I’m sinking in the quicksand of my thought
And I ain’t got the power anymore

*David Bowie, Quicksand (1971)*

**CHAPTER 1**

**GENERAL INTRODUCTION**
Rationale and Aims

Evidence-based Guidelines

Quality of care for patients has become an important health care issue, not only for patients and caregivers, but also for managers, policy makers, health insurance companies and ministries of health. One of the most important instruments in improving and justifying patient care is the development of evidence-based medicine (EBM) which is defined as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients”[1]. The foundation of EBM was laid down in 1972 with Cochrane’s research report “effectiveness and efficacy”[2] in which he advocated the use of clinical epidemiology and controlled studies when assessing the effectiveness of medical treatments. His observations resulted in the thorough evaluation of health care interventions, and the use of randomized controlled trials and systematic reviews when deciding on the effectiveness of a medical intervention. Medicine became evidence-based instead of observationally or anecdotally based. Empirical findings are used to bring order with regard to the appropriateness of interventions. Interventions with the highest level of evidence (level A: meta-analysis or randomized controlled trials) are deemed more appropriate then interventions for which only consensus evidence is available (Level D: expert consensus). When all evidence on a specific topic is systematically collected and summarized into statements to assist practitioners and patients to make the most appropriate health decision, we speak of evidence-based guidelines[4].

The last decade saw the development of evidence-based guidelines in all forms of health care[4]. Increasingly, health professionals make clinical decisions for individual patients based on clinical guidelines. Health spending of governments and health coverage by insurance companies nowadays are mostly guided by EBM[4-6]. The current interest can be motivated in different ways: the ambition to provide the best possible care, rapid developments in the field of medicine, an acknowledgment of inappropriate care because of variations in care provided, and the continuous rise of health care costs that lead to the demand for more efficient treatments[1].

Evidence-based Guidelines in Mental Health Care

In the field of psychiatry, a number of evidence-based guidelines have been made available over the last twenty years[7]. Several authors stress that guidelines in mental health care are often based on lower level evidence when compared to other health guidelines due to the multidisciplinary character, ethical issues, and the nature of the interventions in mental health care[8-10]. For EBM, randomized controlled trials (RCT’s) are the gold standard. However, when dealing with highly vulnerable psychiatric patients, such as suicidal patients, randomization, or not intervening when necessary is regarded as unethical[11, 12, 13]. Excluding suicidal patients from RCT’s is common practice. Blinding of participants to randomization in psychotherapy trials is also not possible due to the nature of the intervention. Also, within nursing, RCT’s are simply not standard[8, 14]. These and several other arguments are problematic for the development of pure evidence-based guidelines in multidisciplinary mental health care. Still, the EBM methodology offers a good starting point.

Multidisciplinary Guidelines in Dutch Mental Health Care

Dutch mental health care was relatively late in developing guidelines[8, 15]. The first Dutch guideline on the treatment of depression in mental health care was released in 1997 and was largely monodisciplinary. During a conference organized by the Ministry of Health in 1998, it was acknowledged that guideline development is a complex process that demands the collaboration of all professions involved with patient care[8, 13]. The five main disciplines in Dutch mental health care (psychiatrists, general practitioners, psychotherapists, clinical psychologists and psychiatric nurses) took the lead in formulating multidisciplinary evidence based guidelines. Technical and secretarial support was offered by the CBO (Quality institute for Health Care) and the Trimbos-Institute (Netherlands institute for mental health and addiction). Since then, 15 Dutch multidisciplinary guidelines have been produced[15].

The Need for a Dutch Guideline on the Assessment and Treatment of Suicidal Behavior

In the Netherlands, about 1600-1800 persons a year die by suicide, and it is estimated that 99,600 suicide attempts take place annually[16]. Each year, 15,000 patients are treated in emergency departments, and 9000 are hospitalized after an attempt[17]. A recent study on disability weights placed suicide and suicide attempts at 11th on the list of most burdensome diseases in the Netherlands. This places the burden of suicidal behavior on patients between dementia and breast cancer. Also, suicidal thoughts are considered
to be as disabling for patients as alcohol dependence and severe asthma, and the burden after non-fatal suicide attempts is thought to be comparable to the burden of heroin dependence and initial stage Parkinson's disease.

Suicide has a great impact on society. The emotional impact on people bereaved by suicide is enormous, and relatives of suicide completers show a heightened risk for suicidal behavior. In the Netherlands, the direct medical costs for treatment of the 15,000 patients treated every year after suicide attempts in emergency departments are estimated to be around 36 million euro a year. However, direct costs are only a part of the financial burden of suicide. To calculate the total costs per suicide, three types of costs are to be taken into account; direct costs (e.g. demand on emergency services, funerals), indirect costs (loss of contribution to economy via paid work, family responsibilities) and intangible costs (pain and grief of family, loss of chance to experience all that life holds). In the UK, estimated total costs per suicide range from 1.5 million euro to 1.7 million euro. No comparable economic studies have been done to estimate the costs of suicide ideation, but given the costs of depression, which reportedly 90% of people with suicide ideation suffer from, the costs are likely to be large. A recent cost-effectiveness analysis of a web-based self-help program to reduce suicide ideation reported that for each significantly improved individual, €34,727 of societal costs were saved.

Although attempted suicide frequently occurs in Dutch Mental Health Institutions (MHI’s), up until 2012 there was no national evidence-based guideline on the assessment and treatment of suicidal behavior. The assessment and treatment of suicidality was dealt with only to a limited extent in other mental health guidelines (such as those for depression or schizophrenia). The depression guideline for general practitioners also only briefly dealt with suicidal behavior. Individual professionals could only adhere to foreign guidelines such as the guidelines from the American Psychiatric Association or the British National Institute for Health Care and Excellence. Local guidelines were available in a limited number of MHI’s and when available, lacked important elements. Results of the analysis of 505 completed suicides in Dutch mental health care services suggested that quality of care for suicidal patients could be improved by implementing clear standards for the assessment and treatment of suicide risk. Furthermore, international guidelines suggested that the risk assessment of suicidal behavior should be carried out systematically. It was also reported that many mental health professionals are not adequately trained in suicide prevention during postdoctoral training and therefore lack confidence and knowledge in dealing with suicidal behavior. Furthermore, after a suicide, professionals were anxious regarding the inspectorate of health care because it was unclear what criteria were used to determine adequate care for suicidal patients.

Based on these findings, one of the most important recommendations in the advice on policy given to the Ministry of Health on the strengthening of suicide prevention was the development of a separate guideline on the assessment and treatment of suicidal behavior. This national guideline should combine state-of-the-art scientific evidence with expert consensus and also consensus knowledge of patients and their family. When developed and authorized by the professional organizations of psychiatrist, psychologists and nurses, it could serve as the starting point for local protocols and guidelines in Dutch mental health care.

The Multidisciplinary Evidence Based Practice Guideline on the Assessment and Treatment of Suicidal Behavior

This policy advice resulted in the development of the Multidisciplinary evidence based practice guideline on the assessment and treatment of suicidal behavior (PGSB). The PGSB has been produced by representatives of the Netherlands Psychiatric Association (NVvP), the Dutch Association of Psychologists (NIP) and the Dutch Nurses’ Association (V&VN). Representatives of the Dutch College of General Practitioners (NHG) were also involved, as were representatives of patient participation organizations and organizations for relatives bereaved by suicide. The development process was supported by the National Institute of Mental Health and Addiction in the Netherlands (Trimbos Institute). The project was funded by the Netherlands Organization for Health Research and Development (ZON-MW). The EBRO-format was used, which itself is based on the AGREE-method. The EBRO-format emphasizes the evidence-based character of guidelines by translating practice-based issues into concrete questions, which are responded to by a summary of the available evidence. International suicide guidelines such as the suicide guideline of the American Psychiatric Association, the New Zealand Guideline Group and the National Institute for Clinical Excellence (NICE), served as starting points for literature searches, in addition to extensive reviews by the Scottish Government and up-to-date research on the assessment and treatment of suicidal behavior. Conclusions are formulated and a four-fold classification of the level of evidence ranging from level 1 (strong evidence, highly recommended or dissuaded) to level 4 (reflecting experts’ opinions) is provided. Recommendations are provided in terms of (professional) behavior according to available evidence, weighted or not by relevant considerations based on experts’ opinion and/or clinical experience. The PGSB combines the stress-diathesis model and the entrapment model of suicidal behavior to explain the onset and maintenance of suicidal behavior. The integrated model depicts suicidal behavior as the outcome of a process influenced by the interaction of biological, psychological, environmental and situational factors.
Factors. The interaction of which may lead to entrapment. Entrapment is proposed to be the specific condition in which suicidal behavior arises. The PGSB recommends systematic investigation of the suicidal condition of patients by using the Chronological Assessment of Suicidal Events (CASE) interview. Based on its outcome, risk and protection factors for suicide in individual patients are weighted. Subsequently, structured diagnosis, treatment strategy and a safety protocol are determined.

**The Irony of Implementing Guidelines**

In addition to the development of the guideline, the policy advice on the strengthening of suicide prevention also stressed the importance of structured implementation of the guideline. There is a well-known gap between guideline development and implementation of the guideline in daily medical practice. Despite the current development and dissemination of evidence-based guidelines, patients do not always receive appropriate care. For example, although Cognitive Behavioral Therapy (CBT) is recommended in the United Kingdom, the USA and Australia as an effective therapy for anxiety and unipolar depression, evidence is found that few patients receive CBT and that it is often delivered sub-optimally. Studies on both sides of the Atlantic estimated that 30-40% of the patients do not receive optimal care, and 20-25% of the care provided is not needed or even harmful. Multiple structural factors at both professional and organizational levels, such as lack of knowledge, poor outcome expectations, material support, funding and time were found to be common barriers. Guideline implementation is argued to improve adherence to mental health guidelines. The irony is that we have limited evidence-based knowledge or consensus on how to best implement guidelines. Guideline implementation strategies are more often based on the preference and availability of strategies than on evidence on its effectiveness. For example, in the Netherlands, a package of multifaceted implementation strategies (Quality improvement collaborative: QIC) is popular when implementing guidelines in mental health care. However, a systematic review including 72 studies, of which only 2 were randomized, demonstrated that QIC had positive but limited results. Another systematic review on implementation of psychiatric guidelines found a modest effect of implementation on quality of care and patient outcome, but stressed the need for more randomized studies on the effect of implementation on both patient and physicians level. The lack of evidence-based implementation strategies was first noted by Grol in 1999. In 2004, it was concluded that progression had been made. Current interventions did result in clinically important practice changes, although an empirical tested base is still lacking. The suggested way forward is to develop interventions which potential effectiveness on health care professionals and patients is based on solid theory. Next, these carefully constructed interventions should be preferably tested in Randomized Controlled Trials with outcomes assessed at the professional, patient and organizational levels.

**PITSTOP Suicide**

To implement the PGSB in Dutch mental health care, we reviewed the literature on implementation strategies and suicide prevention training programs. Based on our findings which are described in detail in chapter four, we developed an e-learning supported Train-the-Trainer program (TtT-e) to be delivered to the staff of psychiatric departments to implement the PGSB. The Train-the-Trainer model is based on the Adult Learning Theory stating that the best resource for learning comes from peers, and on the Diffusion of Innovation Theory stating that people adopt new information better through their trusted social networks. TtT-e combines a one-day face-to-face training program with an additional e-learning module. This form of blended learning is used extensively in medical education and has been found to be more effective when compared with traditional instructor-based training only. Suicide prevention training has been shown to improve knowledge, skills, and attitudes towards suicidal behavior of both gatekeepers and mental health professionals. Additionally, professional and gatekeeper training in diagnosis and treatment of depressive disorders, which are associated with suicidal behavior, has been shown to result in a reduction of suicide rates. The best comparable initiative to the study proposed here is an ambitious Train-the-Trainer program in the US Air Force Suicide Prevention Program. This initiative included a series of training programs on best practice guidelines that ultimately reached 75% of mental health providers in the US Air Force. At the 6 month follow-up, 44% of trained professionals reported increased confidence in assessing suicide risk, 54% reported increased confidence in managing suicidal patients, 83% reported changing suicide care practices, and 66% reported changing clinic policy in direct response to the training. Importantly, the number of suicides was significantly lower after the intervention than before. The actual number of suicides fell from 68 in the year before the program to 20 in the year after the program. Follow-up data demonstrated a decline of 20 percent in suicide rate from 1998 to 2008 with the exception of one year. This demonstrates that training of professionals in suicide prevention skills can improve the quality of care, and even result in less suicidal behavior.
E-learning

Advances in technology, the rise in costs of health care and the need for continuous education of (para)medical professionals have made e-learning a popular new educational method. E-learning is proposed as a solution to disseminate evidence based psychological treatments on a global scale. Relatively little is known about how to best develop an effective e-learning module on a psychiatric topic. User preferences and effects on outcomes remain unclear, as most developers do not report any data on effectiveness. As the demand for e-learning in mental health is rapidly increasing, and policy makers advocate the use of e-learning to reduce costs, it is of importance to evaluate earlier modules so new modules can benefit from previous experience. In this thesis, we will evaluate the e-learning module that was developed to support a Train-the-Trainer program to implement the PGSB among mental health professionals.

Multicenter Cluster Randomized Trial

It is difficult to test the effect of guideline implementation in an RCT. Implementing guidelines in departments is already time consuming and expensive. It takes some effort to convince departments that are in need for training in suicide prevention to be randomized, and therefore to have a 50% change of having to do several assessments without receiving any training. However, due to the lack of RTC’s, there is still little evidence on effective implementation. To more rigorously test the effect of a multifaceted implementation intervention, we decided to test the effect of our intervention in a randomized trial. For the PITSTOP suicide trial, Mental Health institutions were invited to provide departments for participation during nationally supported meetings and conferences on suicide prevention in the Netherlands from January 2009 until December 2011. Departments were considered eligible for participation if they treated patients aged ≥18 years, if professionals considered there was a need for training in suicide prevention skills, if the training was supported by the institutional board and if institutions were willing to accept costs due to loss of production. Eligible departments were matched in pairs based on primary patient diagnoses and average treatment duration. Members of matched pairs were randomly allocated to either implementation as usual (IAU: control) or IAU + TtT-e (intervention). Outcomes were assessed at the professional, patient and organizational level. We hypothesized that professionals, patients and organizations would benefit from TtT-e.

The Assessment of Suicide Ideation

The primary outcome of our study is change in suicide ideation. We hypothesize that patients treated by multidisciplinary teams who were trained by the TtT-e program would recover more quickly from suicidal ideation as compared with patients treated by multidisciplinary teams who were not trained. Assessing suicidal thoughts is difficult for various reasons. Medical ethical committees are concerned that asking about suicidality might heighten suicide risk, making them more reluctant to improve research involving suicide items. Also, answering questions about suicide, especially at intake, might be burdensome for both patients and interviewers and result in dropout. The assessment of suicidal thoughts would benefit from short and reliable assessment tools. An important element of this thesis was to try to optimize the Beck Scale for Suicide Ideation by using techniques from modern test theory. The test theory most scientists and clinicians use to draw conclusions from questionnaires is the Classical Test Theory (CTT). In CTT, all item scores are summed to a total score that reflects the level of a participant on the latent trait. Although intuitively very strong, CTT has been unsatisfying for various reasons. Person and item characteristics cannot be studied separately, and the standard error of measurement is assumed to be the same for all participants. Questions that cannot be answered using CTT are for example: can a test be shortened without losing discriminating validity or do respondents interpret a given scale in a conceptually similar way over time. Latent variable theory, modern test theory or “new psychometrics” does allow us to answer this type of question. Instead of summing all items to a single total score, mathematical models express the association between an individual’s response to an item and the underlying latent variables.

We applied modern test techniques to test 1) if the 19 item Beck scale for Suicide ideation can be shortened without losing discriminative validity when classifying patients as being at elevated risk for suicidal behavior and 2) whether participants have the same conceptual understanding of suicidal behavior at baseline and 3 month follow-up (whether the scale is measurement invariant). Finally we conducted a randomized trial among students to assess the impact of responding to the Beck Scale for Suicide Ideation among healthy participants on their mood.
Outline of the Thesis

This thesis is divided into three parts. The first part (chapter 2-4) is about the development of the intervention and the different hypotheses of the trial at the three different levels: the professional; the patient and the organizational. The second part (chapter 5-9) describes the results of our intervention at these different levels. The third part (chapter 10-12) focusses on the improvement of the assessment of suicide ideation. In more detail, chapter 2 describes the design and hypotheses of the PITSTOP suicide study at both the professional and organizational level. We hypothesize that attitudes, knowledge, skills, competence and confidence of mental health care professionals towards suicidal behavior are more likely to improve by the application of an e-learning supported Train-the-Trainer program when compared to implementation as usual. Chapter 3 describes how we assessed both the clinical and the cost outcomes at the patient level. We hypothesized that individual suicidal patients treated by professionals who were trained by would recover more quickly from suicidal ideation as compared with patients treated by professionals who were not trained via our intervention. Next, we examined whether our intervention can be regarded as cost-effective compared to implementation as usual with regard to change in suicide ideation and change in quality of life. Chapter 4 offers a detailed description of the rationale and outline of our intervention taking existing similar programs and international research into account. Chapter 5 reports the results of our intervention on professionals thereby testing the hypotheses described in chapter 2. In chapter 6, we show the results of our intervention at the patient level as described in chapter 3. Cost-effectiveness outcomes are described in chapter 7. Via interviews with key players of mental health institutions we investigated the impact of our intervention on the implementation of the guideline, and the effects of the intervention at the organizational level to which we referred already in chapter 2. Chapter 9 provides a post-hoc evaluation of our e-learning module. The module was offered additional to the face-to-face training, and we aimed to describe the feasibility of e-learning among mental health professionals. The last part of the thesis focuses on the assessment of suicidal ideation. Chapter 10 offers a computer adaptive simulation on Beck Scale of Suicide Ideation. Chapter 11 further validates the Beck scale for Suicide Ideation by testing its measurement invariance. Chapter 12 tested the possible negative effect on mood of answering questions about suicide.

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