Tailored implementation strategies in nursing care

The implementation of the (S)AE-guideline

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Status:	Definitief onderzoeksverslag
Datum:	05-07-2012
Beoogd tijdschrift:	Journal of Advanced Nursing (JAN)
Aantal woorden:	3493
Aantal woorden vlg. tijdschrift	5000
Aantal woorden summary:	300
Aantal woorden samenvatting:	299
Referentiestijl:	Harvard
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Stage-instelling	MUMC+, Maastricht, afdeling CardioResearch

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NEDERLANDSE SAMENVATTING

Titel: Tailored implementatie strategieën in de verpleegkundige zorg: de implementatie van de (S)AE richtlijn.

Inleiding: Om verpleegkundigen en onderzoeksassistenten te onderstenen bij het herkennen en melden van AE's en SAE's, werd de (S)AE richtlijn ontwikkeld. In eerdere studies werden de interventies om deze innovatie te implementeren geselecteerd op basis van barrières of potentiële barrières, maar zonder het gebruik van een theoretisch raamwerk. Verder onderzoek is daarom nodig naar het gebruik van theorie om de implementatiestrategie voor de (S)AE richtlijn te tailoren.

Doel: Om de meest geschikte, op theorie gebaseerde tailored implementatie strategie te bepalen om de (S)AE richtlijn te implementeren, en om de verpleegkundige uitkomsten op individueel en groepsniveau te evalueren van de tailored implementatie van de (S)AE richtlijn, bij verpleegkundigen en onderzoeksassistenten op een research afdeling.

Onderzoeksvraag: Wat zijn de verpleegkundige uitkomsten op individueel en groepsniveau van de implementatie van de (S)AE richtlijn, door gebruik te maken van een op theorie gebaseerde, tailored implementatie strategie, op een research afdeling?

Methode: Een single case studie. De onderzoekspopulatie bestond uit onderzoeksverpleegkundigen en –assistenten werkzaam op een research afdeling. Het contingentiemodel van van Linge (2006) werd gebruikt om de implementatie strategie te tailoren, die bepaald werd door middel van de WIK en WAK vragenlijsten. Drie maanden na de implementatie werden de uitkomsten gemeten door de 'vragenlijst naar knelpunten en behoeften' en een focus groep interview.

Resultaten: De evolutiestrategie was de best passende implementatie strategie. De vragenlijst naar knelpunten en behoeften lieten positieve resultaten zien. Het focus groep interview liet zien dat de richtlijn correct was gepresenteerd, maar ze gebruikten deze niet.

Conclusie: De verpleegkundige uitkomsten op individueel en groepsniveau van de tailored implementatie van de (S)AE richtlijn zijn redelijk positief.

Aanbevelingen: Een langer durende vergelijkbare case studie word aanbevolen met herhaalde metingen van zowel procesverloop als implementatie-uitkomsten op individueel en groepsniveau.

Trefwoorden: Tailored implementatie, verpleegkundige zorg, case study.

ENGLISH ABSTRACT

Title: Tailored implementation strategies in nursing care: the implementation of the (S)AE-guideline.

Introduction: To support nurses and research assistants to recognize and report AE's and SAE's, the (S)AE guideline was developed. In earlier studies, the selection of the interventions to implement this innovation is mainly chosen on identified barriers or potential barriers, but without the use of a theoretical framework. Therefore, further research on the use of theory to tailor the implementation strategy for the (S)AE guideline is necessary.

Aim: To determine the most appropriate, theory based tailored implementation strategy to implement the (S)AE guideline, and to evaluate the individual and group nursing outcomes of the tailored implementation of the (S)AE guideline among nurses and research assistants at a research department.

Research question: What are the individual and group nursing outcomes of the implementation of the (S)AE guideline among nurses and research assistants, by using a theory based tailored implementation strategy, at a research department?

Method: A single case study. The study population included research nurses and research assistants working at a research department. The contingency model of van Linge (2006) was used to tailor the implementation strategy which was determined by the WIK and WAK questionnaires. Three months after the implementation, the outcomes were measured with the Barriers and Facilitators assessment instrument and a focus group interview.

Results: The evolution implementation strategy was chosen to be the most appropriate implementation strategy. The Barriers and Facilitators instrument showed positive results. The focus group showed that the guideline was presented properly, but they did not use the guideline.

Conclusion: The individual and group nursing outcomes of the tailored implementation of the (S)AE guideline are rather positive.

Recommendations: A longer lasting similar case study is recommended with repeated measures of both process development and implementation outcomes at the individual and group level.

Keywords: Tailored implementation, nursing care, case study.

INTRODUCTION

There is an increase in research tasks performed by nurses. These nurses work under different names, such as research nurses or research assistants, and for different specialties or sponsors. Although many tasks overlap with general nursing, it has grown into a defined specialty with specific objectives and justifications (V&VN, 2011).

One of the tasks of a research nurse is to report Adverse Events (AE), and Serious Adverse Events (SAE) to the sponsor of the specific study. AE are any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product but which does not necessarily have a causal relationship with this treatment (Pieterse, 2010). SAE are any untoward medicinal occurrence or effect that at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing inpatients' hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect or is a new event of the trial likely to affect the safety of the subjects (Pieterse, 2010).

Adverse Events and Serious Adverse Events are important factors in conducting clinical trials. To support nurses and research assistants to recognize and report AE's and SAE's, the (S)AE guideline was developed at a research department in an academic hospital in the south of the Netherlands.

Nurses are increasingly engaged with implementation of innovations. An innovation is an idea or object that is perceived as new by an individual or unit of adoption (Rogers, 2003). Implementation is defined as a process-oriented and planned execution of structural innovations and/or (evidence based) improvements in professional practice, within the functioning of an organization or the structure of health care (Hulscher et al., 2000). The grounds of this increased engagement might be a result of the environment of the (nursing) policies within the health care organizations, the personal motives and ambitions of nurses, and the nursing profession (van Linge, 2006). Two systematic reviews on the effect of strategies to implement evidence based innovations in nursing care were conducted (Francke et al., 2008; Hakkennes & Dodd, 2008). It is important to first identify specific barriers to change using theoretical frameworks of behavior change and then develop strategies that deal with these barriers. The review of Davies et al. (2010) also concluded that the use of theory is needed to understand barriers in implementation research. Based on these reviews, professionals are increasingly interested in tailored implementation strategies, which are strategies to improve professional practice that are planned taking account of prospectively identified barriers to change (Baker et al., 2010).

The (S)AE guideline is such an innovation and there are several models to implement this guideline stepwise in health care by using a tailored strategy. One of them is the innovation

contingency model (van Linge, 2006) which assumes that a relationship between the demands of the innovation and characteristics of the context is necessary for a successful implementation. Factors which influence the effectiveness of implementation of innovations might be related to individuals, social environment, organizations, and the societal environment (Grol & Wensing, 2006).

Research has shown that in most of the studies, the selection of the interventions to implement innovations is mainly chosen on identified barriers or potential barriers, but without the use of a theoretical framework (Van den Boogaart et al., 2009; Pagliari et al., 2003; Foy et al., 2004). Such a framework is necessary to understand the relationship between barriers and to make a decision about the best interventions to influence these barriers positively (Hakkennes & Dodd, 2008; Davies et al., 2010). Because most of the studies did not use a specific theoretical framework, it is unclear whether the barriers were interpreted properly. As a result, the selection of interventions tailored to these barriers might be wrong. Therefore, further research on the use of theory to tailor the implementation strategy is needed.

PROBLEM STATEMENT

Research has shown that the selection of the interventions to implement innovations is mainly chosen on identified barriers or potential barriers, but without the use of a theoretical framework. This decreases the strength and efficiency of the implementation. Therefore, further research on the use of theory to tailor the implementation strategy for the (S)AE guideline is necessary.

AIM

The aim of this study was to determine the most appropriate, theory based tailored implementation strategy to implement the (S)AE guideline, and to evaluate the individual and group nursing outcomes of the tailored implementation of the (S)AE guideline among nurses and research assistants at a research department.

RESEARCH QUESTION

What are the individual and group nursing outcomes of the implementation of the (S)AE guideline among nurses and research assistants, by using a theory based tailored implementation strategy, at a research department?

METHOD

Study design

A single case study was conducted, because the focus of this study was to develop an in-depth description and analysis of the case (Creswell, 2007). In this study, the case consists of the tailored implementation strategy which was studied at a research department. At this department, many new activities are implemented (i.e. studies) and there is a high interest for conducting research. Although most case studies collect qualitative data, the use of quantitative data is also possible (Polit & Beck, 2008; Yin, 2009). In this study, quantitative and qualitative data was collected to increase the validity of the measurement of the implementation outcomes.

The contingency model of van Linge (2006) was used to tailor the implementation strategy (see figure 1). This model assumes that discrepancies between necessary and existing conditions determine the actual implementation strategy (van Linge, 2006). The contingency model exists of three theoretical fundaments. First, the configuration approach which is a dynamic system approach where the base is formed by basic beliefs and needs. Several systems are involved in innovation processes, such as the innovation, the organization where the innovation process takes place, the external environment, and the involved persons. There is a strong configuration when the beliefs and needs match the explicit values of the system and the operational features. Second, theories about the existence of layers of systems. Innovations have operational characteristics, explicit values and the basic concepts that underlie an innovation. Third, the strategy contingency approach which stated that there is no best way to innovate, but several ways which can be effective, but under different circumstances.

For a successful implementation of the innovation, a fit between the innovation, the organizational characteristics, the characteristics of people and the environment must be realized.

[Figure 1]

The duration of the study was five months, from January 2012 until May 2012
The development of the (S)AE-guideline was finalized in January 2012.
In February 2012, the tailored implementation strategy was determined. When the strategy was finalized, the guideline was implemented according to that strategy. In May, data were collected to evaluate the outcomes of the implementation and the implementation process. Table 1 presents an overview of the procedures.

[Table 1]

Population

The study population included research nurses and research assistants working at a research department. Research nurses and research assistants were included if they: 1) were in the possession of the BROK-certificate (Good Clinical Practice course; in Dutch: Basiscursus Regelgeving en Organisatie voor Klinisch onderzoekers certificaat); 2) worked at least two months at the CardioResearch department. After two months, new staff is adequately incorporated to independently perform work activities; 3) worked at least 12 hours per week at the CardioResearch department; 3) had the authority to notify (S)AE to the relevant institutions.

Research nurses and assistants were excluded if they: 1) were planned not to participate in the study (pregnancy, change of job, change of function at the department).

Sample size calculation

The greatest strength of case studies is the depth that is possible when a limited number of individuals are being investigated (Polit & Beck, 2008). Although there are no rules for sample size (Yin, 2009), a minimum number of five participants were necessary to determine the implementation strategy and to evaluate the outcomes of the implementation. Due to the small number of nurses and assistants, all who met the inclusion criteria were invited to participate in the study.

Data collection

Data were collected at two moments, at baseline and at three months follow-up. See table 2 for an overview of the data collection. At baseline, the data to determine the implementation strategy were collected by questionnaires.

[Table 2]

To determine the implementation strategy, the observed innovation characteristics (WIK), and the observed department characteristics (WAK) were measured with validated questionnaires developed by the research group 'invoering van verpleegkundige innovaties' of the nursing science department, University Utrecht. The results of these questionnaires indicate one or more configurations that lead to a configuration profile: the regulation-oriented team/innovation configuration (α 0.87), the goal-oriented team/innovation configuration (α 0.76), the team-oriented team/innovation configuration (α 0.91), and the development-oriented team/innovation configuration (α 0.89). The questionnaires

consists of 12 items each to answer on a five point Likert-scale: fully disagree (score 1), disagree (score 2), do not agree nor disagree (score 3), agree (score 4), and fully agree (score 5).

When the decision was made about the implementation strategy, the guideline was implemented at the CardioResearch department. The principle investigator (LA) was responsible for the execution of the implementation.

Because of the deadline to conduct the study, the outcomes of the implementation were measured three months after the start of the implementation, by the Barriers and Facilitators assessment instrument (Peters et al., 2002). The barriers and facilitators for change were based on a literature study by Peters et al. (2002), and an expert panel consensus procedure. Items found were divided in four categories: innovation characteristics (α 0.65), care provider characteristics (α 0.63), patient characteristics (α 0.68), and characteristics of the organizational, social, political and societal context (α 0.66). The items were translated into questions and the instrument was tested.

The instrument consists of 17 general questions about the implementation of guidelines or innovations which can be changed in such way that they address the specific guideline or innovation and time of measurement. The questions were answered on a five point Likert-scale: from fully disagree (score 1) to fully agree (score 5).

It was intended that the questionnaires could be completed during working hours.

To evaluate the implementation process, a focus group interview took place among the participants at the research department (van Linge, 2006). The invitation was sent by e-mail. The topics of the interview are presented in table 2.

The interview was performed by the principal investigator and took about one hour. It was intended that it took place during working hours. Questions that were asked in the interview were: 1) *Did you used the guideline?/Were there opportunities to use the guideline?* 2) *Is the guideline easy to find?* 3) *Were there any barriers to the use of the guideline?*

Ethical considerations

The study was conducted according to the principles of the Declaration of Helsinki (October 2008), and the Wbp (Personal Data Protection Act) (July 2000). Permission to conduct the study at the research department was given by the head of the department.

Subjects who met the inclusion criteria were informed by the investigator at a general meeting. All invited nurses and assistants received information about the study and the

informed consent form. A week time was given to consider their decision. The subjects were asked to sign an informed consent form prior to any study-specific procedures being performed.

Data analysis
Quantitative data was collected in Statistical Package for the Social Sciences (SPSS) version 17. For qualitative data, in this study the focus group interview, the NVIVO 9 program was used.

Only descriptive statistics were carried out to describe the results of the WIK and WAK questionnaires and the results of the Barriers and Facilitators assessment instrument. The mean scores of the WIK and WAK questionnaires were translated to percentages. The basis of the interpretation of these scores is formed by the configuration profile that arises from the transfer of the scores on the summary statement (see appendix 2). When analyzing the (mis)fits between the innovation and the department, a number of developed standards will be used.
The frequencies of the scores on the Barriers and Facilitators assessment instrument were computed. Some questions are formulated positive, others negative. To find out which items are barriers, the percentages disagree and fully disagree of positive questions (1-4) and the percentage agree and fully agree of negative questions (5-15) were needed (Peters et al., 2002).

The focus group interview was tape recorded and the data were transcribed verbatim by the principal investigator (LA). The text was read and notes were made (Creswell, 2007). The analysis consists of three phases of coding: open, axial, and selective coding (Strauss & Corbin, 1990).
Together with the outcomes of the barriers and facilitators assessment instrument, the analyzes consisted of making a detailed description of the case and its setting (Peters et al., 2002).

RESULTS

Implementation strategy

Three nurses and five research assistants signed informed consent. All of the participants were female, because there are no male staff members at the department. The age varied from 25 to 47 years. All participants completed the WIK and WAK questionnaires. The results are presented in figure 2.

Strictly speaking, there is no internal fit of the innovation and the department, and therefore no external fit. In that case, the 'therapeutical strategy' would be the most appropriate strategy (van Linge, 2006). However, due to high scores of the innovation in almost all layers, a multiple internal fit of the innovation may exist. The analysis showed that in the team-oriented and the goal-oriented configuration, the innovation does not fit well with the department. In that case, the 'evolution strategy' fits best with the department. The implementation strategy was eventually determined based on the results of the WIK and WAK questionnaires and experience of the department with the implementation of innovations.

Eventually, the evolution strategy was chosen to be the most appropriate implementation strategy for the department.

[Figure 2]

In the evolution strategy, the interventions are focused on moving of all layers in at least two configurations (van Linge, 2006). The interventions were based on moving of the team-oriented configuration and the goal-oriented configuration, because these configurations had the lowest scores on the summary statement (figure 2). For the team-oriented configuration, the intervention contained teambuilding, communication about the progress of the process, sharing experiences, and shared responsibility for the correct application of the guideline. For the goal-oriented configuration, the intervention contained measuring outcomes, ICT support, and rational persuasion (van Linge, 2006).

Evaluation of the outcomes

Three months after the implementation, two nurses and research assistants completed the Barriers and Facilitators assessment instrument. The results are presented in table 3. The number of nurses who scored 'disagree' and 'fully disagree' of positive questions (1-4) and 'agree' and 'fully agree' of negative questions (5-15) are presented as barriers. The number of nurses who scored 'agree' and 'fully agree' on the positive questions and 'disagree' and 'fully disagree' on the negative questions are presented as facilitators. The number of nurses

who scored 'do not agree nor disagree' are presented as 'no barriers nor facilitator'. The scores were calculated into percentages.

[Table 3]

Fourteen of the fifteen items on the questionnaire were mentioned as facilitators by the nurses, because they had a score of 57,1% or higher. Five of these items had a score of 100% as a facilitator. One item had a score of 71,4% on 'no barrier nor facilitator'. Four items were mentioned as a barrier by one nurse each (14,3%).

Evaluation of the implementation process
A week after the completion of the Barriers and Facilitators assessment instrument, the focus group interview took place among 1 nurse and 2 research assistants. Although the guideline was presented properly, they indicated that they did not use the guideline, but rather the guidelines that were provided by the specific study that they work with. The reason is that there are minor differences between the (S)AE guideline and the guidelines from the studies. Although they did not use the guideline, they mentioned that it is important that this guideline will be included in the overall quality of the department as a reference. The guideline will eventually be included in the quality systems of the hospital, which is a good development according to the participants.

DISCUSSION

This study describes the individual and group nursing outcomes of the implementation of the (S)AE guideline among nurses and research assistants, by using a theory based tailored implementation strategy, at a research department. The results were assigned into implementation strategy, evaluation of the outcomes, and evaluation of the implementation process. These results show that the outcomes are rather positive.

Most of the items named in the Barriers and Facilitators assessment instrument were mentioned as facilitators. This means that the implementation is successful so far. There were barriers mentioned by one out of seven nurses, but most of the nurses did not saw these items as barriers. Barriers found in earlier studies about tailored implementation strategies in nursing care were lack of time and lack of knowledge (Van den Boogaart et al., 2009; Pagliari et al., 2003). These barriers were not specifically found in this study. However, it is unclear whether all barriers were identified by the instrument (Baker, 2010).

In the interview, participants said that they did not use the guideline, but they did mentioned the importance of the guideline for the department. In the results of the WIK and WAK questionnaires, we see that in the team-oriented configuration the organization is willing, but doesn't seem to perform it. This could be explained by the fact that the participants do not work as a team, but more individually at the department. These results could be interpreted with the ASE-model (de Vries, 1988), which has general scientific acceptance and explains behavior by linking Attitude, Social Norm and Self-efficacy with Behaviour and Behavioural Intention. By using teambuilding, communication about the progress of the process, sharing experiences, and shared responsibility for the correct application of the guideline as interventions for the team-oriented configuration, the social norm may be influenced to change the behavior.

In addition, in the goal-oriented configuration, ICT support was one of the interventions to present the guideline, which was well received by the participant. Only one out of eight participants did not participate in the data collection due to increased workload. Therefore, it can be concluded that measuring the outcomes is found to be important to the participants. As a result, the interventions in the goal-oriented configuration seemed to be successful.

The focus group interview showed that the team did not use the guideline. Implementation processes take time, sometimes several years (Grol & Wensing, 2006). The study was conducted in five months which is either too short a time to see the results of the implementation. Van Os-Medendorp et. al (2008) also used the contingency model to

implement a nursing programme and the duration of the data collection took two years. The implementation was reasonable successful. More time is needed to measure the results of the implementation. However, it is unknown when results can be expected of tailored implementation strategies.

The positive results on the Barriers and Facilitators assessment instrument and the focus group interview can be explained by the use of the tailored implementation strategy. The implementation strategy and interventions were chosen based on the WIK and WAK questionnaires and therefore fit well with the participants and the department. However, the study was limited by the lack of a control group. Therefore, it was not possible to compare the tailored implementation strategy with the standardized implementation strategy.

There were several limitations to this study. First, the study was conducted in five months, therefore, the effectiveness of the implementation could not be measured properly. Second, the principal investigator was a part of the team at the department which could caused information bias. However, knowledge about the department and the participants is necessary to make a decision about the implementation strategy. Therefore, the decision was made to carry out the interviews by the principal investigator.

A single case study was conducted, because the focus of this study was to develop an in-depth description and analysis of the case (Creswell, 2007). Because a small number of participants were included in the study and the case consisted the tailored implementation strategy specific for the department, the generalizability of the results is limited to the nurses and research assistants of the department were the study was conducted.

CONCLUSION

The individual and group nursing outcomes of the tailored implementation of the (S)AE guideline are rather positive. Although the results of the Barriers and Facilitators assessment instrument are positive and the interventions in the goal-oriented configuration seemed to be successful, the participants at the research department do not use the guideline in this stage of the implementation. This can be explained by the fact that the study was conducted in just five months which is too short a time to see the actual result of the implementation.

Recommendations

A longer lasting similar case study is recommended with repeated measures of both process development and implementation outcomes at the individual and group level.

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Table 1, Overview of the procedures.

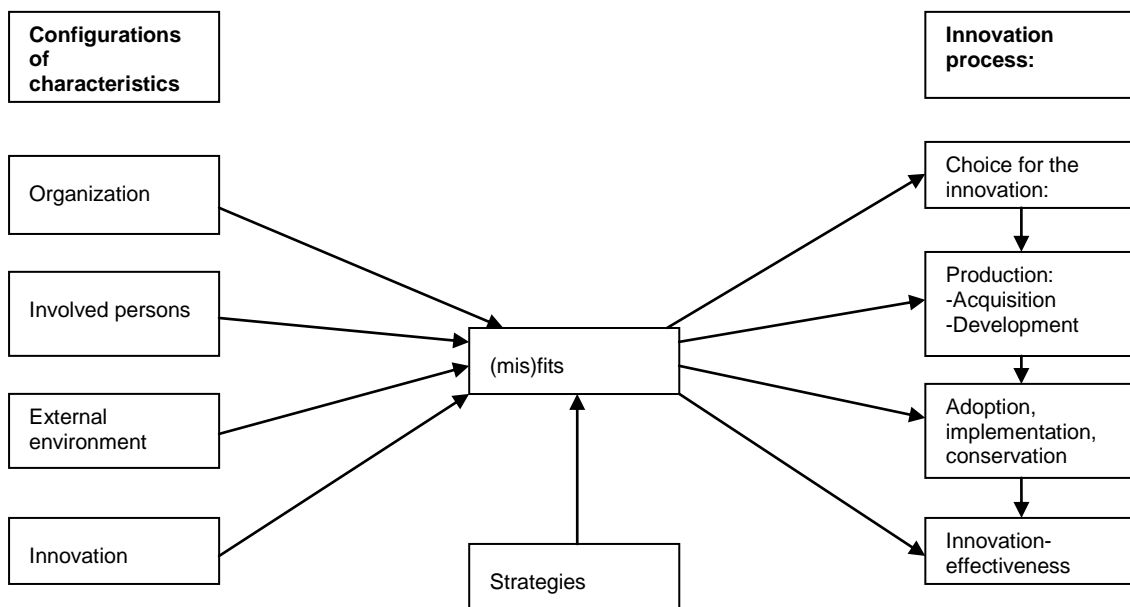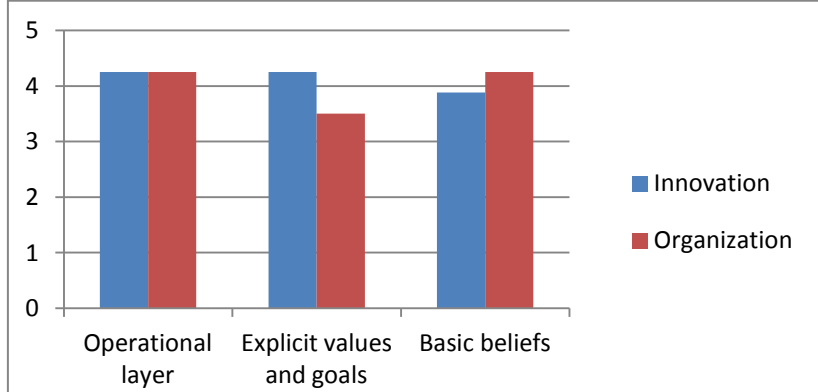|	January 2012	February 2012	March 2012	April 2012	May 2012
Development (S)AE-guideline finalized	■				
Determining the implementation strategy		■			
Implementation		■	■	■	■
Evaluation					■

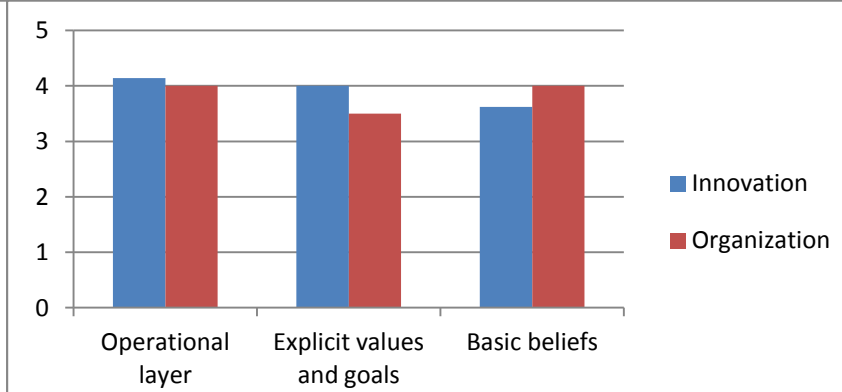**Figure 1, The contingency model of van Linge (2006).**
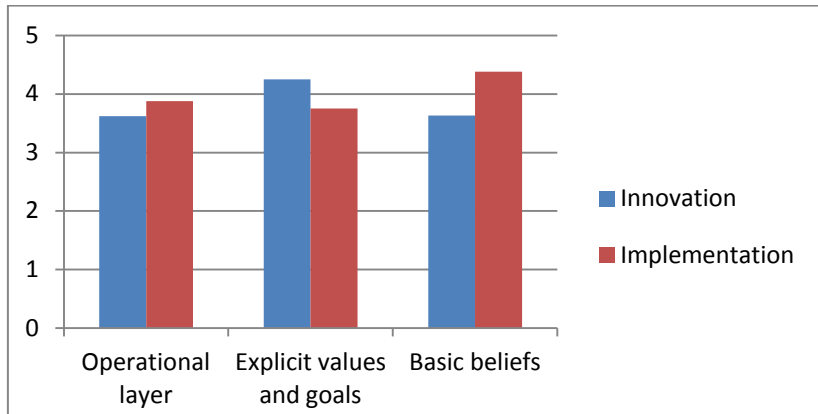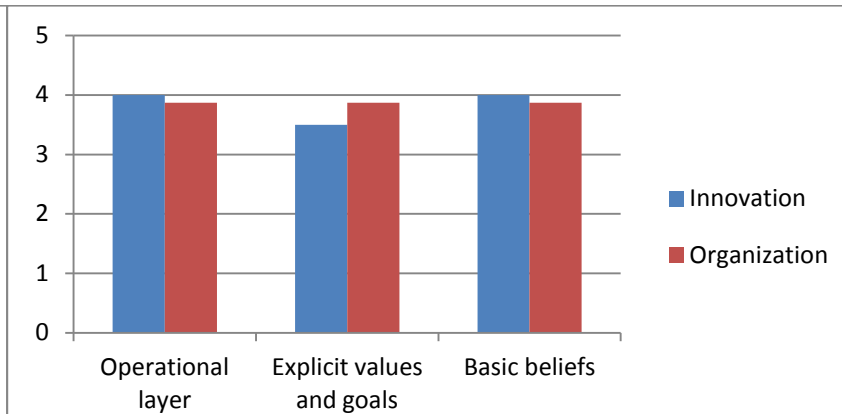
Figure 2, summary statement of the WIK and WAK questionnaires.

Table 2, Overview of the data collection.

Parameter	Measurement	Time of measurement
Implementation strategy	Observed Department Characteristics (WAK) and Observed Innovation Characteristics (WIK) questionnaires	baseline
Evaluation of the outcomes	Barriers and Facilitators assessment instrument	Two months after implementation
Evaluation of the implementation process	Focus group interview Topics: • Presenting/providing the guideline • The implementation strategy • Duration of the implementation • Timing of the aspects of the implementation • Completion of the questionnaires • Unintended effects	Two months after implementation

Table 3, Barriers as measured with the Barriers and Facilitators assessment instrument.

Items on the questionnaire	Number of nurses mentioned item as barrier (%)	Number of nurses mentioned item as facilitator (%)	Number of nurses mentioned item as no barrier nor facilitator (%)
1. This guideline leaves enough room for me to make my own conclusions.		5 (71,4)	2 (28,6)
2. This guidelines leaves enough room to weigh the wishes of the patient.		5 (71,4)	2 (28,6)
3. This guidelines is a good starting point for my self-study.		2 (28,6)	5 (71,4)
4. The lay-out of this guideline makes it handy for use.		4 (57,1)	3 (42,8)
5. The guideline can easily be abused in the medical disciplinary.	1 (14,3)	5 (71,4)	1 (14,3)
6. I did not thoroughly read or remembered the guideline.	1 (14.3)	4 (57,1)	2 (28,6)
7. I wish to know more about the guideline before I decide to apply it.	1 (14.3)	4 (57,1)	2 (28,6)
8. I have problems changing my old routines.		7 (100)	
9. I think parts of the guideline are incorrect.		6 (85,7)	1 (14,3)
10. I have a general resistance to working according to protocols.		7 (100)	
11. Colleague's do not cooperate in applying the guideline.		7 (100)	
12. Other doctors do not cooperate in applying the guideline.		7 (100)	
13. Managers/directors do not cooperate in applying the guideline.		7 (100)	
14. Working with the guideline is too time consuming.	1 (14,3)	5 (71,4)	1 (14,3)
15. The guideline does not fit into my ways of working at my practice		5 (71,4)	2 (28,6)