar process occurs for stopping insulin infusions or missing an insulin bolus. They are accessed via the insulin tab in the main screen, but the process is otherwise essentially identical to ensure ease of use and minimize errors. The process is also identical if insulin or nutrition rates are overridden or changed in the middle of an intervention interval, though they require a further entry.

Figure 5: Screen-flow for turning nutrition off, an atypical, extra intervention.

4.0 Discussion

Successful implementation of a clinical protocol is heavily dependent on human factors. Perceived effort can also have a major influence on compliance and clinical outcomes [17]. By minimising the number of screens and touches in a given interaction, the real and perceived time and effort required by nursing staff is reduced. It is important that the time taken and ease of use for this interface is comparable to, or better than, current successful paper-based protocols such as SPRINT [6, 9]. In this regard, computerized systems offer default entry, which can minimize unnecessary data re-entry and any resulting transcription errors. The trade-off is that this information still requires checking and spurious default entries may be too easily ignored, turned off or worked around.

Computerized medical decision support protocols have potential to be more efficient than paper-based protocols in achieving compliance to protocol suggested interventions [11, 28, 29]. Achieving a high level of compliance is vital to the success of a clinical protocol [20, 21]. Hence, the interface design and human factors are a critical link in developing successful TGC protocols.

The GUI was designed in an iterative process and is still subject to ongoing refinements as wider clinical pilot trials are ongoing. Changes were made based on feedback from clinical staff in focus groups that tested early designs. In initial designs, high importance was placed on the accuracy of data entry with information used for calculations requiring checking and confirmation prior to calculation. Although this initial process was linear and intuitive, it was time-consuming and frustrating to nurses with the previously entered data being correct in the vast majority of cases. Thus, while employing an entry checking

process further increased the accuracy of the data entered, the extra effort meant that compliance would be affected. In such case, users seek workarounds, rather than using the system as designed, reducing efficacy of the protocol. Hence, a focus was made to ensure data entry accuracy (the benefits) without the need for checking (the real or perceived effort), which the methods selected accomplish with minimal automated checking for safety.

Streamlining the user interaction process involves a trade-off between the burden of data entry and checking, the potential increase in risk, and introducing additional opportunities for error. Importantly, in this case, the potential for extra introduced error can be no worse than a paper-based protocol, which *must* assume that all instructions are being followed.

Removing the requirement of explicitly checking previous data means that any mid-intervention treatment changes need to be recorded by nurses on the computer. Instead of being prompted to enter the changed information, nurses need to use their initiative to input a treatment change into the GUI, so that details are correct for the next calculation. Psychologically, this approach should empower users to own the use of the system, providing objective feedback [17], and thus the quality of TGC.

Although entering changes in the middle of an intervention period is not difficult, it is easy to forget to enter these details immediately as there are other, often more important, events in the ICU that nurses need to attend to. Therefore, allowances were made by design to record changes at a later time, and then specifying when the change occurred to minimize interference, as the model-based controller only requires them when making calculations at intervention times. When times are not recorded accurately there will be

some effect on the accuracy of the model-based controller. However, any loss of accuracy is likely to be negligible compared to that introduced if the change was not recorded. The only exception is when enteral or parenteral nutrition administration is stopped, as leaving insulin infusions on after stopping feeding increases the risk of hypoglycaemia [30].

This latter requirement requires that a new BG value be measured and a new calculation be made in the systems current form, although the GUI does not prescribe it explicitly, showing how a system such as this can be used within a clinical practice culture. In this case, that choice is left to clinical practice rather than prescribed by the GUI. This design choice leaves the current GUI design as a more flexible tool suitable to a wider range of clinical practices.

For acceptance by the nursing staff, STAR must be perceived as an improvement on the existing method (SPRINT in this case). Although reducing effort has been the focus of design, the nature of computerized protocols means that they are more complex, and may be more time-consuming. However, computerized protocols are generally thought to reduce the perceived effort when compared with equivalent paper-based protocols [17]. Additionally, turnover of nursing staff in wide-spread clinical implementation means that training becomes a relevant issue. Pilot trials typically have extra staff and attention not available in everyday work practice. A system that is easy-to-use and easy-to-learn can significantly reduce the down-time associated with extra training, potentially reducing implementation costs and overall error rates, as well.

Calculation times may also be a factor in perceived effort. The run time of calculations carried out by the controller directly influences the time taken to use the system.

However, through improved control, fewer BG measurements may be required, and the fact that STAR will thus be used less overall, may outweigh this increase in time taken for a given interaction. Currently, STAR requires on average 2-4 less measurements per day saving a minimum of ~10-20mins of measurement effort alone [31], thus the calculation period of ~1-5secs or less is likely negligible.

One limitation of any design is that it is never complete. Examining Figure 4, the visual alarm of a page requesting a new BG measurement (panel 2) is not necessarily required. It could be eliminated, along with one touch, without loss of utility, by moving straight to the BG entry panel (panel 3). Further such limitations and avenues for improvement may arise with ongoing use.

Point of care blood glucose sensors that can directly upload measurements are currently available, and seem one logical next step for computerising TGC, as well as pumps which can stream data directly into a computer system. This much more automated data entry would remove much of the current potential for data entry errors, as well as removing a step from each interaction with the computer. However, regulatory issues and ensuring the fidelity of this transmission make this more complete level of automation problematic at this time.

Further, a computerized system offers many added possibilities not addressed in this design. In particular, a great deal more data entry could be included for other uses, such as tracking organ failure as a response to TGC [9], monitoring the impact of drug therapy [32], or using model-based metabolic markers in sepsis or other diagnostics [33, 34].

Such possible additions were not in the focus of this case study, but their addition or use could be included using a similar design approach.

However, specific additions that should be mentioned include the interface of this type of system to computerized patient records and pharmacy prescription records, and the ability to better audit care decisions. The first case allows more streamlined data management and for that data to provide more insight to other doctors as a patient moves to less acute wards or settings, as well as enabling better logistics. The second illustrates how a computerized system can retain all that data to allow auditing of treatment selections, as well as patient or protocol performance over a ward or cohort.

In summary, this case study design has highlighted several fundamental design and human factors lessons that could be generalised to any interface design. They include:

- Minimize words and clutter, including the maximising button sizes so they don't require specific dexterity. Both will minimize user effort, error and misuse.
- Minimize the touches and interactions required to minimize error and effort
- Minimize the data entry to minimize sources of unintended error, including the use of automated, rules based data entry checking where appropriate
- Minimize the error and effort of any data entry methods (via design and testing)
- Minimize the number of confirmations to minimize user effort and frustration
- Use colour coding to enhance ease and intuitiveness of use, and thus minimize effort and error
- Do not underestimate the value of end-user focus groups and feedback

These lessons all focus on using design to minimize effort and error. The end result is a focus on simplicity that is often not fully addressed in device design [22-24].

5.0 Conclusions

Poor interface design and/or complexity can result in significant errors in providing care in the intensive care unit. This case study focuses on the user interface design and development for the new STAR control protocol, which has been designed to replace the less adaptable and flexible paper-based SPRINT in the Christchurch ICU. The GUI was designed using an iterative approach with changes made based on human factors principles and clinical feedback. The interface is designed to present information in a clear, concise manner that minimizes real and perceived user effort, and to require a minimal amount of interaction and data entry. The resulting improvements should help to increase the compliance of the protocol and achieve better TGC and patient outcomes. More generally, the overall approach and methods for design are easily generalisable and can serve as a template for a more human factors centered approach to protocol interface design to best promote maximum compliance and minimum error.

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