CHAPTER 9

General Discussion
GENERAL DISCUSSION

The main objective of this thesis was to study the implementation and evaluate the effectiveness and cost-effectiveness of a classroom based CRM training in the Intensive Care Unit. In this chapter the main findings, interpretation, implications and methodological considerations of the studies are summarized and discussed.

The main findings are subdivided into the three main research aims of this thesis:
1. Develop a sound study design with according instruments to evaluate CRM;
2. Study the implementation of CRM;
3. Assess the effects, costs and cost-effectiveness of CRM.

MAIN FINDINGS

Aim 1: Study design with according instruments

The study design was developed to assess the effects of CRM in the ICU, as well as to describe the process that explain such effects. What makes this study unique relative to other CRM evaluations is the combination of the long follow up of one year, the assessment of behavioural change with observations, and the use of matched control units. The matched control units protected the study against secular trends and sudden changes [1]. As recommended and used by several authors [2–4] the framework of Kirkpatrick was employed to distinguish different levels of effect, notably reaction, attitude, behaviour and organization [5]. A mix of different instruments was used in order to explain the effect on the levels of Kirkpatrick’s framework, such as observations, questionnaires and administrative data. Next to Kirkpatrick levels, the study design paid particular attention to practicalities of implementing CRM.

Two instruments had to be developed and validated to assess the constructs that were described in the study design. The first was a new observational method for assessing non-technical skills through quantifying explicit professional oral communication of healthcare professionals, called EPOC. The results, presented in Chapter 3, show good inter-observer reliability for the EPOC in two highly different settings. These findings indicate that the observers have been well-trained and that the framework is comprehensive and clear. Furthermore, it means that the EPOC is solid for use in scientific research and can be applied to other settings as well.

The second newly developed instrument was the SafeTeam questionnaire. The study presented in Chapter 4 demonstrates that this questionnaire has a high reliability and validity to measure, respectively the attitudes towards and behaviour regarding behaviours that optimise Situational Awareness (SA). Examples of these behaviours are monitoring whether everybody is still alert or asking for advice. Based on the hypothesis
that a positive attitude and more applied behaviours is associated with a better SA, this questionnaire can be used as a proxy to measure SA.

Aim 2: Implementation of CRM
Barriers and facilitators
The barriers and facilitators to follow up on CRM initiatives developed during the training were studied in Chapter 5. The findings show that support of the management for patient safety before the training is a positive determinant of the number of perceived facilitators after the training. A significant relationship was found between the perceived barriers and facilitators after CRM training and Taking action. The more barriers are perceived, the less action is taken; and the more facilitators are perceived, the more action is taken.

The analyses of the separate barriers and facilitators after CRM revealed that each healthcare level provides important determinants. The facilitators with the most impact are: Being convinced of the benefits of CRM (perception of the innovation), having everybody engaged with CRM (social context), and that CRM fits well with existing work processes (organizational context). Analogously, the most influential barrier is forgetting the content of the training (individual context).

These findings can be corroborated by existing literature. Greenhalgh et al. [6] postulate that being convinced of the benefits is a ‘sine qua non’ for further adoption. Weaver et al. [7] highlight the importance of engaging everybody during the implementation of a team training, especially the ‘socially powerful’ individuals. The importance of finding a fit is emphasized by Salas et al. [8] who describe that CRM training works best when the gap between knowledge and practice is bridged. They advise to use simulation. Additionally, Salas et al. state that CRM training should be recurrent and refreshed periodically, upon it is not forgotten.

Applied strategies to implement CRM
Chapter 6 demonstrates that all three ICUs that received CRM training successfully launched several initiatives, each using a different implementation strategy. Furthermore, all ICUs have taken several steps to sustain their approach for the foreseeable future. Despite the variety in strategies, three similarities can be seen between all three implementation processes that were crucial at the start of the implementation. Firstly, all units reported problems with communication during the orientation phase. This acknowledgment of a performance gap in communication is an indication that the participating ICUs, or at least the pioneers, possess a sense of urgency to change. This is an important first step for further implementation [9]. Secondly, all ICUs allocated structural time for quality improvement, even before CRM, and for change after CRM.
Thirdly, despite having different strategies, all units had a clear vision regarding their goals and strategies concerning CRM.

The results of Chapter 6 reveal that all three ICUs had a clear, yet different, vision on what they wanted to accomplish with CRM. This vision determined their follow-up process and resulting changes. The first ICU showed a strong resemblance to the system change framework of Kotter [10]. In this ICU they started with implementing ‘quick wins’, such as an additional white board. The implementation of the second ICU was characterized by integrating the development of checklists in the Comprehensive Unit-based Safety Program [11]. The implementation by the third ICU can be characterized with the social movement approach [12], in which CRM served as a ‘mutual vocabulary’ for existing initiatives.

All ICUs indicated that they used the plans of actions that were formulated during the CRM training as a starting point for their follow-up initiatives. The role of the coordinating nurse and the development of checklists are themes that recur in each ICU and are in line with CRM topics such as leadership and standardized communication [13]. All ICUs mention the costs of CRM and a lack of implementation expertise as important barriers during, respectively, the orientation and the change phase. The fact that CRM was perceived by the implementation leaders as a new and promising way to improve patient safety was regarded by all three ICUs as a facilitating factor for receiving CRM training, as too was the aspect that the whole staff was educated. Finally, all ICUs reacted very positively in the End-of-Course-Critique.

**Aim 3: Effectiveness and cost-effectiveness**

*Multi-layered evaluation of CRM using Kirkpatricks evaluation framework*

In Chapter 7 Kirkpattricks evaluation framework for training programmes [14] was used to assess the effectiveness of CRM training. This framework distinguishes four levels of evaluation: 1) reaction; 2) learning; 3) behavioural change; 4) organisational impact. The first reaction to the training was positive, however, three months after CRM participants attributed only a moderate change in their behaviour as a result of CRM. Attitudes towards tactics to optimise situational awareness, measured at the second level of the Kirkpatrick framework, were stable, despite a small and not significant increase in the intervention group. Self-reported behaviour regarding tactics to optimise situational awareness did improve as a result of CRM training. At the third level of the Kirkpatrick framework, there was no change in explicit professional communication.

The fourth and last level of the Kirkpatrick framework comprised multiple measurements. Patient outcomes such as length of stay and complications were not affected by the CRM training. Scores on the dimensions of the patient safety culture show
an upward trend in both the intervention and control departments. The way people respond to errors – the error culture – changed in the ICUs that received CRM training. In this group, respondents perceived themselves and their colleagues as being more aware regarding errors and being more socially oriented on the occasions they occur. Furthermore, after the training, participants responded that they thought it was important to overcome errors in the future and, to a lesser extent, be less error-aversive. These changes reflect the core principle of CRM of recognising and preventing errors, and mitigating the consequences when errors do occur. Job satisfaction and affective commitment increased in the intervention group,

Costs and cost-effectiveness
In Chapter 8 the costs and cost-effectiveness of a classroom based CRM training and its implementation in comparison with usual practice was evaluated. The results show that the costs are around 1000 Euros per staff member of the ICU attending the CRM training or on average 90 Euros per admitted patient when the costs are spread over one year. CRM training was not cost-effective in comparison with usual practice with regard to mortality, readmissions within 24 hours and length of stay.

GENERAL INTERPRETATION
This thesis provides insight in how CRM leads to effect and what this effect means. Based on the main findings, both aspects are subsequently discussed. First the working mechanism is discussed, followed by the interpretation of the effectiveness. Lastly, the recommendations following the interpretation will be stated.

The working mechanism of CRM
Based on the results presented in the current thesis it can be concluded that classroom based CRM training is a way to initiate, stimulate and/or facilitate quality improvement in health care, by raising awareness of, and creating a shared perspective on, the threats and opportunities in the work processes. CRM participants perceive that errors can be more openly discussed and try to anticipate possible risks. It can be argued that these changes make the staff more receptive for patient safety and quality improvement initiatives, and that CRM can even be utilized to develop such initiatives.

This mechanism is reflected by the finding that all three intervention ICUs developed and implemented their own locally-owned initiatives. The multitude and diversity in initiatives echoes the catalysing effect of CRM on new and existing quality initiatives. Furthermore, it indicates that CRM helps participants to recognize, address,
and handle safety issues. Therefore, CRM could be used to develop (non-)clinical interventions bottom-up as well as provide the necessary basis for these interventions.

The flexibility in the direction or choice which CRM follow-up initiatives are elaborated and implemented provides opportunities but also creates pitfalls. An advantage of this flexibility is that the initiatives can be tailored to the specific situation and can be integrated with existing programs. For instance, Tapson et al. [15] used CRM training to successfully enhance the appropriate use of venous thromboembolism prophylaxis in surgery. A pitfall of the flexibility is that a large number of CRM initiatives can be overwhelming and may lead to implementation exhaustion.

While providing the basis, improvements at the sharp end require a further implementation of CRM initiatives that go beyond the two days of training and a year-long course of activities of the CRM change teams after the training. In words of Maynard [4] “it [CRM] is not a one-time fix where an organization can send their staff members and physicians to the training and think everything will be fine.” It requires preparation and implementation, both of which require time and dedication. A clear vision on this multifaceted implementation process should form the base of the follow-up strategy. This strategy should probably be close to their own previous experience with the implementation of other projects. Structural time should be made available for preparation and implementation. The implementation should be tailored to the specific situation, depending on what goals are to be achieved using CRM.

During the process of implementation it is important to acknowledge that there are factors that impede or facilitate this implementation of CRM and the following initiatives. As Chapter 4 shows, it is important that everyone involved is convinced of the benefits, is engaged with CRM, does not forget the content and can apply CRM in daily work. In order to overcome the barriers and profit from the facilitators, such aspects should be considered before, during and after CRM training. Furthermore, acceptance of basic concepts may decay over time [16]. A strategy, as advised by Maynard et al. [4], could be to organize CRM meetings afterwards to repeat CRM theory, develop new initiatives and share best practices.

A next step for units that already have received CRM training could be the formation of a network of trained units to horizontally share information and knowledge, which in turn might evolve into a CRM community [17]. Within such a community units could evaluate each other in a peer-to-peer review, offering a voluntary, non-punitive, objective assessment of opportunities to improve [18]. This already partly exists in the form of internal audits and safety rounds. Pronovost and Hudson [18] argue that such reviews should internally motivate participants to optimise the quality of care. This
internal motivation should lead to better results than the minimum adherence based on external motivation in terms of rules and regulations.

**The effectiveness of CRM**

One of the reasons that instigated the present evaluation were the inconsistent findings of CRM on a behavioural and organizational level, as shown in a systematic review by Rabol and colleagues [19]. This thesis showed no changes in behaviour or patient outcomes, despite the fact that participants perceived errors and risks differently and all three intervention ICUs launched several CRM initiatives.

The explanation for this lack of effect in behaviour and patient outcomes can be found in the nature of CRM training itself. CRM, especially as applied in the current thesis but also in general, has a focus on creating awareness and not specifically to change behaviour in a certain direction. Rather, it stimulates participants to think of their own initiatives, for themselves, their team and their organization. Using the causal chain of Brown et al [20], CRM training can be perceived in this way as a generic intervention directed on organisational processes, rather than a specific intervention that is focussed on predefined clinical outcomes. This open bottom-up approach leads to a diverse range of follow-up initiatives varying from session to session and from ICU to ICU, as was shown in Chapter 6. This diversity has several implications.

Firstly, the effect of CRM is difficult to capture with one general outcome. All ICUs start with their own initiatives, each affecting different outcomes. Therefore, it is possible that an outcome, for instance the use of a checklist, would change in the one situation, but remained unaffected in the other. This exemplifies the difficulty in defining an outcome that is applicable in all units, especially when the evaluation is designed even before the training, in accordance with scientific discourse.

Secondly, it can be questioned whether general behavioural patterns, for example during a regular handover or routine procedures, is likely to change as a direct result of these focused interventions within the evaluation period of one year. It can be argued that these initiatives influence behaviour by changing the safety culture. When the implementation of CRM initiatives is perpetuated over time, it will change the way people think about issues regarding safety and quality. This resonates in the social norms, which partly determines behaviour [21]. Behavioural change through culture takes much longer than one year, for instance, in aviation it took around 40 years to gradually, but steadily, establish the safe culture that exists today [22]. However, once established, the change will be very robust.

Thirdly, even if all ICUs started with a similar intervention, the success of its implementation can still be influenced by other factors. Support of the management for
patient safety before CRM was received, was found to increase the number of facilitators to implement CRM initiatives (Chapter 4). Moreover, readiness for change is a known factor that influences whether or not new innovations will be adopted [23]. Another influence might be the level of implementation expertise. In Chapter 5, all ICUs experience difficulties in starting up the implementation of CRM initiatives after the training. It is reasonable to assume that CRM change teams that have a high level of expertise regarding implementation, will be more likely to have a successful adoption of CRM initiatives. Whether it is one of the above stated factors or yet another cause, the fact remains that the effect of CRM training is susceptible to such influences, that go beyond the training itself.

These explanations of the lack of effects of CRM training in the present thesis on behaviour and organization, should be taken into account when an evaluation is conducted. It would, for instance, be interesting to distinguish long and short term study objectives. With a shorter follow-up we recommend to focus on small and more specific interventions, ideally initiatives that were developed during the training. Such interventions are relative rapidly developed and quickly adopted in trained departments. Consequently, evaluation studies could focus on more specific errors or adverse events that are related to the topic of the specific intervention. When CRM is studied for a prolonged period of time, it can be expected that CRM is more embedded in the organization and there is enough time to develop and implement larger and more difficult interventions. Furthermore, the combined effect of the different interventions could have an impact on patient outcomes as length of stay.

With regard to the effectiveness and cost-effectiveness in terms of clinical outcomes future studies should consider to use an endpoint derived from the focus or content of the training. For instance, the Keystone ICU quality improvement programme had a broad scope, yet used central line-associated bloodstream infections as main example [24]. This allowed Herzer et al [25] to use these infections as primary outcome to successfully show the cost-effectiveness of the whole programme.

All in all, based on the results of the current thesis, we can conclude that the two-day classroom-based CRM training, as delivered in this thesis, does not change behaviour or patient outcomes by itself, yet changes how participants think about errors and risks. It is plausible that when CRM is combined with other initiatives, is prolonged over a period of time, and incorporated in a more focussed, multifaceted implementation strategy, it may have effect on behaviour and patient outcomes.
IMPLICATIONS

The newly derived insights based on this thesis lead to the following implications when either considering to apply CRM (implication for practise) or to evaluate the effect of CRM (implications for research).

**Implications for practice**

The most important implication for practice is that CRM can help participants to recognize, address, and handle safety issues. The multitude and diversity in initiatives reflect the catalysing effect of CRM on new and existing quality initiatives. In this way CRM can be utilized to start or to stimulate the optimisation of patient safety. This thesis does not recommend a specific implementation strategy, but highlights important aspects that should be taken into account when implementing CRM:

- **Be ready for CRM.** All ICUs acknowledged the existence of a performance gap, allocated structural time for CRM and had a clear vision on the implementation. With regard to the latter, it is important that adequate expertise on implementation is present.

- **Convince, involve, connect and repeat.** This thesis shows that these aspects are important to follow up on the plans of action that are formulated during the training.

- **Use the ideas that are developed during the CRM training.** All ICUs used these plans as a starting point for their follow-up initiatives. It ensures involvement and guarantees that it connects with existing work processes as it is bottom-up developed.

- **Calculate the costs.** The thesis estimates the costs of CRM on 1000 euro per participant, including preparation, implementation and personnel time during the CRM training. By using the cost calculation a more precise estimate for a particular context can be calculated. This provides an insight and creates awareness in the financial arrangements of CRM training and the subsequent implementation initiatives.

**Implications for research**

This thesis substantiates the argument stated in the general introduction and the second chapter of this thesis that CRM training focusses on latent, non-clinical, aspects [26] and has to be viewed as a generic intervention that generates specific interventions [20]. This is important when designing an evaluation of a CRM training, especially when the effect is
measured in clinical outcomes. Therefore, based on this thesis it is suggested to consider one of the following approaches when evaluating the effect of a CRM training:

1) **Concentrate the CRM training around a specific intervention**, for instance a checklist for handovers or a standard operating procedure for emergency situations. In this way it is possible to define endpoints before the training is conducted and perform a pre- and post-measurement. Additionally, this specific intervention provides a concrete example during the CRM training of how theory can be translated into practice. It is important that the specific intervention is the product of a detailed needs analysis at the start of the study design, as the focal intervention must connect with the CRM training, must be actual problem, and must be aligned with the needs of the personnel. Moreover, the specific initiative should be properly implemented, as CRM is not merely a button that can be pushed to attain certain outcomes. Furthermore, it will be hard to find a control department. A downside of this way evaluation is that it narrows the open and bottom-up approach compared to a training that is not concentrated around a predefined intervention.

2) **Implement a safety initiative independent of the training**. This independent safety initiative should be implemented in an intervention (with CRM training) and control (without CRM training) group with equal efforts to implement the initiative. The hypothesis with this approach would be that a CRM trained department will adopt this new initiative earlier with a higher sustainment, based on their newly derived insights of the CRM training. Ideally a pre-and post-measurement is conducted in both intervention and control group.

3) **Use endpoints that are mentioned during the CRM training**. With this approach the endpoint are perfectly aligned with the training. The baseline measurement should be conducted directly after the training, in order to minimize the influence of the training. This baseline measurement could in turn be used to provide input for the development of the intervention that was mentioned during the CRM training. Downside of this approach is having no control group and that intervention and measurement are dependent.

**METHODOLOGICAL CONSIDERATIONS**

Although the present study was carefully designed and tried to learn from previous flaws in design and methods, some methodological considerations have to be mentioned. The number of ICUs that received CRM training is limited. In order to broadly assess effectiveness, the present study used a mixed method approach and closely monitored
the participating ICUs. This enabled us to draw conclusions from multiple instruments and perspectives and to seek justification in these conclusions. This process is called triangulation and is the major benefit of a mixed method [27]. The downside of this approach is that it is time-consuming, thereby limiting the number of ICUs that could be included, especially because the current study is bound to a maximum duration of three years as a prerequisite of the governmental fund that made this study possible. This limitation on the number of participating ICUs is unfavourable in terms of the statistical power of the study. The benefit, however, was that there were enough ICUs willing to participate in the present study as a control unit, which enabled a thorough selection process to take place so that the best match for the intervention units could be made.

Although the mere presence of a control group is a methodological strength, it is a limitation that the experimental condition of intervention and control was not randomized. Randomization was impossible since only four ICUs, including the pilot ICU, were able to meet the organisational and financial requirements of being an intervention unit. This level of commitment of intervention units was essential to ensure a close resemblance with the situation in which there was no study. Furthermore, it ensured that the ICUs were motivated and receptive for change. Since such motivation is a known factor for successful implementation [23], it should be taken into account as a contributing factor of the initiatives that were developed after the training. We selected the most comparable department from the remaining sample. Thus, we successfully performed a paired controlled trial, but randomisation was not possible, which limits the validity of our results and may have resulted in an overestimation of effects. On the other hand, we gained pragmatic value, because in practice departments need to be ‘ready’ for an intensive intervention like CRM, which was certainly true for the departments that met our criteria. In addition, the control departments were still of great value since they reflected the influence of direct observations in a department as well as the influence of the national patient safety campaign. Moreover, in Chapter 8 a false positive effect of CRM on mortality was identified based on the data of the control departments.

Unfortunately, we were unable to assess errors, incidents, or adverse events as a measure of patient outcomes. A pilot study showed that it was not possible to observe adverse events without detailed knowledge of the patient and intensive care expertise. Therefore the registration of complications that is supported by the National Intensive Care Evaluation (NICE) was used. However, this registration was still in its infancy, and therefore did not provide useful and reliable data. It was, however, possible to determine reliable quality indicators such as length of stay, death on the ICU, and readmissions within 24 hours, with detailed patient mix correction. We expect these indicators to behave in the same way the complications would have, if measured reliably. Based on this
line of reasoning it is not likely that we would have found a reduction in incidences or adverse events as a result of the training within this time frame. It seems that CRM needs more time to have an impact on general terms as incidences or adverse events.

Both newly developed measurement instruments, the EPOC observation tool and the SafeTeam questionnaire, should be further validated by comparing the results with other assessments. Moreover, both EPOC and SafeTeam were administered in Dutch in a Dutch population. Although, we carefully translated both instruments into English, we have not yet been able to replicate the study with an English population in order to check the translation and the cross-cultural validity.

The last methodological consideration is the fact that CRM training is not always similar across studies, which should be taken into account when generalizing the results to other settings. In the current thesis the training is classroom based and consists of two consecutive days of training. The main principle of human error is mostly similar across described CRM interventions, as well as most content areas, such as communication, team leadership and situational awareness [4]. Differences, however, can be found in a lot of aspects: The exact format, focus and elaboration of the content; The length of the training; Whether the training is held in separate sessions over a period of time or at once; The extent to which simulations are part of the training; Whether it is unit based or part of a large multicentre programme; Whether the whole staff receives CRM training or only a few as part of a train-the-trainer programme.

CONCLUSION

All in all, it is promising to note that all three ICUs in the current thesis, despite their own barriers, visions, strategies, and an overload of measurements, developed multiple quality improvement initiatives and aim to continue doing so.

REFERENCES
