Intervention studies in the health care work environment

Lessons learned

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• chemical substances and allergens, noise and electromagnetic fields,

• the psychosocial problems and strain-related disorders in modern working life.

Introduction

While participating in a NIVA course in Finland in 1996 on prevention of stress and burn-out we found out that all three of us were involved in intervention studies in the health care sector. Each of us had had to launch his study without much guidance from previous research traditions in the field. In time we all became aware of the fact that intervention research in working life is fundamentally different from observational and experimental research on etiology of symptoms and diseases. To a lesser or greater degree, we were forced to step out from the principles of natural science. In our attempts to affect the conditions of work in health care, we had to engage in interactive communication/discussion with our thinking and reflecting "study objects". There went strict objectivity! And if we wanted to study not only individual employees but also groups of employees (such as the staffs of different hospital wards), it became very difficult to adhere to a randomised procedure when enrolling participants to a study. How were we supposed to proceed in questions like these? What could we learn from each other's experience?

On the last day of the course we sat together at the lunch table, discussing how to keep up the contact between us and develop our projects together. We decided to apply for a grant from the Nordic Council of Ministers, who also sponsor the NIVA courses, in order to set up a network for developing intervention research in the health care field. After some deliberation the Council considered our initiative worth financial support and provided us with the resources we needed to convene five seminars over a period of 2 years. We then invited members from other research groups we knew were working in this field, to join our group. Our definite group thus consisted of eleven researchers from four countries. Denmark was represented by Tage Kristensen, Martin Nielsen and Bente Schibye from Copenhagen and Lone Donbæk Jensen from Aarhus; Finland by Marjut Joki and Gustav Wickström from Turku; Norway by Morten Andersen and Reidar Mykletun from Stavanger; and Sweden by Mats Hagberg from Göteborg, as well as Monica Lagerström and Sarah Thomsen from Stockholm.

During the years 1997 to 1999 we met five times, each time for 1-3 days. Our discussions were open and enthusiastic, at times a bit off the theme, but sooner or later returning to it again. The peak experience in trying to improve our understanding of the relations between the questions and concepts we were interested in, was the formulation of the "Sirdal model", which is an attempt to combine the perspectives of the staff (a healthy and stimulating working environment) and the patients (high quality treatment, care and service) on health care work. We conceived this model in a remote mountain hotel in Norway, our discussions alternating between foggy and bright, just like the weather outside. The model was developed on the basis of Sarah Thomsen's introduction concerning the role of the patients in the work environment of health care workers and is presented in her and her co-worker's paper.

This issue of "Arbete och Hälsa" includes chapters on all the main themes we discussed in our seminars: principles of research, alternative designs, choice of outcome variables, measuring of physical and psychological work load, the role of the patient, practical challenges in the field, description of the process, as well as ethical considerations.

We decided to sum up our articles under the title "Lessons learned" rather than "Guidelines for" as we do not yet feel ready to proclaim any definite recommendations.

Today the occupational strain on the health care personnel makes headlines all over Europe. The ageing populations and the increasing possibilities of examinations and treatment poses growing demands on the health care sector. At the same time it becomes difficult to find additional financial resources for the activities needed and harder to recruit qualified staff. Interest in actively monitoring and improving the working conditions of the health care employees has steadily increased over the last few years and so has the interest in evaluating the effectiveness of various approaches. This is why we think that our experiences may be of interest to others, who are carrying out projects to improve the working conditions in the health care sector and want to systematically evaluate the results of their endeavour.

We frankly admit, that we find intervention research difficult in many aspects: to decide on the compromise between a design that is optimal for research and one that is facilitating active participation in changes, to initiate and implement interventions, to select significant processes to report and to include in analyses of cause-effect relations, as well as many others. From the researcher this requires a mix of rational thinking and interpretive speculation. In addition, it requires social competence to be able to react intuitively in a suitable way in varying, suddenly arising situations. We want to share our experiences and opinions with others, because we think interventions hold many promises of identifying causes and testing solutions, that are not possible in more traditional research.

Ms Taru Koskinen has assisted with the technical preparation of the manuscripts and Ms Hilary Hocking has checked the language.

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Content

Integration of quantitative and qualitative methods in intervention research

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Abstract

The old controversy between qualitative and quantitative approaches to the
study of workplace stressors and workers´ health may be bypassed by
looking at them as complementary to each other. Especially, intervention
research would profit from the integrated use of both approaches when it
comes to validity and reliability of the data. This applies to assessment of
both the work and health related problems as well as the effects of the
intervention. Also quite practical issues must be considered, such as the
question of status for the two approaches within the research group, the
possibility to integrate the two methods, not only conduct them in separate
and parallel processes, and the sequencing of the approaches. Five different
methods of integration are proposed: 1) a qualitative approach as a found-
ation for the design of a quantitative study, 2) qualitative studies to gain
deeper insight and better analyses of the results from a quantitative study, 3)
quantitative research to study frequencies and distributions of phenomena
discovered by qualitative approaches, 4) parallel and integrated use of
qualitative and quantitative approaches, and 5) quantifying qualitative data.

The old controversy

Most textbooks in qualitative research methods introduce themselves with state-
ments about the need for alternatives to the dominating tools of the quantitative
research methods. These statements always include defences for the relevance and
quality of the qualitative research methods, implying that they perceive them-
selves as under continuous pressure from the established "big brother" from the
dominating paradigm of quantitative research methods (e.g. 10, 13, 14, 18, 27).
There are some reasons for the apparent underdog position of the qualitative

research methods that are difficult to deny. As pointed out by Miles (1979, p. 591):

> The most serious and central difficulty in the use of qualitative data is that methods of analysis are not well formulated. For quantitative data there are clear conventions the researcher can use. But the analyst faced with a bank of qualitative data has very few guidelines for protection against self-delusion, let alone the presentation of unreliable or invalid conclusions to scientific or policy-making audiences. How can we be sure that an "earthy", "undeniable", "serendipitous" finding is not, in fact, *wrong*?

Qualitative research methods are also by themselves a heterogeneous group of approaches, both in the ways data collection and data analysis are undertaken, but also concerning their underlying philosophies. The philosophical controversies between the quantitative and qualitative techniques are great, as they are within the various fields of qualitative research. Some (e.g. 15, 20) argue that the gaps between the defenders of the various positions are so great that an integration between the two could rarely take place within the same project. Fred Kerlinger's famous Aristotelian statement that *"There is no such thing as qualitative data. Everything is either 1 or zero"* stands is standing against Berg's (1989) dictum that all data are basically qualitative "To a raw experience, we may attach either words or numbers". Likewise, Campbell (1974) stated that all research ultimately has a qualitative grounding. The issue may be reduced to knowing when it is useful to count, when it is difficult, and when it is inappropriate to count at all (8). As stated by Miles & Huberman (1994, p. 40) the question is to recognise "…when data are non-standardised and we have no clear rules for saying what is variation and what is error". The issue is basically whether we are taking an analytical approach to understanding a few controlled variables, or a systemic approach to understanding the interaction of variables in a complex environment (23).

Integration of paradigms as a new trend

The development of applied research is short-circuiting the influence from the castles of the fundamentalists. A trend may be seen towards "hybrid" studies with the side-by-side applications of the quantitative and qualitative research methods (19), and this new development is pointed out in one of the leading textbooks on qualitative analysis (16). Frequent attempts to combine the two old enemies are probably first to be found in evaluation studies (e.g. 21), that definitely face the need for creative design and methods in applied settings, and thus may be more likely than others to break the old ice.

Other examples appear as well, for example, for worksite health promotion (12), education and training (11), health education planning (4), and health psychological topics (26). This flexible approach is also defended by Yin (1984) in his often-cited book on case-study design. Action research (6, 5, 7), as seen in workplace intervention studies, lends itself most readily to integration of the two paradigms in the same project (12).

When using participative research designs, the need for active and open two-way communication between the workforce and the researcher is no doubt a necessity. The forms and content of that interaction differ depending upon the situation, the actual problems, the agents involved and the phases of the study. The researchers may well find themselves in active dialogues with the organisation and in the core of the change process, taking on multiple roles, including taking notes for the research diary and preparing the next phase of a quantitative evaluation. The population under study is not the object but the subjects, pushing the construction of their new organisational and social structures. The researcher is forced to lay aside the traditional demands for objectivity, which has been regarded as one of the cornerstones of the natural sciences (28). Moreover, to manage the change and direct or give advice on the process of development, the researcher is bound to take notice and keep records, mainly made up of qualitative data.

Thus, the action research paradigms, especially with a participative approach, will inevitably violate some of the traditional requirements of the quantitative approach, while at the same time creating a considerable amount of qualitative data that must be the basis of decision-making in the project. These same data can also be used when reporting the process and outcomes of the project. However, the process of integrating the quantitative and qualitative research methods is not straightforward (e.g. 2). Moreover, even when the practical integration is undertaken and the research report written, it is still difficult to get the study published, since so few journals are prepared for this new trend (28). As a consequence we get to know rather few examples of integrated qualitative and quantitative research designs.

The idea of integrating the quantitative and qualitative paradigms is based on the belief that the strength of each of the two paradigms can add value to the final lessons learned from a project. The argument typically includes a listing of the value of each of the two approaches, as briefly stated in table 1.

Table 1. Characteristics of quantitative and qualitative research methods.

Quantitative methods	Qualitative methods
Purpose: To explore or predict events, states or outcomes, or explain co-variations or causal relationships between variables, including the evaluation of changes in target variables over time.	**Purpose:** To find and define meaning of social processes and events through the understanding of the individuals' experiences, the interpretation and the attributions, as well as illuminating points of view in important issues and presenting the insiders' views.
Ways of interpretation: Deductive, with focus on verifying and final outcomes.	**Ways of interpretation:** Inductive, focus on the discovery of phenomena and processes, as well as the process of discovery itself.
Measurements: Objectivity is the ideal, and reliability should be documented.	**Measurements:** Subjectivity is accepted, validity is the top priority.
Analysis: Specified rules and conventions that guide the researchers and assist the reader to evaluate and even replicate the study.	**Analysis:** Few rules and strong debates on the emerging structures that are proposed for standardising the ways of analysing data. Still some defenders of "the art of analysis" who refuse any conventions and systems. Difficult to attain "inter-subjectivity" in data interpretation. Studies are not presented in ways that make them replicable for other researchers.
Generalisability: Generalisabilty is the raison d'être.	**Generalisability:** Generalisabilty is normally not the goal, but the focus is kept on examples, phenomena, processes and relationships between processes and their contexts.

Few researchers have addressed the issue of how to actually integrate the use of qualitative and quantitative research designs and methods in the same study. The model we present for integration is partly based on the suggestions given by Steckler et al (1992). However, it differentiates between five variations of the integration theme, instead of the four introduced by Steckler and co-workers. Moreover, the model also leans towards discussions made by Rossman & Wilson (1991), classifications made in the review study by Greene et al (1989), as well as the models proposed by Miles & Huberman (1994). We also drew upon Sieber's (1973) list of reasons for combining quantitative and qualitative methods.

1. Using qualitative methods for learning about the organisation and making optimal research designs before any quantitative measurement takes place

Most intervention research projects will lean upon and profit from high quality pre- and post-test measurement with the use of quantitative techniques. Good questionnaires are without a doubt of great value to document the state of problems and levels of health complaints before and after the intervention has

taken place. The quantitative data makes it possible to apply statistical comparisons of the "before" and "after" states, according to agreed upon conventions. A questionnaire study may also map out some of the obstacles and problems that the intervention should address. If a participative approach is considered, data from surveys in the area of interests constitute an important foundation for the discussion with the involved workforce.

However, standardised questionnaires may be of limited value for these purposes, due to their general character and the lack of anchoring in the actual organisation studied. By using qualitative techniques in this early phase of the study, the researcher may carry out formal and informal interviews with significant actors in the organisation, and attend important events to get ideas for the phrasing of questions to be included in the questionnaire surveys to follow.

Moreover, identifying the themes and topics which should be focused on in the intervention is only partly possible from quantitative pre-test measurements. The start-up point of organisational intervention always provides the opportunity for many discussions and arguments, and creates a considerable amount of data if they are recorded appropriately in the researchers' diaries. Possible areas for intervention and the dynamics underlying them are often made visible from the obstacles and frustrations discussed.

Qualitative study as part of the planning of quantitative approach for pre- and post-test measurements, and also to identify obstacles and problems at work

Conducting quantitative pre- and post-test measurements to map problems and evaluate effects

Results of quantitative study
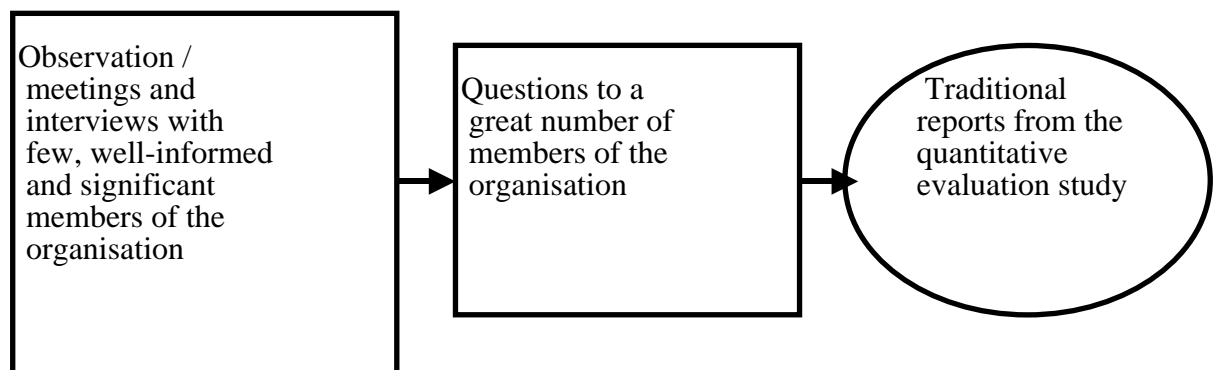
Figure 1. Using qualitative methods for learning about the organisation before relevant quantitative measurement can be conducted.

This process is illustrated in figure 1. The qualitative research processes are seen as a prerequisite for optimising the quantitative part of the study by design and measures. The qualitative research processes are seen as an important and necessary way of integrating the two paradigms in order to develop the methods for quantitative measurements and get important information on how to profile the intervention. Miles and Huberman (1994) make the point that the process may

continue with a third step, i.e. a new qualitative study that deepens and tests more systematically the hypotheses developed in the first and second steps.

2. *Use of qualitative research methods to gain a better understanding of the results from the quantitative study*

The second way of integrating qualitative and quantitative approaches lies within the use of the former to add new data, as well as adding valuable background to the analyses and interpretation of the results of the quantitative results (figure 2). While the quantitative measures will give an apparently "exact" documentation of states and changes, very little information is available from this approach with regard to the actual processes and the perceptions of these processes over time. This applies both to the way the actual intervention programme was run, and to the effects it had on the organisation. Moreover, the quantitative study may have identified subgroups that may be worthwhile studying more in depth by qualitative methods in order to gain a better understanding of the problems and processes involved.

To improve the understanding of the situation and the way it changes, if the research group is involved with the organisation during the change processes, they may record in their notebooks lots of information on positive compliance or resistance, as well as conflicts along with the change processes. The qualitative information on the fit between changes to take place - and the material, organisational, social and personal contexts - is often of great interest. The qualitative approach is here used to attain a more detailed and informative report, by adding information which may be of considerable significance to the understanding of the change phenomena, but which would pass unattended without the qualitative contribution. According to Miles and Huberman (1994), the process may continue by designing a third step with a new quantitative study or experiment, based on the knowledge gained in step one and two.

Quantitative study undertaken to explore, evaluate, explain or predict

Qualitative study undertaken to find the meaning and significance of processes and events, for instance in sub-groups identified by the quantitative study

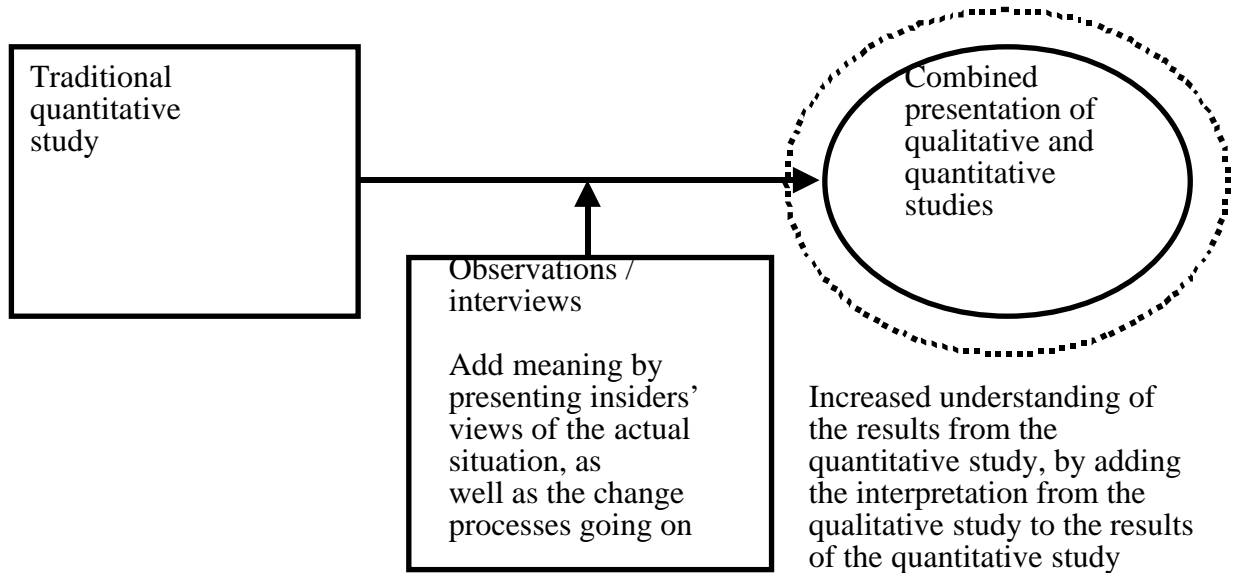*Results of qualitative and quantitative studies integrated in the same presentation*

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│ Traditional     │                   ╱  Combined     ╲
│ quantitative    │────────────────▶ │  presentation  │
│ study           │          ▲       │  of qualitative │
│                 │          │        ╲ and quantitative╱
└─────────────────┘          │         ╰ studies ──────╯
                    ┌─────────────────┐
                    │ Observations /  │
                    │ interviews      │
                    │                 │
                    │ Add meaning by  │
                    │ presenting      │
                    │ insiders'       │
                    │ views of the    │
                    │ actual          │
                    │ situation, as   │
                    │ well as the     │
                    │ change          │
                    │ processes going │
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Increased understanding of the results from the quantitative study, by adding the interpretation from the qualitative study to the results of the quantitative study

Figure 2. Use of qualitative research methods to gain a better understanding of the results from the quantitative studies.

3. Use of quantitative research methods to study the frequencies and distribution of phenomena studied in depths by qualitative methods

The third way of integrating quantitative and qualitative approaches is opposite to the ones presented above, in that the qualitative study is undertaken first. The phenomena in focus are studied in depth, leaving the researcher with a good understanding of the actual perceptions and opinions held by the workforce involved. The phenomena may be work-related problems, coping strategies, or perceptions of change as effects of on-going interventions. However, the methods do not allow for any suggestions about the generalisability of the results. The next appropriate step is therefore to design and conduct a quantitative study on a relevant and representative sample in order to increase understanding about how widespread a phenomenon is, and how it is distributed in the population. The quantitative study must be carefully designed on the basis of the knowledge gained through the qualitative processes, in order to represent the findings from the latter in valid ways in the survey to be conducted. Another possibility is to run a series of quasi-experiments on the basis of the findings from the qualitative study in order to explore possible causal effects. This approach is illustrated in figure 3. Again, the process may continue by designing a third step with a new

qualitative study to get deeper insight, based on the knowledge gained in step one and two.

In-depth studies to create meaning and understanding of a social phenomena

Conducting a quantitative study to increase the knowledge of the phenomena in the population

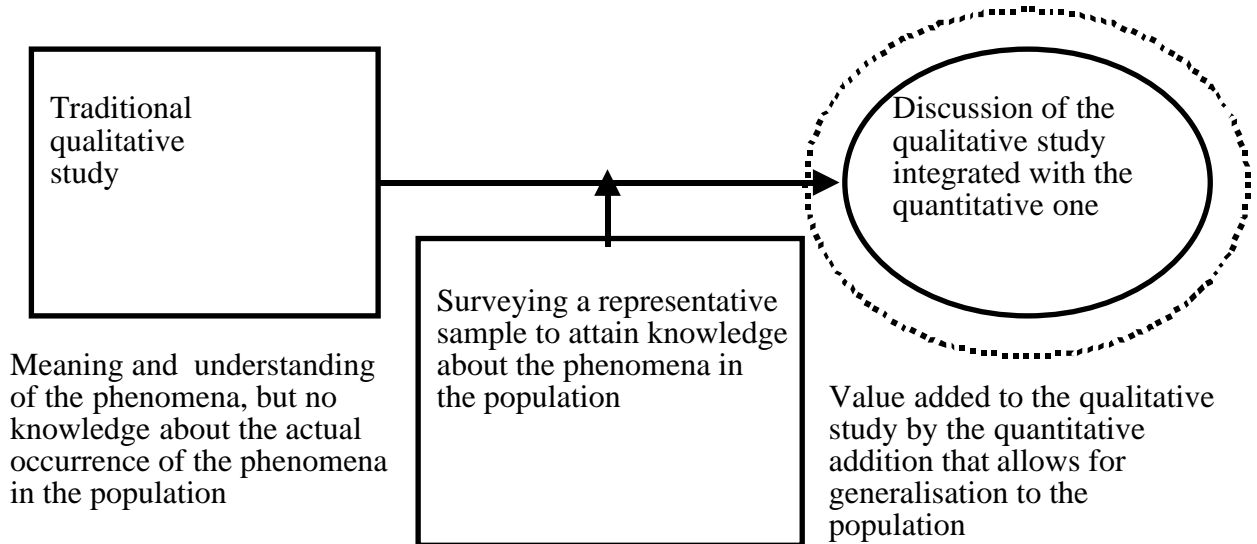*Result of the integrated quantitative and qualitative studies*

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┌─────────────┐                    ╭─────────────╮
│ Traditional │                   ╱ Discussion of ╲
│ qualitative │                  │  the          │
│ study       │───────┐          │  qualitative  │
│             │       │          │  study        │
│             │       │     ┌───▶│  integrated   │
└─────────────┘       │     │    │  with the     │
                      │     │     ╲ quantitative ╱
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        │ Surveying a │
        │ representative
        │ sample to attain knowledge
        │ about the phenomena in
        │ the population
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Traditional qualitative study

Surveying a representative sample to attain knowledge about the phenomena in the population

Discussion of the qualitative study integrated with the quantitative one

Meaning and understanding of the phenomena, but no knowledge about the actual occurrence of the phenomena in the population

Value added to the qualitative study by the quantitative addition that allows for generalisation to the population

Figure 3. Use of quantitative research methods to study the frequencies and distribution of phenomena established by qualitative methods.

4. Parallel use of quantitative and qualitative research methods in the study of the same phenomena

The fourth way of integrating quantitative and qualitative approaches is rather different from those mentioned above. It contains the simultaneous use of both approaches in the study of more or less the same phenomena. Each approach is perceived as equivalent to the other in relevance and scientific status. Since the methods used are different, they will inevitably end up with somewhat different, although not contradicting, outcomes. Each method contributes with unique explanations and makes the total understanding of the researched phenomena richer. On the other hand, the outcomes of the different approaches will also meet on some common ground, providing a unique possibility of discussing the validity and the reliability of the study. The process is illustrated in figure 4.

Quantitative study to explore, evaluate, predict or establish causalities between variables

Integrated and separate result of the quantitative and qualitative studies
Unique part of the explanation = value added

Qualitative study to create meaning and understanding

Traditional quantitative study

Cross-validation by mutually confirming results

Traditional qualitative study
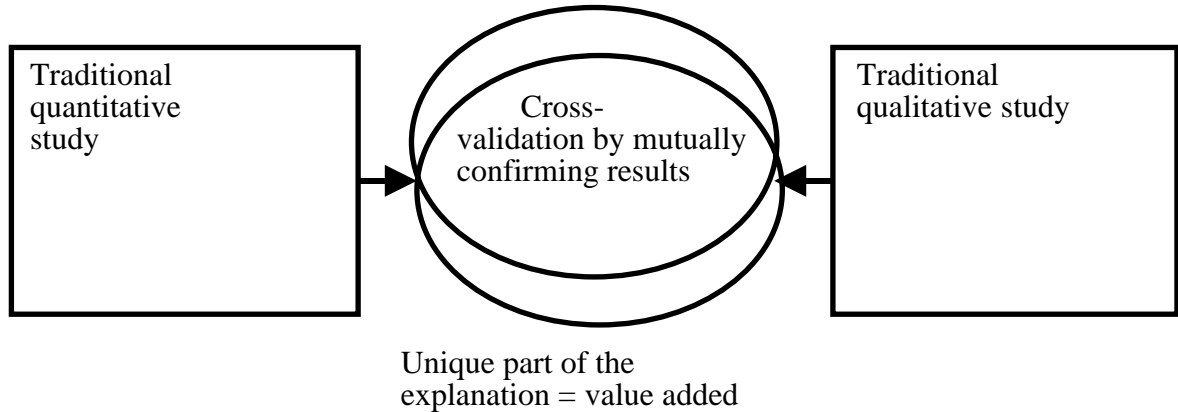
Unique part of the explanation = value added

Figure 4. Parallel use of quantitative and qualitative research methods in the study of the same phenomena.

This dual research process is a useful and natural design to apply in intervention research requiring fieldwork. The quantitative measures are adequate to get some firm data for the evaluation of effects, and also for the identification of trouble factors and obstacles at work, as well as the frequencies of health complaints. The strength of the quantitative method in covering great samples with little effort is obtained, and is especially useful in intervention research, granted the validity and reliability of the measurements, and that the sample studied is of relevance and is representative for the population. On the other hand, the qualitative study can easily be conducted along with the work of implementing an intervention process in the organisation. The implementation is time-consuming and requires intensive contacts between the consulting agent (who may or may not be part of the research group) and the organisation. With some minor efforts, this process may generate valuable data for analysis on qualitative grounds. It may be discussed whether intervention researchers should feel a special obligation to undertake this dual-process research design. As pointed out by Miles and Huberman (1994), in the case of multi-wave studies, cycles of data collections are followed by field-work. Such design allows for improvement of fieldwork by pointing out areas of intervention based on the collected data. However, the reverse is also possible, where the fieldworkers' experiences are included in the next data collection wave.

5. Quantifying the qualitative data

The fifth and final way of integrating quantitative and qualitative approaches is also rather different from the other four, and seems to be overlooked in the discussion provided by Steckler et al (1992). The core of this process is the

possibility to categorise and quantify data from interviews and observational studies. Data will be transformed from words to numbers, and can be used as data for statistical analysis with non-parametric procedures. Statistical tests can be undertaken on even small numbers of observations, granted the adequacy with respect to sampling procedures.

Qualitative study to create meaning and understanding	*Transforming qualitative information to quantitative data*	*Results of the quantitative analysis of results*

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┌─────────────────────┐      ┌─────────────────────┐           ⬠
│ Observation /       │      │ Categorising,       │      Traditional
│ interviews          │ ───► │ coding and analysing,│ ───► quantitative
│ Varying number of   │      │ using non-parametric │      reporting of
│ persons             │      │ statistics          │      results
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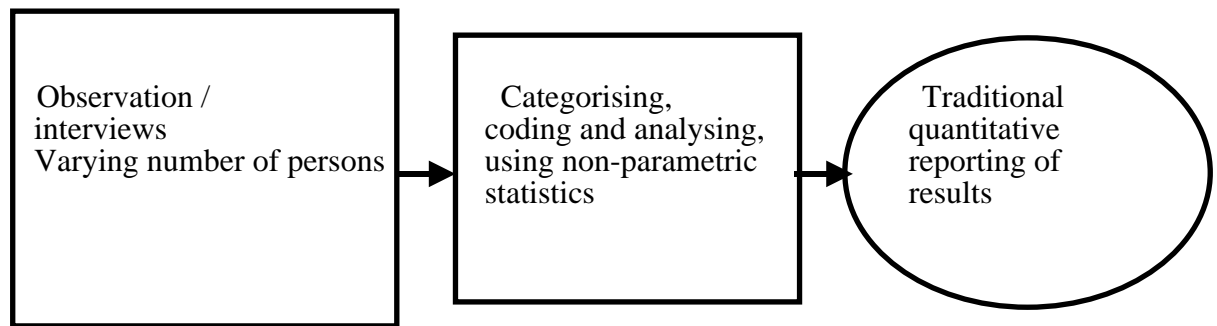
Figure 5. Quantifying the qualitative data

Conclusions

Although the philosophies behind the quantitative and qualitative research methods are as far apart as ever, it seems not only possible but also necessary to combine the two approaches in applied research projects. In workplace intervention research the two seem to thrive together. This applies to the use of a qualitative method approach to obtain the initial understanding of the organisation and also as a basis for creating questions to surveys undertaken in the pre-test phase of the intervention. Furthermore, the simultaneous use of both the qualitative and the quantitative approach during the intervention process seems natural and offers a parsimonious use of resources. Finally, the quantification of qualitative data makes it possible to use quantitative data analysis of data that in the first place were qualitative, which also seems to be an appropriate approach.

   We have outlined five different ways of integrating the two approaches to gain added value and increased knowledge from the process studied. Most emphasis is placed on how qualitative approaches may fit into the quantitative approaches, filling in with information and in-depth understanding where the quantitative approach is not optimal or adequate by itself. However, it should be pointed out that quantitative approaches may take a somewhat similar position by giving directions to the design of intervention studies, for instance in finding the relevant samples in the organisation. During the data-collection phases in the intervention project, the quantitative approach may add information on background, overviews, and also help to avoid "elite biases" in the qualitative approach (i.e. talking mainly to high-status respondents). During analysis, quantitative data may supplement the qualitative data by showing the generality of specific observations,

correcting the "holistic fallacy" (i.e. monolithic judgement about a case), and verifying and casting new light on qualitative findings (24).

The point of departure for our reasoning is pragmatic, because we consider the use of the two approaches a strength to relevant intervention design, and valid and reliable evaluations of problems and outcomes of the intervention. To gain benefit from this integrated use of approaches, we agree with Greene et al (1989) that the research group should actively consider the complementary differences across methods and the purpose of using them, the phenomena being studied, and the implicit paradigms used. Also quite practical issues must be considered, such as the question of status for the two approaches within the research group, the possibility of integrating the two methods and not only conducting them in separate and parallel processes, and the sequencing of the approaches.

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Design of intervention studies to improve the health of health care personnel

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What is the potential of health improvement among health care personnel?

Health care personnel are a large occupational group of approximately 600,000 in Sweden, representing 28 % of the total female work force (22). The large number of employees in the health care sector implies that prevention of even small excess risks may yield substantial cost-benefit results. There are similarities in the exposure to physical and psychosocial working conditions within occupational groups in the health care sector that may facilitate preventive actions. All work organization in the health care sector should comply with the ordinances in Sweden, Denmark, Norway and Finland concerning internal control (12). This implies a mandatory continuous evaluation of changes in the work system by common surveillance methods. In the Nordic countries the organization of health care is comparable between countries, and this facilitates the transfer of knowledge about health care sector improvements between countries.

There are many identified and characterized risk factors in the health care sector. Ergonomic factors such as patient transfer causing over-exertion back injuries have been reported with relative risks up to 6 (11). A relative risk of 6 may translate into an attributable and theoretically preventable fraction of 83 %.

What are intervention studies?

In an intervention study the investigator actively changes the exposure. The randomized controlled trial (RCT) is the standard for evidence-based medicine and practice. However, in the field of interventions for occupational health personnel, few RCT-studies are published. There are many explanations for the absence of RCT in interventions targeting the health of health care personnel. An important reason is that it may be hard to actually implement intervention measures in a randomized manner. Furthermore it may be even harder to randomize administrative changes in organizations and groups, since this may cause union disputes and management conflicts.

In randomized controlled trials the double blind assignment, where neither the participant nor the investigator knows whether a particular participant has been assigned to a study group or a control group, is an essential feature. Obviously it

would be hard for the participant to get a control assignment for administrative change or patient transfer devices (24).

There are continuous changes occurring at all work places. These changes may be minor or major. Observational studies of the natural change occurring at different health care workplaces may be an alternative to intervention studies (21).

To evaluate the results of interventions, different variables can be used. Usual endpoint variables, such as occupational diseases, days of sick-leave or disablement pensions, have a long latency period before changes after an intervention can be observed in a surveillance system. Intermediate variables, such as discomfort and grievances, may be early indicators of intervention effects. Changes in exposure may be the most sensitive measure of an intervention aimed at changing the exposure. In this chapter the effect of the intervention is defined as the difference in endpoint variables, intermediate variables or exposure.

What designs have been used?

Before-after evaluation

In this evaluation model, conditions before the intervention are compared to those measured after the intervention (Figure 1). This model is the basic one and the most common model used for evaluation of interventions. However, there are biases associated with this model, since differences seen when comparing the conditions before and after the intervention could be due to factors other than the intervention. The main drawback is that the natural course of time, for example spontaneous healing, can explain the effect. Other factors that might bias the interpretation are changes in legislation, and in production etc. that are not controlled for. An example of this kind of evaluation is the study performed by Garg and Owen (6), where exposure was measured before and after work improvements.
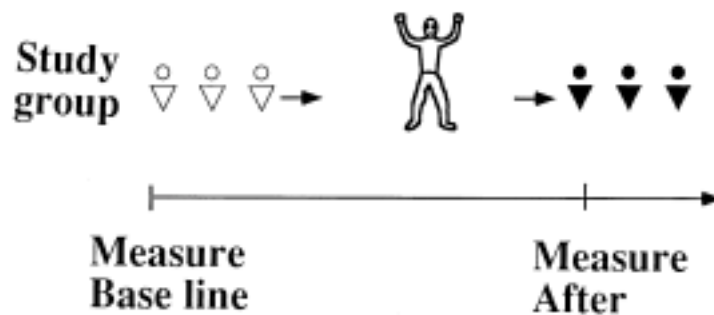

Figure 1. The before-after evaluation, where the effect is the after measure (post-test) subtracted by the base line measure (pre-test).

Study group-referent group evaluation

In this model the conditions and effects are measured before the intervention, both in the group receiving the intervention and in a referent group, where the partici-

pants do not receive an intervention (Figure 2). Thus it is possible to control for external changes and time factors such as legislation, economic development, season etc. However the effect caused, for instance by the expectations (Hawthorne effect), cannot be controlled for, since the study group receives special attention. The Hawthorne effect is the tendency for the personnel to change their behaviour because they are the target of special interest and attention, regardless of the nature of the intervention (7). In medicine this is called placebo effect. A placebo acts by decreasing anxiety, by meeting the expectations of the patient. The human placebo response is characterized by a conditioned response (1). An example of this type of study is extra ergonomic teaching to nursing students that were compared to students receiving the normal curriculum (9).
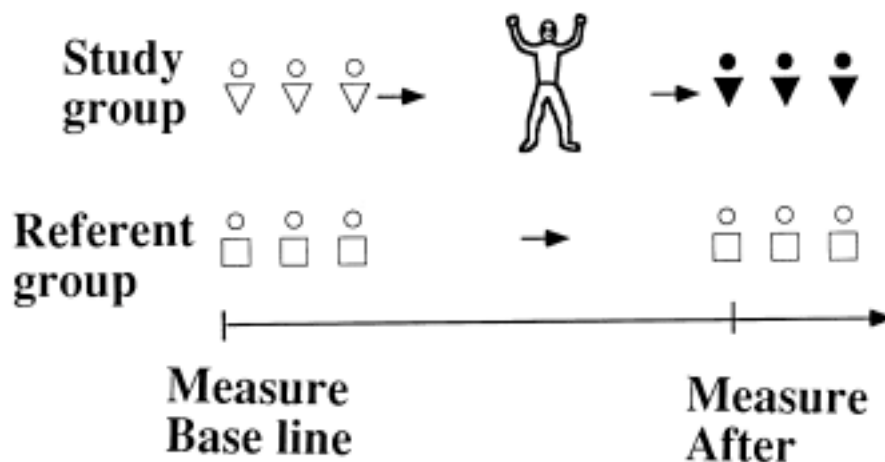

Figure 2. The study group-referent group evaluation, where the effect is the after measure in the study group subtracted by the base line measure in the study group and divided by the effect in the referent group.

Study group-control group evaluation

In this model the control group also receives an intervention programme that is expected to have little or no effect (Figure 3). This model allows us to control for the effect of expectation and other external factors that could affect the evaluation. The model allows for multiple comparisons between two or more study groups that receive different intervention programmes. A drawback of this type of evaluation model is the "spill over" effect. This means that if for example a study group receives a programme of physical training, and is compared to a control group receiving a course in ergonomics, it is possible that the study group will tell the control group about the training, and thus initiate training also in the control group. This type of "spill over" effect can reduce differences between groups and thus bias the evaluation. An example of this type of evaluation is extra training of student nurses, where both the study group and the referents received training (23).
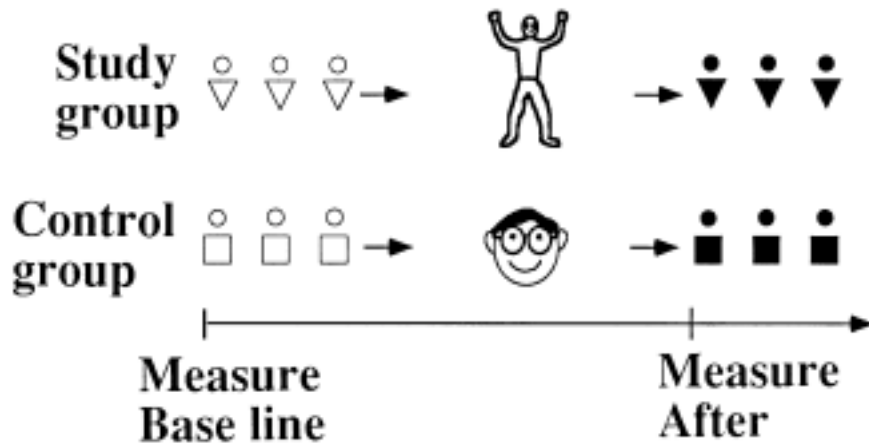
Figure 3. The study group-control group evaluation, where the effect is the after measure (post-test) in the study group subtracted by the base line measure (pre-test) in the study group and divided by the effect in the control group.

Study group-control group evaluation with crossover

This is the same model as the previous one, but after a designated point in time the programmes are exchanged between the groups (Figure 4). This means that after crossover the control group will be the study group and the study group will be the control group. If effects are recorded after the study group programme in both groups, there is strong scientific evidence for a positive effect of the study group programme. The drawback of this model for evaluation is that it is hard to perform in real life. There are both practical and ethical aspects of eliminating an intervention that is believed to have positive effects. The model may be useful when trying to evaluate combinations of different programmes. The combinations of different programmes can be tested in different groups in a Latin square design. An example of this type of intervention is where nurses received three types of programmes, one each year: physical training, training in patient-transfer technique and training in stress management (10).
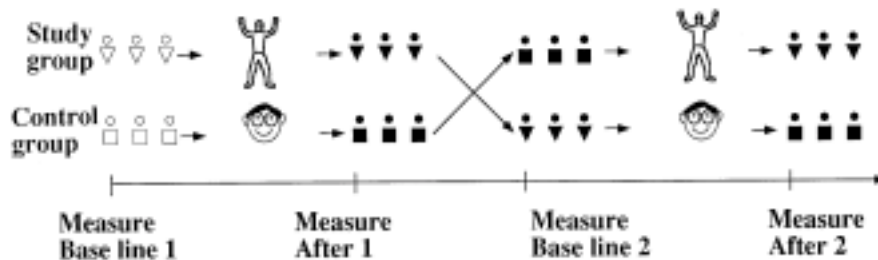

Figure 4. The study group-control group evaluation with crossover, where the effect is the after measure in the two study groups subtracted by the base line measure in the two study groups and divided by the effect in the control groups.

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What interventions are feasible?

Vaccination programmes or screening for infectious diseases may prevent long-term disability among health care personnel and thus be economically feasible (4, 16, 19).

Psychosocial problems, e.g. "burnout", are widely debated today, but there are no clear studies of the benefits of prevention. Ergonomics programmes may result in substantial reductions in injuries (5).

Adequacy of sample size

The sample size needs to be big enough in interventions studies (14). It can be determined by power calculations, where the power is defined as the ability of a study to demonstrate an association if one exists (13). If variables are quantitative (on an ordinal, interval or ratio scale) the number of subjects required is less than if the variable is on a nominal scale (case, non-case).

Newer epidemiological designs for evaluation of interventions

The case-crossover epidemiological design was introduced in 1991 (15). In the case-crossover design each study person is both case and control. So far there is no study which applies this technique in order to study occupational risk factors among health care workers. Personnel with acute occupational injuries can be studied for risk factors such as different types of stress preceding the accident event, for example working understaffed for at least 4 hours. The occurrence of this stress can be compared within the individual during a control period, for example the day before. In this type of analytical study the size of risk factors can be used to evaluate interventions.

So-called ecological studies focus on the comparisons of groups, organizations, hospitals etc rather than individuals (18). In a classic case-control or cohort study, the biological effect of different exposures can be studied, for example the risk related to the number of individual patient transfers. In ecological studies, on the other hand, it is possible to study the ecological effect of systems and policies that affect the whole group, hospital etc, for example the care system in the wards, the work organizations, the health and safety policy, and the quality assurance programme. In the continuous change of work systems and organizations, this type of study seems feasible for the evaluation of organizational change as the intervention.

Criteria for evaluation of intervention studies

When evaluating an intervention study, general scientific guidelines should be followed (see for example (20)). The framework of assignment, assessment, analysis, interpretation and extrapolation can be used as a checklist for the evaluation. Studies where there is little likelihood of bias are of greater value than studies where the likelihood of bias is greater. Sound sampling, sufficient sample size, randomization of intervention, the investigator blinded to intervention,

participant blinded to intervention, adequate referent/control group, long follow-up period are all factors that will add validity to the study.

Although performing randomized controlled trials requires substantial resources and planning, this design of evaluation has the highest credibility in evidence-based medicine. However, we cannot only rely on randomized controlled studies of interventions before we recommend actions to improve the health of the health care personnel. In addition, other designs such as observational studies with post "test" measurements need to be used. Natural interventions, such as new legislation or new work organization, may be an opportunity for observational studies. Furthermore qualitative studies of interventions can be of guidance in implementing successful interventions.

Qualitative research methods can address the important issues of how to initialize and implement interventions in health care (2, 3).

Participatory approaches in intervention designs

Participation is the key to managing the change process (8). Participatory research is where the personnel and management jointly define the goals, process and evaluation technique for an intervention study. In intervention studies the personnel may themselves determine the intervention, where the initiative may be feedback of health outcome such as back injuries (17). Even if the type of intervention is determine by the researcher (or the management) the process and the content of the changes may be determined by the personnel. This has proved to be very successful where ergonomics teams are concerned (5).

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Interventions for better health in health care workplaces: Individual or organisational level?

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Abstract

Two levels of workplace interventions for health promotions are discussed in the present paper – the individual versus the organisational. The case is put forward for the prominence of the organisational level in order to achieve primary prevention effects, although individual-oriented interventions may be quite successful in relieving health problems. Moreover, the paper discusses the tailoring of interventions related to the question of a two-level control of the problem and the solutions: the individual and the organisational. It is acknowledged that many individual-level interventions are appropriate because the individual clearly controls the problem and its solution. Also, when no control can be achieved, either by the organisation or the individual, because the problem is inherent to the nature of the work itself and, the work must continue, it is argued that both organisational and individual-oriented interventions should be used. Apart from this, organisational-level interventions should be recommended. The issue of participation by the workers in the design of the intervention is discussed. Participative approaches are recommended, and one example is briefly summarised.

Introduction

The scope of this paper is to discuss advantages and disadvantages of different types of workplace interventions for health promotion in health care workplaces. These issues are addressed by considering two levels of intervention: the individual and the organisational. Some interesting questions arise from the issue of who controls the factors causing the problem as well as who determines their solution. The issue of possible under-reporting of workplace problems and health complaints by the workforce is briefly addressed, as well as the particular problems of introducing intervention programmes that are likely to occur in these settings.

Some limitations have to be set in order to narrow the scope of the present discussion. Interventions may be undertaken at different times and at different levels. For instance, specialist teams may undertake interventions during the

planning period, when the workplace is under construction, or during the period of organising work. Interventions at such levels may include ergonomic issues, workplace design, tools and equipment, how to organise work groups, resource allocation and management routines. Although the processes at this stage are considered by the present author to be of the utmost importance for good work-place design, these types of interventions are not discussed here. The focus is on interventions that take place after the organisation is set up with infrastructures, manpower, management, routines and patients.

Levels of interventions

Health promotion is a growing field of activity in western societies. Two different types of health promotion programmes at the workplace may be identified in the research literature. The first type is motivated by a general societal imperative for reducing health problems and related costs. Programmes such as these may be introduced as a public health initiative by some societal agency and operate on state or municipal funding. Alternatively, they may operate at a commercial level, where some stakeholders earn money on the intervention programme. Initiators behind these programmes look for a place where their programmes can easily be implemented. These actors also address the workplaces as markets (41). Since the work environment is a bounded community in which there are daily interactions and both standardised and informal communications, this environment offers special advantages as a location for various health promotion and risk reduction programmes. Examples of research on health promotion unrelated to specific work problems is presented by Gregg et al (1990) and Dawley (1987). Likewise, Jason et al (1989) reported on results from unspecific programmes for smoking cessation. A combination of general health promotion and work-related stress reduction programmes has also been attempted (e.g. 30).

The second type of programme aims at counteracting work-related health problems. Within this type, two main approaches seem to exist: The intervention may be focused either at the individual level or at the work environment level, or both. Geurts & Grundemann (1999) distinguished between (1) worker- versus work-oriented interventions and (2) primary versus secondary/tertiary interventions. Worker-oriented interventions focus on the individual (or group), while work-oriented interventions focus on the work environment (or organisation). Primary prevention is concerned with taking action to modify or eliminate the sources of stress, while secondary / tertiary prevention is aimed at the reduction or elimination the effects of stress.

In reviewing the overall practice of stress prevention and intervention at the workplace Kompier and Cooper (1999) conclude that most activities are primarily aimed at the individual rather than the workplace, and that there is a focus on secondary / tertiary prevention rather than primary prevention. The same conclusion can be made on the issue of burnout (31). However, in the field of musculoskeletal pain, Westgaard & Winkel (1997) identified higher frequencies of work-oriented as opposed to individual-oriented intervention studies.

Individual-oriented programmes focus on employee behaviour or symptom changes, either as a response to, or independently of, the context in which the person is working and the potential hazards in the work environment. Research on interventions programmes aimed at the level of the individual worker is increasing and short-lasting effects have been demonstrated to an extent that may be cost-effective for the employer (17). Shi (1993) evaluated a stepwise health promotion programme in an energy production plant, and found that the economic benefits of health promotion at the workplace are related to their costs. Cost-effectiveness increases with the level of interventions undertaken, and the greatest cost reductions are obtained when environmental policies are added to extensive individually focused programmes.

The organisationally focused intervention programmes are undertaken to improve workers' health by means of imposing changes in the work environment. For instance, in stress research, this is expressed as stressor elimination or reduction, and often referred to as primary stress prevention (7, 24). In line with health improvement policies in society at large, organisationally focused pro-grammes for health promotions aim at eliminating or reducing the possible negative impacts of the organisational aspects of the work environment that may impair the somatic or psychological well-being of the employee.

Bellingham (1990) argues against the reliance upon individually focused health promotion programmes, and claims that they only show effects in "healthy organisations". Moreover, workers' unions have long claimed that the implemen-tation of individually focused health promotion programmes, including traditional stress management programmes, may delay necessary work environment improvements (17, 29). Kilbom (1988) states that, as far as musculoskeletal pain is concerned, interventions should preferably be multi-disciplinary, since this problem has a complex and multifaceted aetiology. It should be noted that individually focused stress management programmes have been shown to give only limited and short-lasting effects, and interventions should therefore be focused on changing or eliminating sources of stress in the working environment (7). Moreover, chronic, organisationally generated stressors may be resistant to reduction through individual coping efforts (23). Quale (1981) argues that organisational interventions, as opposed to individual ones should be made for ethical reasons unless interventions focused on environmental factors are impossible, or they take a long time to implement. However, it can also be argued that health is ultimately the individual's own responsibility. This issue should be clarified from an ethical point of view (40).

Organisational-level interventions for health improvement are defined here as planned, programmatic and structured activities, in which selected organisational units engage in a task or a sequence of tasks, where the task goals are related directly or indirectly to organisational improvement (13, p.113), and where effects of these improvements on individual workers' health are evaluated. The focus, thus, is on activities or processes aimed at changing some part of the organisa-tional structures that constitute the working conditions of the individual worker, and not on programmes directed at the individual. The term organisational

structure includes here administrative regulations, time schedules, distribution of tasks, as well as the social and cultural structures at the workplace. Work ergonomics, available technology and its use, along with the architecture and availability of physical space for work also contribute to the effects that the organisational structures may have for the individual worker, and should therefore, in the context of intervention studies, be included in our conception of organisation.

Organisational structures are, in the broad sense, structures that shape the demands and action alternatives of the members of the organisation, offering more or fewer possibilities and use of personal, social and organisational resources. In every organisation there will be some processes of adaptation and accommodation between the workforce and all other elements of that organisation. A sub-optimal or dysfunctional relationship will reduce the effectiveness of the organisation and increase stress on the individual worker (35). Addressing these problems with one-sided health promotion programmes aimed at the individual, such as physical exercise, or training or educational programmes restricted to changing the individual's attitudes, abilities or coping strategies, should only be undertaken after an evaluation of both individual weaknesses and organisational dysfunction. However, it should be added that programmes such as seminars, relaxation training and a combination of these two, have definitely been shown to be effective in improving the health of female hospital staff. Positive outcomes of physical exercise as workplace health promotion have also been demonstrated (6, 15, 37), see also Westgaard & Winkel (1999) for an extensive review of workplace interventions against musculoskeletal pain).

Arguments for moving the focus from the individual level to the organisational level also rely upon some scattered research findings on stress and coping, and upon health benefits from various levels of health promotion programmes. Shinn & Morch (1983) and Shinn et al (1984) conducted an often-cited study, where they found that coping strategies on an individual-, social- and organisational level were used to counteract stress and burnout by employees in the helping professions. Coping strategies at the social interaction level were frequently used, and were related to reduced levels of burnout, while individual-level strategies were not. The number of respondents reporting availability and use of organisation-level strategies was low. In the survey part of their study, organisation-level resources were mentioned as available by 18 % of their respondents, while 38 % of these respondents mentioned such coping strategies as the preferred resources for assistance to workers under stress. In the protocol analyses part of their study, they found problem-focused coping strategies at the organisational level to be the most effective strategies in reducing stress and burnout problems. In addition, Shi (1992) evaluated the relative effects on employee health benefits from various levels of comprehensiveness of workplace health promotion programmes. In general, the benefits in reduced risk behaviour and improved health status increased with an increasing level of intervention comprehensiveness, with the greatest effects occurring when the intervention contained both extensive individual-level programmes and also work environment improvements.

It might be argued that, being isolated from bringing about changes in the organisational working conditions of that individual, individual-level interventions should not be recommended. It might be unethical to direct the intervention programmes towards individuals only, and allow the organisation to continue to produce health hazards (23, 29). The individually focused programmes should therefore perhaps be used for two purposes:
1) When organisational programmes must wait for implementation, and
2) When individuals need support for taking responsibility for their own health.

Apart from these instances, organisationally directed programmes involving participation by the staff should be recommended from learning and ethical points of view. However, there is still a lack of research-based evidence to show that organisationally focused work promotion programs are the most effective health promotion programmes for workers in any organisation, also including health care (7, 19, 26, 28). Thus we are caught in the dilemma of carrying out the individual-level interventions which have demonstrated their effects, or acting more ethically and addressing organisational health hazards when making health promotion in health care workplaces.

Tailoring interventions to problems

Tailoring an intervention includes gaining knowledge about the health problems, the workplace hazards and / or individual attributes that contribute to the offset of these health problems, as well as the exercises of identifying who have caused the problems, and who may control their solutions. Below we will address the issue of causes and control of these causes on a more general level. However, the health problems of the health care workers are quite complicated from an aetiological point of view and, consequently, it is quite difficult to tailor good interventions that cover all types of problems. For instance, musculoskeletal pain has no single documented neurological, inflammatory or other pato-physiological cause. The pain is supposed to have a multifactorial aetiology (1, 27, 38), developing from complex interactions between external psychological and physical loads, individual psychological and biological characteristics, and psychological and biological reactions (3, 4, 25). The causal mechanisms may be even more complex. The experience of pain itself may increase the negative effects of external stressors, or provoke psychological and biological reactions that maintain or even increase the experience of pain. A vicious circle may thus be established (5, 9, 36). No single intervention contains a cure for all of these types of problems, and some of them may not even be cured by worksite health promotions. We probably cannot expect strong effects from narrowly focused programmes, such as training in lifting or working techniques, relaxation skill, or conducting stress- and burnout workshops. Comprehensive programmes should probably be recommended, although they leave the researcher with difficulty in tracing causal relationships between cure and effects.

Health care workers are likely to underreport both their health problems and the obstacles and stressors at the workplace, because of their professional training, where high quality care for the patient and the fulfilment of the patients´ needs are defined as the important goals. The patients are the very objects of the work, and as such it may be distressing for the caregiver to present the patients as problems. Nurses and auxiliary nurses are even trained at school to overlook aspects of their work that are disgusting to others in an untrained workforce. The patient is a human being who may add both good and bad elements to the work of the care-giver. Some may provide humour, boost the caregiver's identity and self-esteem, and give various types of social support. On the other hand, other patients may be quite the opposite, being threatening and dangerous, and destroying the pride and self-esteem of the care-giving staff. Some patients are also quite unpredictable in their cooperation with their caregivers. Even the patient's close family and friends may unexpectedly interfere with the process of care-giving. Thus, the patient and his social and cultural environment add some unpredictability to the work of the caregiver, making coping with work demands difficult if the time schedule is rather tight. The patient is not a stable product of the work of the caregiver. He is partly active in the process, and partly a product.

In most cases the patient will suffer more from pain, discomfort and lack of control over his/her own life than the health worker does. Social comparison processes will therefore be likely to increase suppression of their own problems. In some cases, the owner of the health care organisation will run surveys to identify weak areas in the service quality provided, and journalists will pick up examples of low levels of service and make sensational reports in various media. Moreover, the owners and managers may not be trained to uphold the quality of the work environment as well as that of the service and treatment, and if so they are not likely to raise the awareness of health and workplace problems for their staff. Again, these processes will contribute to ignorance about and suppression of possible perceptions of health problems.

These blurring factors are likely to create problems for measurements of the actual conditions in the organisation with regard to workers' health, and to the structures and magnitude of the workplace problems. Moreover, it is likely that an intervention project will raise the workers' awareness of such problems. Post-test measurements will therefore be conducted on subjects with a better understanding of their situation, as compared to the same subjects in the pre-test condition. One may argue that this will make comparisons between the results from these two measurements difficult, and it may be hard to demonstrate positive effects of the intervention.

The relationships between the elements of those who have caused the problems and those who may control the solutions to the problems may be illustrated in a two-by-two table (fig 1) where some examples are added to illustrate the issue. The design of an intervention must address the agent that controls the solution. However, participation by the agent who controls the problem will lead to a better solution (e.g. smoking at work or bad working postures). This leads into the issue of information feedback loops and participatory intervention techniques.

| | | Problem controlled by the employee himself / herself | |
		Yes	No
Solution controlled by the work organisation	Yes	Q – I Smoking at work Lack of competence Risk-taking behaviour while working	Q – II Time pressure Lack of autonomy Heavy lifting Adequate tools Aggression from patient or patient's family
	No	Q – III Psychological fitness Physiological fitness Smoking cessation Overweight	Q – IV Working with bent and rotated back Patients with severe pain or facing crises and death

Figure 1. Locus of control over the risk factors

In Quadrant I (Q-I, fig 1) we find problems controlled by the employee, while the solutions to these problems are controlled by the work organisation. Clearly, smoking can be prohibited at the workplace by regulations, as is commonly observed at all health care institutions today. Likewise, lack of competence is at the outset an individual problem, but the employer is in charge of training oppor-tunities. Risk-taking behaviour at work is also an individual problem at the outset. However, the employer may influence such behaviour by training, regulations and even sanctions on risk-taking. Problems of these types need to be solved by the employer who is in charge of the solution, but this has to be done in cooperation with the employees who own the problem. The intervention must be tailored accordingly, with a focus on the organisation and with participation from the employees (see below).

The problems of Quadrant II (Q-II, fig 1) are of a different type, since the individual worker does not control the problem, while the employer controls the solution. Clearly, the employer may reduce the time pressure by hiring more staff or reducing the amount of work. More autonomy can be provided through empowerment. Technological aids can reduce heavy lifting. Aggressive patients and relatives can be calmed down by organisational means that raise the quality of care. Providing tools and equipment is also a task controlled by the employer. In this case, the adequate intervention is focused on the organisation. However, there will be a need for a dialogue with the employees, including training to implement new ways of working.

Quadrant III (Q-III, fig. 1) presents problems that should be addressed by individually focused interventions. In the context of Scandinavian working life, training for fitness – psychological or physiological – would still be a matter of

concern for the individual, although many employers organise, facilitate and even pay for such training Ursin et al, 1993). The intervention must be focused on the individual, asking for organisational support.

Quadrant IV (Q-IV, fig. 1) displays problems that are inherent to the nature of the work, and thus cannot be controlled or avoided, such as working with back bent and rotated, and coping with the emotional demands from patients suffering severe pain or facing despairing life crises and death. The interventions have to be carefully tailored to these problems. The organisation should contribute by paying constant attention to the problem, facilitating intervention processes, and providing follow-up for the individual. Support has to be organised and the workforces´s the individual must be supplied with adequate coping skills that may make these stressors tolerable. The employees have to be trained for and conscious of the issues involved. Even if these problems are by nature the most difficult to solve, interventions should not avoid them. Expertise and the experience of the individual have to meet in a dialogue, at times also including the patient. The strategies needed may require the combined involvement of the individual, the organisation and the patient (Thomsen et al, this volume).

The principle of workforce participation – description of the process

For the purpose of this paragraph we will focus on the problem of musculoskeletal pain. If the observed relationships between psychological factors and musculoskeletal complaints reflect causal mechanisms, interventions to reduce musculoskeletal pain at the workplace may also be focused on the psychological aspects of the transactions between person and environment. Focusing on the individual, such interventions have been successful for relaxation training, stress seminars, and physical training (6, 37). However, to the extent that work environment contributes to musculoskeletal pain, the continuous one-dimensional focus on the individual seems to contain some ethical problems, as discussed above (23,29).

Because of the complexity of the musculoskeletal pain problem (19), there is a need for developing an approach which also focuses on organisational and psychosocial processes. An approach of this type must be both sufficiently structured to demonstrate valid and reliable effect measurements, as well as sufficiently flexible and holistic to cover the actual problems that contribute to the psychologically mediated musculoskeletal pain problem. Moreover, the approach should draw upon expert knowledge, and balance it against the experience and ideas of the employees and their leaders in the organisation in question. It is a popular saying in Scandinavia that "a person knows best himself where the shoe hurts". However, the expert who has seen several people taking off their shoes has also gained some valuable, although often complementary knowledge about the problem. This also applies to the observer who has repeatedly seen the buying of new shoes that will cause the person more pain. The expert should take part in planning and organising intervention programmes. The knowledge of the expert should be applied to make sure that attributions made by the employees or the employers on the issue of causal relationships should dominate the programme.

The Norwegian Work Environment Act states that the workplace should be equipped and organised in ways that protect the workers against both somatic and psychological injuries. Workplace safety committees, including representatives from both the employer and the employees, are to be arranged at each workplace to monitor the work environment. These committees include representatives from both the employer and the employees. They have a potential to democratise the organisational power structures in identifying obstacles, threats and dangerous work factors, which should be addressed in order to improve the work environment. There is strong empirical evidence for the benefits of including the workers in the processes of understanding problems at work when problem identification is the goal (11, 12). To illustrate this point, we will use an example from one of our own organisational-level intervention studies (26). We wanted to develop a strategy for interventions that could meet the requirements outlined above, as it could be an example of how to apply the principle of "Internal Control of Work Environment and Safety" at the ward level. To be tested, however, the strategy also had to contribute to the solution of concrete workplace problems and develop competence in strategies and methods of improving work environment. This defines the project as also being action research (21). The actual "treatment" or intervention method consisted of ten steps:

1. The research group attended a staff meeting to present the project and clarify department compliance with the programme.
2. The staff meeting then appointed members to a "Local work environment committee" (LWEC). The department leaders were automatically included in the committee along with union representatives to "balance" influence from employers and employees. From the action research perspective, the LWECs constituted an important aspect of "the participative approach" in this study. The committee was granted support from the research group (project leader (researcher) and occupational health service representative (nurse), who attended all meetings. Each LWEC consisted of 6-8 members.
3. A pre-test was arranged by administering questionnaires for stress, work-related problems, mood and health including musculoskeletal pain.
4. Data-feedback was given to the LWECs, and a staff meeting and group discussions were arranged to clarify the staff's interpretations and their perspectives on how to improve the work environment. Again, the participative strategy was included in the process.
5. The LWEC developed concrete action plans based upon a) the research results, b) the group discussions from the staff meeting, and c) the view of the researchers attending the group. The action plans were formulated in a language that was shared by the staff; the content of the plans was relevant to their experience of work; and the problem-solving processes were adapted to the relevant organisational characteristics. The content of the plans was arranged under headings such as "Problem Descriptions", "Remedial Actions", "Person Responsible for Remedial Actions", "Time Limits", "Priority", "Evaluation".

6.   The LWECs carried out their plan step-by-step, often involving other staff from the department in the actual improvement of work processes. Also in this step, the participative strategies were included in the process.

7.   The LWECs arranged monthly meetings to discuss processes, progress, and obstacles. In total each committee held 7-8 LWEC meetings per year.

8.   Outcomes were evaluated by the same questionnaires that were used for the pre-test measurements, and supplemented with qualitative data from the committee discussions and observations of improvements in the working environments (Mykletun & Wickström, this volume).

9.   Results were presented to the LWECs and the staff meetings, and interpretations were discussed with them.

10. The departments were responsible for continuing the process on their own, and drawing upon the expertise of the research group when needed.

The entire programme lasted for twenty months. At the end, the LWECs evaluated their experiences and the effects of the committees' work. The proportion of problems solved varied between departments, but none of the committees had problems left, on which no working process was started. Most difficult to solve were problems that depended on cooperative solutions with some other departments, and also with the maintenance staff. It was also difficult to solve problems requiring attitude or behavioural change within the project departments themselves. The objective changes of the work environment and the organising of work had taken place, and important change processes were still in progress.

The method constitutes a model for organisational learning at the workplace (16). The participative approach facilitated a process of learning concepts about work environment problems; how to categorise them, and to turn such problems into solutions. The orthopaedic department managers slightly changed the LWEC working model into a general meeting for department management when the project period was over, but still kept the focus on work environment problems that turned up as cases among all other problems that the meeting had to handle. The laboratory department did not continue the LWEC process when the project period was over, partly due to change in leadership that also introduced alternative management ideas with less emphasis on the participative approach. Thus, the intervention programme mainly succeeded in improving objective working conditions, and also became a model for new management procedures at one department. The programme also succeeded by diffusing into several other departments as a new strategy for problem-solving, especially in relation to organisational and psychosocial work environment problems. These diffusion processes were facilitated by the third author in her role as a nurse at the Occupational Health Service Unit.

Conclusions and recommendations

The issue of focusing interventions on the individual or on the organisation has been discussed. Clearly, addressing the individual is the easiest way to establish a

programme, and also by far the most common. Health promotion for the individual at the workplace is presumed to be more effective, as compared to the alternative of addressing the individual as a member of the local society. The programme can be tailored to the exact problems faced by the workforces. The workplace can be seen as an entity with boundaries, and stronger communication systems and power structures compared to society in general. Compliance to any intervention programme aimed at health promotion of the workforces should therefore be higher at the workplace. Increased efforts in workplace health promotion programmes should therefore be recommended.

From a scientific research perspective, the individually oriented intervention is to be preferred. Working with the individual allows the researcher to make experimental designs in a field setting, including the randomisation of individuals on trials or programmes. The main exception from the ideal demands of experimental research is the need to inform the subjects about the purpose and content of the experiment, and to allow them to withdraw from participation at any moment. However, there are also other pragmatic reasons for addressing the individual in health promotion programmes at the workplace. Intervention programmes focused on the individual should be recommended when the individual definitely controls the solution, while the organisation has no control at all. There are good reasons for the work organisation to facilitate such interventions, since the workforce may gain more value by better health and working ability.

However, strong arguments have been raised for shifting the focus from the level of the individual to the level of the organisation. The arguments are supported by some research findings and also by ethical and pragmatic considerations. Most individuals choose organisational solutions more often than individual solutions when suggesting coping strategies to deal with stressors at work. Thus, interventions addressing organisational issues should be more readily accepted, since they are in line with the "local theory" of the workforces. The ethical reasons for organisation-level interventions are mainly related to the possibility that focusing on changing the individual may delay or even prohibit improvement or removal of factors in the working environment that constitute hazards to the workers' health and well-being. When the health hazards remain the same, they will constitute continuous threats to the workers' health.

Some problems in the work of the health care workers can be solved – others cannot. Problems that are not under the control of either the individual worker or the organisation belong to the latter type. These kinds of problems are inherent in the nature of the work, and cannot be avoided. The issue is how much relief can be provided by buffering the individual against the potential harms. Interventions must combine expertise with workers´ experience, and patients may also be involved. Moreover, these interventions must combine organisational and individual foci.

It has also been argued that workplace interventions for better health for the health care workers are a very tricky undertaking. The health problems are complex with multiple aethiological factors. No single strategy will cure these complex problems, and broad intervention programmes are therefore to be

recommended. Moreover, as a result of professional training, the content of work and also structural factors, the health problems and problems of workplace stressors are likely to be underreported, especially at the beginning of a project, making the measurements difficult. No good solutions seem to exist to avoid this latter problem.

Addressing the organisational level does not mean the exclusion of the individual worker. It is argued that participation from the workforces is of great importance to achieve success when making workplace interventions. Although it is time-consuming, the approach is recommended for interventions in the health care sector.

Organisation level approaches are impossible to undertake when fulfilment of anything but quasi-experimental design requirements is to be obtained (8, 39). Randomisation is not possible, and it is difficult to control the influence from factors that are external to the intervention process itself. Nevertheless, the present author defends organisation-level interventions as the most appropriate. The reasons are both ethical and practical. However, interventions only on the individual level may be defended in some instances. This applies to problems where the employee herself owns the problem and also controls the solution to that problem.

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Patient and personnel perspectives in intervention studies of the health care work environment

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Summary

The purpose of this chapter is to advance an argument for including both patient and personnel perspectives in intervention studies of the health care work environment. The authors identify eleven studies that examined both perspectives. The outcome of interest in the studies is quality of care. In order to achieve this outcome, however, personnel satisfaction and health must be considered. Results of the studies indicate that improving personnel's work environment may not necessarily guarantee improved quality of care. The authors suggest a new research paradigm and provide an example of an ongoing project that embodies the integrated approach.

Introduction

The present chapter focuses on the importance of expanding traditional work environment research to include the patient perspective. The chapter includes a literature review of research on the relationship between personnel and patient satisfaction and well-being, as well as an in-depth description of an intervention study that attempted to study both perspectives. Finally, an integrative model for future intervention projects in the health care sector is presented.

The employee perspective

Studies of the psychosocial and physical work environment have traditionally focused on the employee. The logical endpoints of such a focus are job satisfaction, turnover, and mental and physical well-being. This focus is just as prevalent in studies of health care personnel as it is in industry. However, from a public health perspective, the well-being of health care personnel has potentially wider ramifications than that of factory workers. Job dissatisfaction in industry may lead

to absenteeism, resulting in increased costs and decreased production. However, dissatisfaction of health care workers has a tendency to lead not only to absentee- ism and exhaustion, but also to "dysfunctional attitudes" such as dehumanisation and callousness towards patients (16). The question is what are the consequences of such behaviour on the quality of care provided? The logical way to answer this question is to include patient-oriented parameters in work environment studies.

The patient perspective

Focusing on the patient's perspective has traditionally been the strategy of quality improvement programmes. This customer/client focus has been an almost holy principle. Hospital quality enhancement initiatives focus almost exclusively on identifying and improving patient flow, diagnostic and treatment schedules and nursing care. In fact, health care organisations are often legally obliged to provide quality improvement/assurance programmes (18). At the same time, the organisa- tion, structure and financing of the health care sector have undergone significant and far-reaching changes. These changes all too commonly result in psychosocial stress, discontent and unhappiness among staff, as well as increased sickness, absenteeism and turnover. Both from a theoretical and practical point it is thus of interest to study the possible interaction between work environment issues, patient satisfaction and medical outcome.

Literature review

The purpose of this literature review is to give a picture of what kinds of studies have been done combining personnel and patient satisfaction with health. In addition, it examines the kind of models, designs, hypotheses, outcome measures, results and conclusions employed in these studies. Finally, future needs for research on this topic are identified.

According to Wallis (20), occupational psychology has traditionally looked at the link between satisfaction, stress and performance at work. However, we still do not really understand how these factors interact. He makes the argument that it is not necessarily expedient to use motivational theories based on industry, such as those of Herzberg or Hackman and Oldham, to explain stress and satisfaction in the service sector, particularly health care, because of their essential differences. For example, traditional sources of "motivation", such as financial incentives, are usually not the most important motivators in health care, nor are they often available. Further, while profit is the traditional sign of performance in industry, in the caring professions it is the quality of service provided that should be evaluated.

However, using quality of care as the primary performance indicator for health care workers is not unproblematic. In a pilot project designed to increase nurse satisfaction (and indirectly quality of care) Wallis (20) identified a dilemma: patients and personnel's needs are sometimes at odds with each other. In this project, a change in practices that had originally been desired by nurses, and that also would have improved continuity of patient care, was later dropped as being

unsatisfactory because it was "not in the patients' best interests". Wallis concludes from this, and other studies, that: "coping strategies like absenteeism, avoidance of certain discretionary aspects of one's job, neglect of interpersonal relations with colleagues: these may all prove successful in minimising *stress*, but at some cost to effective performance". It appears that the personnel were only willing to improve quality to the extent that the new way of doing things was not too labour-intensive. A Danish anthropologist provides another example. In her observations of palliative caregivers, Hansen found that personnel complained about lacking time to spend with patients, but when they had time to spare they spent it drinking coffee or discussing patients with each other (9). Franssén (8), who observed the same behaviour in hospital and nursing home employees, proposed that this contradiction is due to an unwritten law on the ward that nursing personnel should devote more time to each other than to the patients.
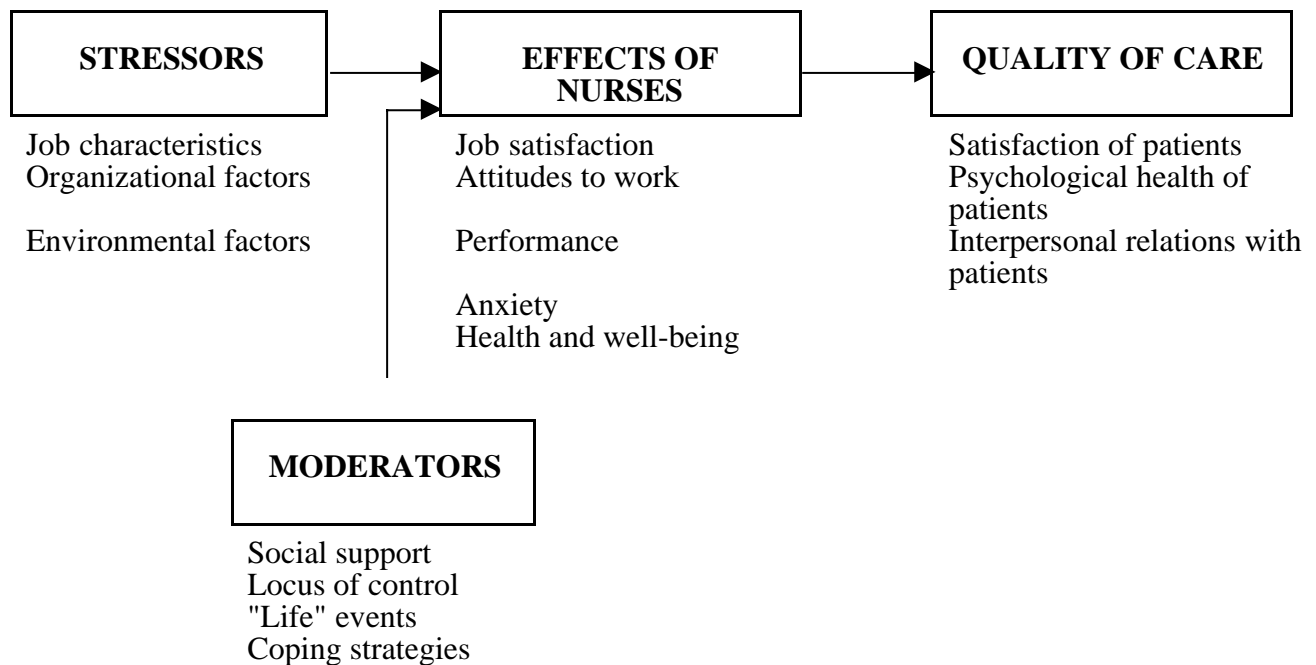
STRESSORS	**EFFECTS OF NURSES**	**QUALITY OF CARE**
Job characteristics Organizational factors Environmental factors	Job satisfaction Attitudes to work Performance Anxiety Health and well-being	Satisfaction of patients Psychological health of patients Interpersonal relations with patients

MODERATORS

Social support
Locus of control
"Life" events
Coping strategies

Figure 1. From Wallis (1987) Satisfaction, stress and performance. Issues for occupational psychology in the "curing" professions. Work & Stress 1(2):113-128.

What seems to be clear from these studies is that one cannot assume that improving the work environment of health care personnel will automatically improve quality of care, and vice versa.

It is this conflict of interest (although it may not always be plainly stated) that is the common denominator underlying all of the studies we identified in this review. The authors of the studies are attempting to discover the mechanisms behind, and effects of, increasing both patient and personnel satisfaction and well-being. The assumption that all of the studies operate on is summarised well by Shortell et al (17): "An optimal performing unit would be one that provides

superior patient outcomes at less cost with high levels of patient, family, and staff satisfaction". This assumption is reflected in the models, hypotheses, and outcome measures chosen by the researchers in our literature review.

Models

We found eleven studies that looked at both quality of care and personnel satisfaction. Three of the studies presented models (figures 1-3). The final outcome of interest for these researchers is not personnel well-being, but quality of care, the primary performance indicator for health care workers. Wallis (20) and Weisman and Nathanson (21) define quality of care partially by satisfaction of patients, or clients. The latter and Shortell et al (17) also give some kind of "objective" measure of quality of care, such as client compliance and risk-adjusted mortality. In the first two figures, staff satisfaction and health is seen as a mediator between stressors and quality of care, whereas figure 3 includes nurse turnover (which can also be seen as an outcome of nurse satisfaction) as a measure of quality of care in intensive care units.

Figure 2. From Weisman, C.S. and Nathanson, C.A. (1985). Professional satisfaction and client outcomes. A comparative organisational analysis. *Medical Care* 23(10):1179-1192.

These theoretical models, which are representative of all of the studies we found, seem to indicate a departure from the traditional view in occupational health of the staff in the centre. While staff satisfaction and health are seen as important contributors to quality of care, they are not the main focus of the research. Rather, the focus is on improving the quality of care provided, which entails closely examining the psychosocial and organisational milieu in which the people who provide these services work.
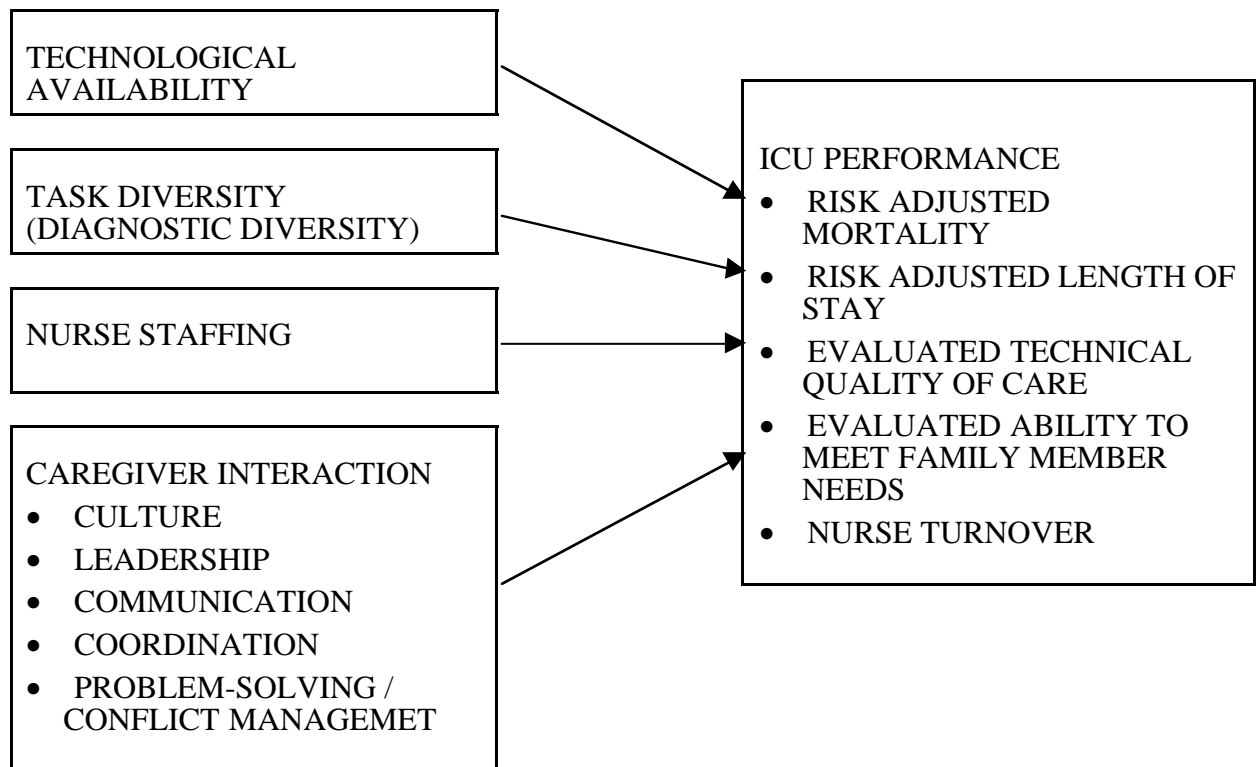
TECHNOLOGICAL
AVAILABILITY

TASK DIVERSITY
(DIAGNOSTIC DIVERSITY)

NURSE STAFFING

CAREGIVER INTERACTION
- CULTURE
- LEADERSHIP
- COMMUNICATION
- COORDINATION
- PROBLEM-SOLVING /
  CONFLICT MANAGEMET

ICU PERFORMANCE
- RISK ADJUSTED
  MORTALITY
- RISK ADJUSTED LENGTH OF
  STAY
- EVALUATED TECHNICAL
  QUALITY OF CARE
- EVALUATED ABILITY TO
  MEET FAMILY MEMBER
  NEEDS
- NURSE TURNOVER

Figure 3. From Shortell et al (1994) the performance of intensive care units: Does good management make a difference? *Medical Care* 32(5):508-525.

Designs

Among the studies examined, six were cross-sectional and three were longitudinal. Only one study had a control group (10). Arnetz and Arnetz (5) surveyed hospital patients and personnel twice, with a one-year interval, as to their work environment (for the former) and satisfaction (for both). Results were aggregated by ward. Weisman and Nathanson (21) interviewed 344 family planning nurses once and their clients (n=2,900) three times over a one-year period. In this study, results were aggregated by clinic. Jones and colleagues (10) looked at aggregate results of a stress management programme on malpractice frequency in 22 hospitals compared to 22 control hospitals. Finally, Aiken et al (1) matched "magnet hospitals" (referring to their capacity for attracting nurses) with comparable hospitals, but the study was still cross-sectional. The other five studies compared hospitals, or hospital units, with each other and conducted regressions to identify important factors and analyses of variance to test hypotheses. All of the studies but one (5) were based in the United States.

Outcome measures

For personnel, the outcome measures used in these studies are job satisfaction, burnout and nurse turnover. For patients, the measures are more varied: satisfaction, risk-adjusted mortality, risk-adjusted length of stay, malpractice

frequency, compliance, (personnel) evaluated technical quality of care, evaluated ability to meet family needs and quality audits.

Hypotheses

As mentioned above, all of the authors of these studies regard quality of care as the final outcome of interest. That said, all of the hypotheses proposed by the researchers involve the health care provider to some degree. The studies include to varying degrees the hypotheses that organisational attributes affect personnel satisfaction and burnout, that caregiver interaction contributes to patient mortality, and that personnel satisfaction has an impact upon client satisfaction and compliance. Weisman and Nathanson (21) summarise these hypotheses in the following way: "The general hypothesis is that organisations with more highly satisfied professional staff are likely to produce higher levels of client satisfaction and better client compliance than organisations with less satisfied staff".

Results

For the most part, the hypotheses put forward by the researchers were not discounted by the results of the studies. However, there were a couple of surprises.

The Weisman and Nathanson study, which was longitudinal, and thus comes closer to meeting scientific rigour than the cross-sectional studies, is perhaps the most interesting. They found support for all but one of their hypotheses. They found that nursing influence and lack of staff conflict were predictors of staff job satisfaction, and that the latter was the strongest predictor of client satisfaction. Furthermore, higher levels of staff conflict in a clinic had a negative effect on client satisfaction through the mediator staff satisfaction. So there seems to be some support for the hypothesis that staff satisfaction is a mediator of patient satisfaction. However, their results also indicated that nursing influence on clinic policies and activities *negatively* predicted client satisfaction. Thus, in those clinics where nurses had a lot of decision latitude, clients were less satisfied. This was the opposite of what the researchers had expected.

Arnetz and Arnetz (7) found a similar seemingly counter-intuitive result wherein higher nursing staff perceptions of work efficiency (working towards the same goal, planning work and decision-making processes) were associated with lower patient satisfaction. In a similar study, the same group found that patients' perceptions of personnel's work environment was one of the most important predictors of their ratings of the quality of care provided in the same ward (5).

Several of the cross-sectional studies also provide evidence supporting the work environment-job satisfaction-quality of care model, although their results must be interpreted carefully. For example, aggregated data from 50 nursing units indicated that job satisfaction could be explained by the presence of participative management styles, and that job satisfaction, in turn explained staff retention (12). In the same study, lower job stress was a strong predictor of quality of care, as measured by a nursing audit. Aiken and Sloane (2) and Aiken et al (3) also found

that burnout among nurses was lower, and patient satisfaction higher, on specialised AIDS units and magnet hospital units than among personnel and patients in other units.

Evidence linking the work environment and work satisfaction with "objective" outcomes such as patient mortality and survival are not as straightforward. For example, while caregiver interaction was found to be related to lower nurse turn-over and staff-evaluated quality of care, it could not predict risk-adjusted morta-lity on the same wards (17, 22). On the other hand, Aiken et al (1) found that patient mortality in magnet hospitals was significantly lower than in matched controls. Furthermore, the only controlled study found reduced malpractice claims in the hospitals that implemented a stress management programme compared to those that did not (10). However, the authors point out that results could have been biased to some degree by self-selection and the fact that there was a decrease in occupied beds in the intervention group during the evaluation phase of the project.

Conclusions

The literature indicates that there seems to be a relationship between organisa-tional attributes, personnel satisfaction/health and the quality of care provided to patients. At the same time, there is also evidence that there is sometimes a conflict of interests between health care personnel's wants and needs and patients wants and needs. For example, increased decision latitude and higher perceived effici-ency among personnel was found to be related to decreased patient satisfaction. Furthermore, the results linking job satisfaction with patient mortality were contradictory across studies.

There is a need for intervention studies in this area in order to determine cause and effect. Such studies would also provide more possibilities for suggesting improvements in the health care environment for both personnel and patients. In the following section, the study by Arnetz and Arnetz (5) is presented in greater detail. Although the study is not controlled, it shows how such integrated studies can provide concrete data on which health care management can base its quality improvement activities.

Case study: the QWC-Project

The Regional Hospital in Örebro, Sweden (RSÖ) has conducted a unique series of questionnaire studies in a systematic quality improvement project called Quality, Work and Competence (QWC). Various aspects of the project have been described in detail in a number of previous reports (4, 5, 6, 14, 15). After an initial survey of hospital physicians' views of their work organisation (4), RSÖ initiated simultaneous questionnaire surveys of staff work environment and patient satisfaction with the quality of care (5). Staff (including physicians) and patient surveys were conducted in 1994, 1995, 1997 and 1999.

The questionnaire instrument used for analysing staff views of their work environment encompassed eleven main indices, or "improvement areas" that

describe various aspects of the work environment and hospital organisation. Beginning with the second measurement in 1995, the questionnaire contained additional questions regarding the hospital staff's perceptions of the quality of care provided on their specific unit. The quality of care instrument describes patients' views about hospital care, summarised in nine improvement areas such as participation in treatment, respect and medical competency. One of these areas describes patients' perceptions of the hospital staff's work environment. Thus both hospital work environment and quality of care were studied from this dual perspective, i.e. both were rated by personnel and by patients. These two questionnaires were developed within the framework of the hospital's overall quality policy and operative goals. After each measurement point, survey results were presented in a systematic way, and every hospital department was given guidelines for how to work with the areas showing greatest improvement potential. Results provided the impetus for improvements that could be measured in follow-up surveys.

One example of change initiated by the first questionnaire results was in the department of geriatrics. The department developed new strategies for both verbal and written information to patients about department routines. By the second questionnaire study one year later, the index mean for "Information-routines" for the geriatrics department increased significantly. The department of hand surgery also succeeded in improving patient ratings following specific quality improvement measures. As a result of the initial study, the department focused on improving "Accessibility" by devising new routines for preparing patients for outpatient surgery. The result was fewer cancelled operations and shorter waiting times. The mean value for this index also improved significantly (5).

The changes initiated were positively associated with significantly higher staff ratings of the improvement areas "Participation" and "Personal development". Compared to the initial measurement, patient ratings of all quality of care parameters were significantly higher after one year, with the exception of "Information concerning one's illness" and "Medical treatment", where no changes were seen.

In addition to concrete results of the change initiatives, some important conclusions about the relationship between patients' ratings of quality of care and personnel's perceptions of stress could be drawn from this study. Patients' favourable perceptions of the staff work environment was a predictor of a positive overall quality rating from patients, a finding that was consistent over time. In addition, there was an inverse association between hospital staff's perception of work stress levels and quality ratings from patients. Thus, hospital departments where staff considered stress levels to be high received lower quality of care ratings from patients.

The QWC project is an example of a structured intervention designed to improve the health care environment from both personnel and patient perspectives. Studies such as these make it possible to study not only specific elements in the work environment, but also add insight to the association between work

organisation and quality of care. While intervention studies in any setting present a number of challenges, the health care environment presents specific issues. The following are some of the challenges that we identified in the QWC project.

1. It is not uncommon for the everyday "clinical reality" to interfere with the scientific rigour of any study (11). Thus, unexpected medical emergencies or any other unplanned changes in ward activity must be considered. Distribution of questionnaires, for example, may not occur as planned if staff attention must be focused elsewhere. Patients' well-being must be prioritised in all events.

2. "Duration of adherence" (13) to any intervention is easily threatened in the health care setting. Staff members who lack interest in the subject being investigated are likely not to adhere to instructions or guidelines of the intervention. Even staff who believe in the goals of a specific intervention may feel that it takes up too much time, interfering with the daily routines and adding additional stress. With the high pressure and fast pace of today's health care system, staff often find it difficult to adhere to the routines of studies that last as long as one year. Once again, patient welfare or safety issues may interfere with a structured intervention, and may cause inadvertent interruption or delay.

3. Many studies, like those presented here, base their analysis on written questionnaires. An assurance of anonymity, both to staff and to patients, is often required in order to achieve acceptable response rates. This limits researchers to studies with a repeated, cross-sectional design, where individuals cannot be followed over time (19).

4. Various forms of bias are possible. In patient as well as staff surveys, social desirability or ingratiating response bias must be considered. Patients may feel dependent on the health care organisation, and thereby choose to avoid expressing negative viewpoints. Selection bias may affect the validity of the responding population; information bias may affect the validity of questionnaire responses.

In summary, there are numerous practical difficulties that may be encountered in the design and execution of intervention studies in the health care environment. Nevertheless, the QWC project offers evidence of concrete, positive results when interventions strive to enhance health care quality from both staff and patient perspectives.

Proposal of a model

The object of this paper thus far has been to establish a case for combining personnel and patient experiences in intervention studies of the health care work environment. There is evidence that the two affect one another, and that improving one stakeholder's circumstances will not necessarily indicate improvement in the other's. Based on this evidence, it cannot be assumed that improvements in health care personnel's work environment will result in corresponding improve-

ments in patient-rated quality of care. If this is the case, and if one accepts that patient outcomes are a relevant measure of performance in the health care sector, then it is important to design intervention studies in this sector accordingly. It is not sufficient to just measure one or the other.

In the light of the above argument, we propose the following model for intervention studies of the health care work environment.
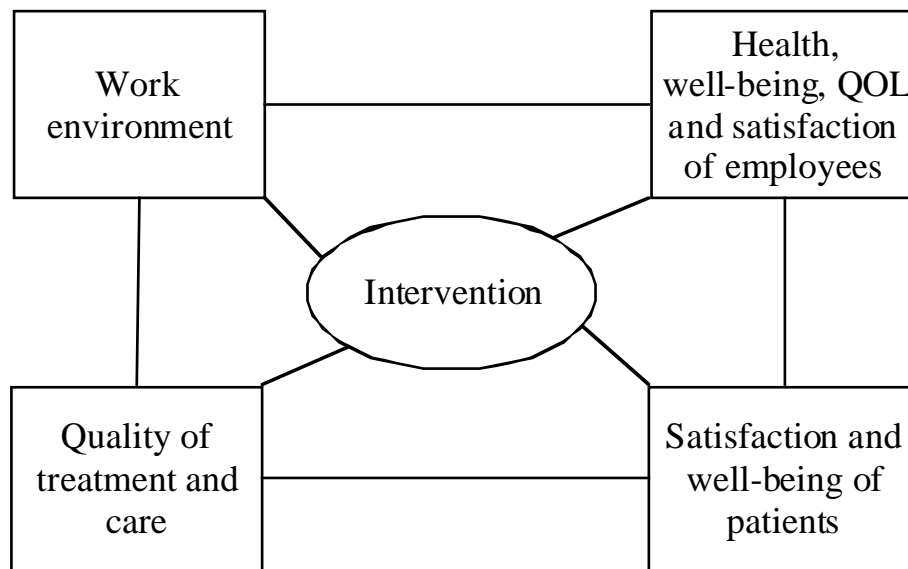

Figure 4. The Sirdal model.

The "Sirdal model" was developed as a response to the evidence presented in the literature reviewed in this paper. The name is derived from the town in Norway at which the Nordic Network for Intervention Studies in Health Care first discussed the concepts and schematised the model. It is based on two assumptions. 1) The four outcomes - personnel's work environment, personnel's satisfaction and health, quality of treatment and care, and satisfaction and well-being of patients - are worthwhile outcomes in themselves; and 2) patients have the ability to judge the quality of health care, including the personnel's work environment. The model was designed as a kind of vision for the field of intervention studies in the health sector. We hope that it will lead to a new way of looking at and performing such studies.

Examples of studies that could be conducted in this area are:
1. The consequences of patient participation on health care quality (such as reduced mortality and increased compliance).
2. The consequences of patient participation on personnel's work environment (such as the need for increased knowledge and changed attitudes).
3. The consequences of personnel participation in decision-making on health care quality (such as reduced waiting times and new methods of treatment).

4. The consequences of personnel participation in decision-making on personnel well-being (both mental and physical).

Comments and conclusions

This chapter points to the importance of applying a holistic approach to studying the health care environment. The review indicates the crucial role work environment issues play in order to create top quality health care. However, one should also recognise the inherent conflict between quality improvement initiatives and healthy work settings. The challenge is to determine the causal relationships between organisational characteristics, such as goal clarity, efficiency and leadership, staff satisfaction and ultimate patient outcome in order to be able to identify characteristics that lead to an optimal care environment for both the provider and the patient.

One unique study is the 5-year and running full-size intervention study at Örebro Regional Hospital. In this real-life laboratory, researchers, managers and practitioners have built a unique knowledge database resulting in theoretical models that are constantly challenged and modified by new data. The project has also generated some important "lessons learned" about conducting intervention research in a health care setting in general, and integrating the patient and personnel perspectives in particular.

There is clearly a need to carry out not only cross-sectional exploratory studies but also to move on to intervention studies. Why not apply the same stringent demands for quality improvement and management enhancement initiatives as we do for medical technologies and pharmaceuticals? It is time to introduce the term evidenced-based management and ensure that the patient focus and the employee focus get equal playing time. Then, and only then, will we be able to create healthy work environments where patients and staff alike benefit.

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The choice of endpoint variables in intervention studies in the health care sector

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The choice of endpoints is one of the fundamental choices in all types of intervention studies. The aim of any deliberate intervention is to change something from what it would have been, to something more desirable. In clinical trials the endpoints are usually mortality, survival time, morbidity, use of medical treatments, or health-related quality of life. In health-related intervention studies in the non-clinical setting the endpoints can be changes in behaviour, symptoms, diseases, or organizational outcomes. An intervention study can have more than one endpoint. In any case, it is of great importance that the endpoints are discussed and determined *before* the start of the project.

When the researchers and collaborators choose the endpoints of a study, the following questions should be kept in mind:

1. *Theoretical background.* It is important that an intervention study is based on explicit theoretical considerations. In scientific intervention studies we want to contribute to the understanding of the research field we are working in. This means that the intervention should be based on hypotheses regarding possible consequences of the intervention. After the study we should be able to draw conclusions of significance for others than the participants in the study (external validity). Most reviewers agree that occupational intervention studies have serious shortcomings with regard to theoretical basis. In their review of the field, Goldenhar & Schulte (1994) conclude as follows: "Theory can help researchers design studies that provide more interpretable and generalizable results. However, all too often, intervention research has been conducted in a "try it and see" manner, primarily based on the individual researchers' intuition and experience .

2. *Study size.* If the chosen endpoint has a low incidence in the chosen population, a large study group and a long follow-up time will be required. This means that the study will be very expensive and sensitive to drop-out from the intervention and control groups. If, on the other hand, the endpoint is change in the exposure at the workplace or change in the behaviour of the employees, a much smaller study size will be sufficient.

3. *Reversibility.* If the disease or symptom of interest is chronic or very stable over time, an intervention study may turn out as a "false negative" study. This has to do with the fact that most intervention studies in this field start off with an average population consisting of different age groups. Some of the participants already have the "disease" (such as burnout, low back pain, or alcohol-

ism) at the beginning of the study. Since these "diseases" are difficult to "reverse" to "non-diseases", the researcher may conclude that the intervention did not have the desired effect. An intervention starting with persons without the disease in question might reach the opposite conclusion. Preventing a disease from developing is not the same as reversing a disease that has already developed.

4. *Reliability and validity.* It is very important that the endpoints of an intervention study are measured with reliable and valid instruments. Blinding should be applied whenever possible, and if not possible, the researcher should make an effort to make sure that the measurement of endpoints is not biased with regard to intervention status (intervention vs. control group). The measures of endpoints should have good responsiveness, which means that changes in the characteristics being measured should be well reflected in changes of the values of the measures.

5. *Developmental chains*. Sometimes it can be useful to include a number of variables that are regarded as a "developmental chain" as endpoints in an intervention study. In a smoking cessation study, for example, the "stages of change" in the process leading to smoking cessation could be very relevant endpoints. These stages are "pre-contemplation stage", "contemplation stage", "preparation stage", "action stage", and "maintenance stage" (8). The inclusion of such stages gives a much more detailed and precise picture of the effects of an intervention than just the prevalence of smokers. Similar stages could be relevant in relation to other effect measures.

6. *Stability of endpoint changes.* Many intervention studies have a very short time frame, and the follow-up period is usually too short (2, 11). In the planning stages of an intervention study the length of follow-up should be carefully considered. Endpoints may show a positive effect if they are measured immediately after the intervention , but most researchers as well as decision makers are more interested in the long-term changes.

7. *Soft versus hard endpoints.* Self-reported endpoints are sometimes considered "soft", while endpoints that are measured using methods from natural science are called "hard". Most studies would benefit from the inclusion of both types of endpoint, and both types should be measured objectively with valid and reliable methods. According to Kompier et al (1998), too many occupational intervention studies include only soft endpoints such as satisfaction or motivation of the workers, rather than hard endpoints such as productivity, quality of products, or absence from work. Other types of "hard endpoints" could be physiological measures or medical diagnoses. In the Stockholm intervention study on urban bus drivers the researchers included biomedical measures, self-reported measures and observational methods in the same study (9, 1).

8. *Floor or ceiling effects.* Intervention studies may underestimate the effect of an intervention if many of the participants are already "healthy" at baseline. For instance, a review of burnout intervention studies demonstrated that many of the participants in these studies had extremely low levels of burnout before the onset of the intervention (7). This corresponds to launching smoking

cessation programmes in groups with high proportions of non-smokers. In such cases only marginal effects can be expected. The solution here could be to target the intervention to those with high levels of the factor in question, or to stratify the analyses after the intervention in order to avoid the ceiling effects.

Before starting an intervention study these eight issues should be discussed and evaluated thoroughly. Some intervention researchers measure a large number of variables at baseline, which makes it possible to embark on a "fishing trip" for significant changes of endpoints after the termination of the intervention. Such ad hoc intervention studies have limited scientific value.

In the next paragraphs I shall go deeper into three questions with significance for the issue of endpoint selection and evaluation: feasibility studies versus aetiological studies, the use of control groups, and the question of control persons versus control work-sites.

Aetiological and feasibility studies

In occupational epidemiology it is customary to distinguish sharply between "exposures" and "diseases". The aim of analytic epidemiology is to identify exposures that increase the risk of disease. Any factor that increases the risk of a disease is called an (aetiological or causal) risk factor. By reducing or eliminating these factors the incidence of disease is reduced, which is the ultimate goal of evidence-based prevention. In most textbooks on epidemiology the study designs are ranked with the case studies at the bottom and the randomized controlled trials at the top of the hierarchy (see Figure 1). This is due to the fact that the randomized trial is considered to be the most conclusive with regard to causal evidence. (In observational studies there will always be problems of interpretation due to bias, confounding and other sources of error).

Intervention studies:	*Randomized trials*
	Quasi experiments
	Natural experiments
Observational studies:	*Longitudinal studies*
	Prospective studies
	Case-control studies
	Cross-sectional studies
	Case-only studies
	Case reports

Figure 1. The hierarchy of research designs.

Suppose that we want to reduce the prevalence of low back pain among the employees who take care of the patients at a hospital. Since the weight of the patients cannot be changed, and since they have to be lifted and moved by the personnel in connection with the normal care and treatment, it is necessary to

learn new lifting techniques which will reduce the exposure of the employees. The research question is: "Does a course in new lifting techniques reduce the occurrence of low back pain among the employees who move and carry the patients?" In order to answer this question a randomized trial is performed. The employees at a number of wards are offered courses in a new lifting technique believed to reduce the harmful exposure leading to low back pain. Employees at other wards performing the same type of work constitute the control group. Low back pain is measured using valid and reliable methods before and several times after the course in new lifting techniques. (Possible endpoints could be clinically diagnosed diseases of the back, self-reported low back pain measured with standard questionnaires, functional disability due to low back pain, absence from work due to low back pain, use of medicine to reduce low back pain, and early retirement or change of work due to low back pain).

Now, suppose that the study is "negative": The occurrence of low back pain is not significantly reduced among those who attended the course compared with the control group. What does this tell us about the causal link between reduced exposure to "harmful lifting and moving of patients" and low back pain? As a matter of fact, it does not tell us anything about the aetiological question. The problem is that we do not know to what extent the new techniques were actually used in the intervention (or control!) group. Figure 2 illustrates all the important steps we have to study in order to be able to answer the aetiological question in a valid way. First of all we have to study the lifting courses. To what extent did the employees actually attend these courses, did they learn what they were supposed to learn, and did they learn the techniques in *practice*? With regard to the last question, it is very common that courses teach new techniques under very unrealistic conditions. (In the case of lifting techniques, the participants may learn how to lift a person without pain and of normal weight. In practice, some of the patients are extremely heavy and in great pain, which makes lifting and moving much more difficult).

Main research question: Does a course in new lifting techniques reduce the occurrence of low back pain?

Specific research questions:

1. *The course: Did the participants acquire the skills?*
   a. How many attended the whole course?
   b. To what extent did the participants learn what they were intended to learn?
   c. Did the participants learn how to do the lifting under realistic conditions?

2. *Implementation after the course: Did the participants use the new lifting techniques?*
   a. Did the working conditions allow the participants to use the new lifting techniques?
   b. Did the participants use the new lifting techniques in practice?
   c. For how long and to what extent did they use the new lifting techniques?
   d. Did the participants teach the new lifting techniques to new colleagues?

3. *The effects of using the new lifting techniques: Was the occurrence of low back pain reduced?*
   a. Was the prevalence and/or intensity of low back pain reduced among those who already had low back pain?
   b. Was the incidence of new cases of low back pain reduced among the employees?

Figure 2. Feasibility and aetiological questions in an intervention study on lifting techniques and low back pain.

The next set of questions is concerned with the implementation of the new techniques after the course. Very often it is seen that the impact of a course is limited because the realities of the normal working routines make it difficult to use the new techniques. These techniques may require more time, the use of special equipment, or the presence of more than one employee. The use of new techniques may also be met with psychological resistance from other colleagues or from patients. All these factors may result in a slow and steady reduction in the actual use of any new technique, and it is important that this is elucidated in an intervention study.

The third set of questions in Figure 2 relates to the aetiological question: Provided that the new techniques are actually used in practice, do they reduce the endpoint: low back pain? Again, the question has to be clarified. New techniques may reduce the incidence of low back pain among those who did not have this illness at baseline; however, they may be inefficient in reducing the prevalence among those who already suffered from the illness. The intervention study should distinguish between these two questions.

This example makes it clear that any researcher performing an intervention study should distinguish between the question of feasibility (Was the exposure actually changed?) and aetiology (Did the change of exposure change the

occurrence of the disease?). If the exposure was not changed (or only changed very little), we should not expect any beneficial effect. To put it briefly: It does not help that the pill is effective if the patient does not take it (feasibility), and it does not help that the patient takes the pill if it has no effect (aetiology).

Before launching any intervention study it is very important to be quite clear about the issues of feasibility and aetiology. This is due to the fact that these two questions lead to different requirements with regard to study design and choice of endpoints. In Figure 3 the main requirements of the two types of intervention studies are shown (10). In aetiologic intervention studies we usually need large samples because the endpoints are diseases/health changes. Most diseases are not very common, which makes it necessary to have large study groups in order to have sufficient statistical power to detect differences.

Aetiological	*Prevention effectiveness*
Large samples	Small samples
Endpoint: health/disease	Endpoint: Exposure
Removing exposure is problematic	Removing exposure is the very purpose
Blinding and randomization desirable	Blinding and randomization superfluous
Results (endpoints) important	Process important

Figure 3. Two types of intervention studies: Aetiological and feasibility studies.

The third point in Figure 3 is concerned with the intervention itself. In aetiological studies, removing the exposure may be a problematic procedure, since the disease process may not be reversible. (Taking cigarettes away from lung cancer patients does not reduce the occurrence of the disease among these patients, since the disease is chronic and fatal). The key message here is that a causal factor will increase the occurrence of a disease, but this does not always mean that removing this factor from those who already have the disease will make them healthier. This is important to remember in occupational intervention studies, since the inter-vention is often performed as a reduction or removal of an exposure believed to be harmful. (The opposite is not considered ethical.)

Blinding is desirable in order to reduce information bias, and randomization is desirable in order to reduce selection bias and confounding. These potential sources of error are of great importance in aetiological studies, and they should always be taken seriously. In practice, blinding and/or randomization may be impossible or extremely difficult in the occupational setting, but this does not mean that the issues of bias and confounding can be ignored. A good reason for

not randomizing is not a good reason for disregarding the reasons for preferring randomization.

In aetiological studies the health endpoints are extremely important, since the aetiological question relates to the risk of becoming sick. Special care should be taken to avoid any differences in measuring the disease endpoints between the intervention and control groups.

If we move to the feasibility question, the recommendations are quite different in many respects (the right column in Figure 3). When we want to study ways in which to change the exposure we do *not* need large samples. Usually it is more important to study the process of changing the exposure under different *conditions* (types of wards, hospitals, nursing homes, homes for handicapped, etc.). Also, it is of importance to study feasibility in relation to different groups with regard to seniority, age, education, culture, and gender. A course may be efficient in those groups who are used to attending courses, but inefficient in those who are not.

With regard to the study endpoint, the endpoint is *change of exposure,* not in health status. This means that observational methods and technical methods (such as videotapes, measurements of physical factors, etc) may be of relevance. While the removal of exposure could be problematic in aetiological studies due to problems of irreversibility, the removal of exposure is the very purpose of a feasibility study. Blinding and randomization are not appropriate, since the active participation of the employees is important in the change process. And finally: the process is important in feasibility studies. This is well illustrated by the example in Figure 2. The whole process, from the participation in a course to the establishment of new ways of working as a permanent feature at the workplace, is a long and complicated process, which needs to be elucidated. Most experts recommend that qualitative methods should be used in the research on this process of change, as opposed to the use of quantitative methods in the assessment of health effects (4).

Figure 3 seems to suggest that the two purposes: to study feasibility and to study aetiology, cannot be combined in the same study. This is not necessarily the case. The point here is to emphasize that the researcher should consider both questions before initiating an intervention study. If the aetiological question, such as the connection between heavy lifting and low back pain, can be considered as "settled", then the researcher does not have to include low back pain as an endpoint in the study. He/she can concentrate on the feasibility question, which has considerable consequences for the design and the costs of the project. If the aetiological question cannot be considered as settled, the researcher has to include both types of question in the study protocol and to design the project so that both feasibility and aetiology can be elucidated in valid ways.

In epidemiology the concept of aetiology is almost always used in connection with the aetiology of *diseases.* In Figure 4, an example illustrates that the term aetiology can also be used in connection with other endpoints. In this example, the study is about the aetiology of interpersonal conflicts at the workplace, and the hypothesis is that the practice of better communication skills can reduce the level of interpersonal conflicts. In this study we need to consider the whole process

leading to a possible reduction in conflicts, in much the same way as in the low back pain example illustrated in Figure 2.

Main research question: Can improvements of communication skills reduce the level of interpersonal conflicts among workers who work in groups?

Specific research questions:

1. *The course: Did the participants acquire the skills?*
   a. How many attended the course as intended?
   b. How much did the participants learn during the course?
   c. Were the participants trained in practising the new skills?

2. *Implementation after the course: Did the participants use their new skills?*
   a. Was it possible for the participants to use their new skills?
   b. Were the participants able and willing to use their new skills?
   c. For how long and to what extent did they practise the new skills?

3. *The effects: Did the use of new communication skills influence the occurrence of interpersonal conflicts?*
   a. Did the new skills reduce conflicts between those who already had conflicts?
   b. Did the new skills prevent new interpersonal conflicts among those who received training?
   c. Did the new skills prevent conflicts between course participants and other colleagues?

Figure 4. Feasibility and aetiological questions in an intervention study on communication skills and interpersonal conflicts.

In this paragraph we have used the term *feasibility* to describe the question of changes in exposure. In clinical trials the terms *compliance* and *adherence* are used to describe the degree to which the patients or participants take the recommended medicine or change their behaviour in the direction recommended by the researcher. In the public health literature the terms *prevention effectiveness* (10) and *performance* (3) have been suggested. In the paper by Habicht et al, the term *performance* covers *provision* (Is the preventive method available?), *utilization* (Is the method being used?), and *coverage* (How many use the method?). It is clear that these terms cover some of the same steps as the models in Figure 2 and 4. Moreover, Habicht et al use the term *impact* in much the same way as we use the term a*etiology*.

The use of comparison or control groups

When the use of comparison or control groups is discussed in relation to occupational intervention studies, it is often stated that "it is impossible to find a workplace where no changes take place" or "the only constant thing is change". In the discussions on control groups or control work-sites it is often assumed that a control group should be a group where "nothing happens". This conception is

based on a misunderstanding of the purpose of including a control group in a controlled trial.

If a person has a headache and takes a pill, she or he will often experience that the headache disappears. Most of us will assume that the pill had the desired effect: the headache disappeared. The problem is that we do not really know anything about what would have happened to the headache if we had not taken the pill. And even worse: *We have no way of knowing this!* We cannot step back in time and repeat the course of events as "our own control person". A lot of diseases and symptoms get better and disappear without any treatment due to the normal functioning of the human mind and body. In many cases we take medicine instead of waiting for the natural cure, and in these cases we attribute the effect to the treatment. This is good for the drug industry, but nonetheless wrong from an aetiological viewpoint.

An effect of a treatment is by definition *the difference between the development of the disease process when taking the treatment and the disease process that would have taken place without the treatment.* Hence, the purpose of including a control group in a trial is to get a precise picture of *what would have happened in the intervention group without the intervention.* The only way to achieve this goal is to find a group as similar as possible to the intervention group. This means that a control group should not be a group where "nothing happens" but a group in which things change in *the same way as things would have changed in the intervention group without the intervention.* This should be the guiding principle for choosing control work-sites or control groups in occupational intervention studies, where randomization is rarely possible.

If we keep in mind that the course of events in the control group should illustrate *what would have happened in the intervention group without the intervention,* then it also becomes clear how the effect should be evaluated. In Figure 5 some of the common flaws in connection with the evaluation of effect are illustrated. In example A in this figure, the difference (D_1) between the intervention group (I_1) and the control group (C_1) before the intervention is statistically non-significant, and the same is the case with the difference between the two groups after the intervention (D_2). In such situations many authors conclude that the intervention had no (significant) effect, which is not necessarily correct. The correct difference is between the situation as it would have been in the intervention group ("I_2") and the actual situation (I_2). This difference (D_3) may very well be significant (In Figure 5A it is about twice as big as the difference between the two groups.). In these cases we tend to get false negative conclusions.
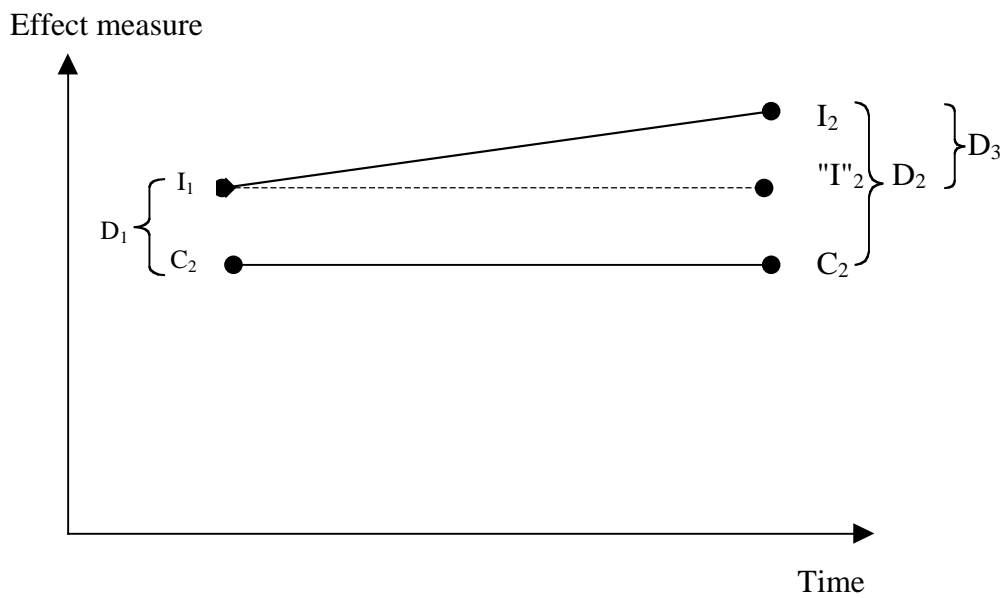
Example A:
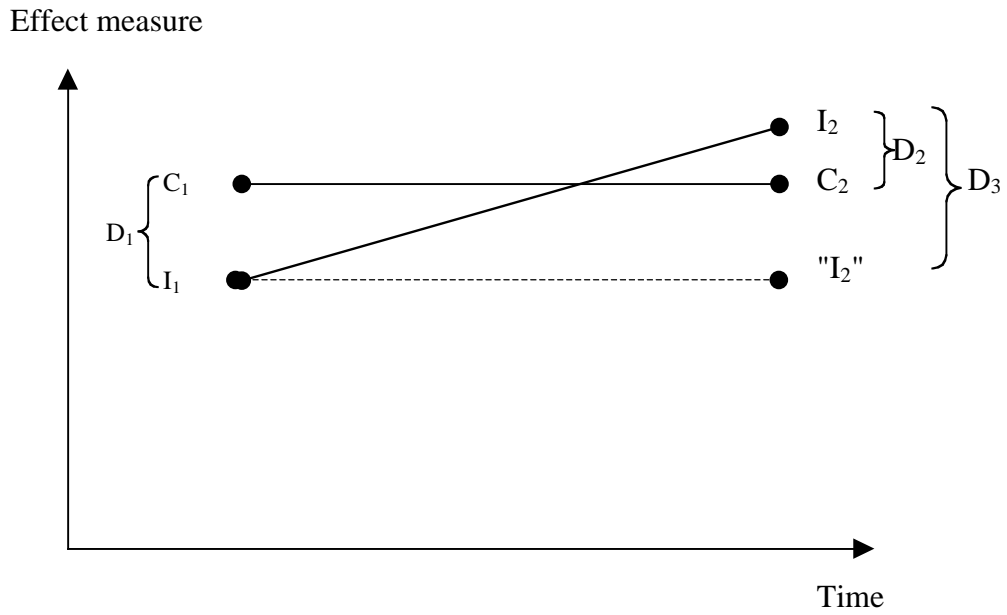
Example B:

Figure 5. Illustration of different developments in the intervention and control groups in intervention studies.

The opposite situation is illustrated in Figure 5B. Here the difference is non-significant before the intervention (D_1), and significant after the intervention (D_2). In this case many authors conclude that the intervention had an effect, when in fact the effect is only D_3 (non-significant).

Control persons or control work-sites?

In medical trials randomization always takes place at the individual level: The patients or participants are randomized so that the groups receiving different types of treatment are as similar as possible. The individuals may be very different, but these differences are "levelled out" when large groups are compared. In occupational intervention studies the unit of intervention is often not the individual but the work-site or the group. This causes special problems for this type of study. In a study with four intervention work-sites and four control work-sites it makes little sense to randomize, since the number of units is so small. In such cases it will be more appropriate to choose intervention and control work-sites in a non-random manner in order to ensure comparability. In practice many considerations will play a role here, and it is difficult to give general rules for this procedure. The only principle that should always be kept in mind is that the control work-sites should represent the hypothetical development in the intervention work-sites if they had received no intervention.

Another guiding principle in occupational intervention studies is that the "level of intervention should correspond to the level of comparison". If the goal is to teach individuals to relax or other types of individual stress management, then it can be appropriate to randomize individuals and to compare the endpoints at the individual level. If, on the other hand, the purpose of the intervention is to reduce the level of interpersonal conflicts at hospital wards, then the unit of randomization (or other selection procedures) is the ward. The intervention should include all relevant persons at the ward and the effect should be evaluated at ward level.

Conclusions

The topic of this chapter is the choice of endpoint variables in intervention studies in the health care sector. It has become clear that this is a central choice, which has consequences for the whole design of the intervention study. The conclusions are of two types: those which apply to all kinds of occupational intervention studies, and those which apply especially to the health care sector.

1. The endpoint of an intervention study can be a measure of exposure (in a feasibility study) and/or a measure of health (in an aetiological study) or both. It is important to clarify this question before deciding on the study design, since it has profound implications for a number of issues.
2. It is important to elucidate the whole causal chain in an intervention study, since this shows "where thing went wrong" if the study turns out to be negative.
3. Intervention studies should include "soft" as well as "hard" endpoints, and these should be measured with reliable and valid instruments.

4. The instruments measuring the endpoints should be sensitive, since it is important to be able to detect even small effects of the intervention.
5. Interventions should be theory-based, since this increases the generalizability of the study results.
6. Endpoints should be measured before and several times after an intervention, and the follow-up period should be long enough to cover detection of expected effects.

With regard to interventions in the *health care sector*, the following four types of endpoints should be included in future studies:

a. Work environment variables. Of particular importance are variables related to exposure to psychosocial, ergonomic and biological factors
b. Variables related to the health and psychological well-being of the employees, such as burnout, chronic stress, self-rated health, absence and labour turnover, morbidity and mortality, and communicable diseases.
c. Variables measuring the quality of treatment and care. The quality of the care can be reflected by survival time, mortality, or health-related quality of life of the patients, or by different cost-benefit measures.
d. Patient satisfaction. The satisfaction and well-being of the patients is of increasing importance in the evaluation of the services of the health care sector.

So far, very few intervention studies in the health care sector have included measures of quality of care or patient satisfaction in spite of the promising results of the intervention studies reported by Jones et al some years ago (1988). There is an urgent need for more studies of this type.

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Psychosocial and organisational risk factors in health care work

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Abstract

In the present paper it is argued that the term "psychosocial factors at work" is rather confusing and should be changed to *Psychosocial and Organisational factors at Work, abbreviated POW factors.* A model for mapping the POW factors at the workplace is proposed, and it is argued that those detailed measurements of such work-related obstacles and stressors are vital for effective interventions to take place. It is also argued that characteristics of the person, such as age and personality, should be taken into consideration when designing interventions for better health or working conditions. While POW factors may be removed, or their effect may be moderated if they are impossible to remove, acceptance of personal characteristics will to a greater extent require adjustment of work to the individual, rotation of some individuals to other jobs, and careful selection when new staff are hired. POW factors take their toll in the sense of lower job satisfaction, burnout, pain and ill health, and thus become expensive for the employer. There is a need for workplace interventions to reduce the problem by either removing the stressors or elevating the problem.

Introduction

The paper discusses the concept of psychosocial factors at the workplace in relation to the health problems of the workforce. The context of the discussion is workplace interventions to improve the health of the workforce, which in this instance is limited to health care workers. The scope of the paper is to present a conceptual model as a tool for such interventions. Some practical research examples are drawn upon to illustrate the discussion. Recommendations are given on how to plan measurements for mapping psychosocial obstacles at the workplace and also make an adequate evaluation of the effects of the interventions.

"Psychosocial risk factors" have been a popular area of research throughout the last 30 years. The name is in itself rather confusing, and the area had to turn to stress theories in order to find a conceptual platform to link unpleasant experiences at the workplace with development of health problems. However, stress theories are not a unified field, which again adds confusion to the research on

psychosocial factors. Adequate research depends, among other things, on good conceptual models as well as valid and reliable measurements. To make good assessments of possible problem factors, the models must be open for a relevant classification of work problems at each workplace. Ideally the assessments should serve three purposes at the same time. They should provide detailed information as a basis for the design of the interventions. They should also allow assessment of change from pre-test to post-test. And finally it would be an advantage to be able to compare one's own results with those found by other researchers in both similar and other types of organisations.

Several conceptual models and also measurement models are in use, and some have generated huge amounts of research. Among the most frequently used models is the one proposed by Karasek (1979) and Karasek & Theorell (1990). The central dimensions in the Karasek model are demands facing the worker and the worker's decision latitude, which includes measures of choice and possibilities to reallocate resources. Johnson & Hall (1988) expanded the model with a dimension of social support. The social support dimension was thought of as a buffer between the stress from work and the possible health problems, which were conceived of as the outcome of the imbalance between demand and decision latitude.

Although the Karasek model has proved to be fruitful it also leaves out important dimensions, such as those related to conflicts, which are central in the stress model proposed by French & Caplan (1970), Kahn et al (1964) and Miles & Perreault (1976). Even in the extended model we find the social factors only as buffers, not as potential problems. Moreover, the work-home interface, which is the sixth element in the Cooper model (54) is lacking in the Karasek model. For the purpose of the present discussion, the stress model proposed by Sutherland & Cooper (1988) is chosen as the base, as the Karasek model is too general for use in workplace intervention research.

The relevance of psychosocial and organisational risk factors for stress

Psychological stress refers here to a state of cognition and negative effects experienced by the person in response to internal or external events (30, 41). Events that tax or exceed the individual's coping resources (28, 51), experiences of role conflicts (23, 54) or imbalance between demands and coping resources (11, 33, 34, 35), situations where set values or expectations are not met (60), or there is a perceived lack of control (31), are all fundamental to eliciting psychological stress. The core of the problem is a sense of psychological threat to some central motivational structures of the individual (29).

The individual never responds with stress to the objective context, but to the cognitive appraisals (29, 52) or step-by-step evaluations (45) of the potential risk factors. What matters is always what the potential stressors, in this case in the working environment, mean to the individual. This meaning will inevitably be influenced by a long list of personal factors, among which age, personality, previous experience, competence and attitudes will play an important role (21, 29,

54). Selection of workforces by age, experience and personality is thus one way to reduce risk factors related to stress at work. Moreover, since cognitive appraisals are central in determining the outcome of the stress processes, interventions containing competence and attitude development programmes should be thought of as highly relevant approaches to workplace health promotion. Adequate information, giving predictability to a certain stressful event, will be a possible resource in the interaction with work stress factors.

In his critical discussion of research on psychosocial factors at work, Kristensen (1996) argues for using three different measures of stress. While subjective experiences will always be of importance, these measures should be supplemented by two other measures of taxing aspects of the work environment. Independent measures are events or processes that can be observed without asking the workforce any questions. In the health care sector such measures are, for example, the patient/staff ratio, registered episodes of violence, or measures of care-load for each patient. These and others can be used as indicators of workload, both before and after an intervention has taken place, and they also allow for estimating change. Kristensen recommends use of group average scores instead of the individual scores, and underlines that the group averages should be based on at least five individual scores on issues relating to the same job. The advantage is to even out the effects of individual differences in perceiving threats and obstacles. Together, these three measures should form a good information base on which the intervention programme may be based. Moreover, he argues that the stressors (events and processes in the work environment) and the stress as a state should not be confused.

The conceptual model that best represents our ways of thinking can be drawn as fig 1. The process follows the flow from left to the right, ending with the outcome (health effects). Personal factors such as age, gender and personality intervene with the process. So do the coping processes, which also include the use of social support (44, 47). Although the model is to be conceived as a flow from left to right, it also includes a flow in the opposite direction. Health outcomes and coping, for instance, will influence the stimulus side, and change the load on the individual. Thus we talk about a transactional model of stress (27, 45, 52).
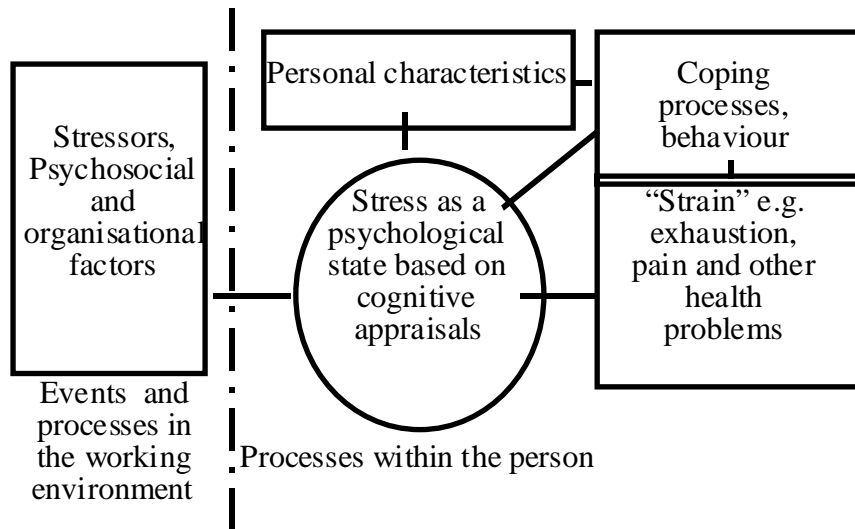
Figure 1. Conceptual model of the stress process for workplace interventions for better health of health care workers. (Modified after Sutherland & Cooper, 1988).

Although not specified in the model, the state of psychological stress is followed by a general activation of the alarm system in the brain (39, 63), which affects all somatic processes either directly or indirectly. The initial psychobiological response to stress affects almost all regulatory systems and organs. The autonomic nervous system, the endocrine systems and the immune systems may be influenced (60), as may biochemical activities of the brain (9).

Consequences of stress are to be found as impaired performances (13, 20, 46), or "strain" in the sense of impairments in general health (53, 60), impairments in quality of life (41), elevated risk of burnout (32, 49), and also increased risks of musculoskeletal pain (2, 5).

Coping is defined as the ability of the individual to reverse the threatening aspects of the situation into more benign conditions, either by changing the external conditions (on the stimulus side, to reallocate resources or receive adequate support) or the interpretations of these conditions or their significance, including also the use of psychological defence mechanisms (29). The perception of control over the threatening aspects of the situation is the core of the coping process (25, 29).

Interventions to improve the health or working conditions of workforces may address only the coping processes (training, better support etc). However, interventions may also be related to several concepts in the model. They may address the working environment, the stress appraisals and stress state, the outcomes (burnout workshops, aromatherapy etc), or the personal characteristics factors (selection and replacement of the workforce). We argue for attacking the stressors' side through organisational-focused interventions (Mykletun, this volume, 7, 12, 15, 40, 43, 48).

Are the stressors in the working environment of health care workers psychosocial or organisational?

The terms "organisational" and "psychosocial" factors at work are often used in an overlapping and confusing way. When using psychological stress theory as a conceptual platform, a wide range of organisational factors may constitute risk factors, and we might discuss whether these are organisational or psychological. When obstacles and stressors at work are in the focus, we need clear ideas regarding the structure and nature of these problems. Again, some similarities might be found in the structures of workplace obstacles and stressors in health care settings. In our own studies (5) we discovered that the staff perceived some rather fundamental configurations of organisational dysfunction. We named them POW factors, as an abbreviation of "Psychosocial and Organisational Work factors". POW factor structures may be generated from questionnaire data through factor analysis. Such factor structures are of course dependent on the type of measurements used to evaluate the organisation. In our case we used both quantitative and qualitative techniques (Mykletun & Wickström elsewhere this volume). The quantitative approach included the Cooper Stress Check, and RJM Work Environment Scale (5). The factors resulting from factor analyses of these scale items were: (1) time pressure, (2) competence problems, (3) monotony, (4) responsibility, (5) social conflicts, (6) poor leadership, (7) career problems, (8) poor institutional policy, (9) work-home overflow, and (10) heavy lifting / strenuous working postures. A closer look at two of the hospital departments under study, also including a qualitative approach with staff meetings and discussions, revealed the following examples:

1)   The questionnaires revealed that the laboratory staff complained about uncomfortable working postures and also about conflicts with colleagues. The discussions at the staff meeting concluded that these problems occurred when collecting blood samples at the patients' bedsides. The laboratory staff worked under time pressure. The rooms had too many beds, there was not enough space for comfortable working positions, department staff were not available for assistance, and the patients did not always cooperate. The problem concerned conflicts with staff outside the laboratory department, often occurring either when the laboratory staff collected their test samples, or when reporting them to the patient departments.

2)   The questionnaires revealed that the orthopaedic staff complained about lack of learning at work. The discussions at the staff meeting made it clear that some lessons were offered during ordinary working hours. However, the staff were reluctant to attend these lessons because their colleagues then had to cover for their ordinary duties. Discussions in the Local Work Environment Committees later revealed that there were no plans for competence development at the department.

3)   The questionnaires revealed that the orthopaedic staff complained about conflicts with other professional groups. Discussions at the staff meeting clarified that this problem was focused on the relationships between the nursing staff at the ward and the medical doctors. The latter had their work organised in relation to seven other wards, and were thus unable to respond to the orthopaedic ward with continuity and stability. Several conflicts and unclear situations emerged, which increased the risk of accidents and mistakes towards the patients.

In a later study of working conditions and health in a residential home for the elderly, the structure of the working environment problems was somewhat different from those described above. First we identified some POW factors including leadership (relationship to leader, distrust, lack of autonomy, communication styles and conflicts, lack of appreciation, role uncertainties and vague expectations). The second group concerned relationships between colleagues (lack of support, communication climate, conflicts and ambiguities, uncertainties and consequences of competition between leaders). The third problem area contained problems intrinsic to the work itself (demands, pace of work, time pressure, responsibilities and high risk of fatal errors). Moreover, we also identified five groups of attributes with the organisational context that applied more to the physical working conditions. These were lack of tools and adequate equipment, monotonous work including repetitive movements and working with back bent forward and sideways, difficulties in moving around and having space for getting the task done, and finally poor indoor climate including dry and dusty air and bad ventilation.

Although some similarities exist between these problem structures, it is important to map them out with pre-test studies in order to identify as exactly as possible the unique problem structure of each work place. In their recommendations to practitioners and researchers, Winnubst & Diekstra (1998) emphasise the importance of diagnosing the problem before attempting to solve it. Their list of measurements includes commonly observed stress factors, such as job demands and autonomy or decision latitude, available backup and social support, available material resources, personal attitudes to the demands of the job, the individual's physical health and strength, and the organisational and extra-organisational conditions for the work. The diagnosis results in a multi-disciplinary approach of "treatment". Their conception of multi-disciplinary attempts includes programmes for 1) socio-medical counselling, 2) quality of work and organisational design, 3) management development, and 4) human resource management.

However, as is evident from the problems and obstacles identified above, this is not only an interdisciplinary activity for experts. Active involvement also from the owner of the institution concerned is essential, since some of the observed problems (i.e. crowded rooms, poor ventilation, speed and autonomy) have to be solved on arenas completely outside the worksite. Some unique problems may be embedded in this issue, since the organisations are mostly owned either by the municipality, country or state, in which case they have restricted budgets and a

very long organisational distance between the work processes and the decision processes with regard to budgets. When the organisations are under political control, they are run at top level rather by practical political compromises, than by genuine interest in the actual mission of the organisations and their actual qualities as working conditions. One would expect that interventions might be given a higher priority if they also gave some pay-off to the effectiveness or quality of the care of the patients, or if patients are included in the intervention (Thomsen, this volume).

In the context of the present chapter, we use the abbreviation POW factors for these terms (5). Since work in the health care sector constitutes a wide range of occupations, tasks, roles and responsibilities, and the contexts of work are varied, as these workplaces are to be found in a wide range of work organisations, the discussion is at a rather general level.

A model for classifications of POW factors

Analysing organisations in order to identify POW factors is by no means a simple task. Departing from the works of Minzberg (1979, 1983) on organisational analysis and functioning, and also upon the classifications of work-related stressors developed by Sutherland & Cooper (1988), a rather comprehensive, but still practical model of work problems and obstacles relevant to the stress state of the individual may be identified. The model of work-related stressors has six main categories. This paragraph gives a brief outline on how to use the model for classifying stressors and obstacles in the work of health care workers.

Organisational factors

A. *Job-intrinsic factors*
   a) task demands (emotional, cognitive, skills), tools and technology unreliable or inadequate, lack of documentation. Notably, the treatment, care and service delivery processes are conducted in close collaboration with the "prosument" (patient and relatives), which may be unpredictable with respect to the degree of co-operation and critical attitudes displayed in the interaction, and the demands placed upon the employee.

B. *The employee's role in the organisation*
   a) role ambiguities (the employee receives insufficient, unclear or ambiguous demands on the product or other aspects of behaviour)
   b) inter-sender role conflicts (the employee is unable to satisfy needs from person A without disappointing person B)
   c) intra-sender conflicts (the employee is exposed to demands from the same source that are incompatible with available resources)
   d) person-role conflict (the employee would prefer to do the task differently from that suggested in the job description)

e)   responsibility (the employee is faced with too much or too little responsibility)

f)   role overload / underload (quantitative and qualitative work over-load, time pressure, overtime, as well as under-stimulating and monotonous work)

C.   *Career development*

      a)   job insecurity (fear of job loss/ threat of redundancy) and use of contract labour force

      b)   status incongruence related to over- or under-promotion

      c)   lack of competence development

D.   *Organisational structure and climate*

      a)   problems due to the horizontal and vertical division of work

      b)   lack of access to the decision-making processes

      c)   lack of effective communication and consultation

      d)   lack of autonomy in one's own work

      e)   workplace policy

      f)   no feeling of belonging and attachment, lack of consideration

Psychosocial factors

A.   *Social relationships at work*

      a)   mistrust in the people, no affiliation

      b)   low supportiveness with, and lack of help from peers, subordinates or superiors

      c)   unbalanced social density (lack of access to other people, or feeling of crowding)

      d)   exposures to abrasive personalities (personal dysfunction at an emotional level)

      e)   technical or authoritarian leadership style, lack of participative leadership style

      f)   pressure to adhere to group standards of performance, status and style of relationships

Extra-organisational demands

This group of stressors includes life events and obstacles facing the person during non-working hours. Such problems interact with workplace demands, and thus either increase the significance of the former, or function as a buffer mechanism that reduces the significance of work-related stressors. Stress problems may be transferred to the work situation, whatever their cause (50). Typically, family problems are likely to interfere with work and vice versa. Since health care workers are mainly females, and females still carry most of the burden of bringing up the children and managing family affairs, the potential is rather high for this

type of problem. Working shifts or evening and night hours may add a burden to family life, and increase the stress potential from this source.

It is recommended that qualitative and quantitative techniques for measuring the obstacles or POW factors are integrated. The qualitative process may be continuous throughout the intervention, and also be the first way of collecting data for later use in the design of items for the questionnaire part of the measurement. The above model of analysis may be applied for that purpose. Moreover, adequate organisational interventions also require a continuous observation of organisational dysfunction. For this purpose it may also be useful to apply the Minzberg (1979, 1983) model of analysis to reveal underlying structures that contribute to the rise of work stressors. According to Minzberg, we can invariably identify five basic parts that constitute the fundamental structure of any organisation. These are the strategic apex, the middle line, the operating core, the support staff, and the techno-structure. New technology and especially computerisation of work are normally to be found at all these levels, although their use and also their significance as stress factors will vary between organisational units.

Within this fundamental structure, several basic processes and functions are invariably to be identified. These include the flow of formal authority (normally presented as the organisation chart), the flow of informal communication, the ad-hoc decision processes, the sets of work groups and their inter-relationships, and the flow of regulated activities (including production processes and the delivery of services). Moreover, several interest groups, internal (employee associations) as well as external (governmental agencies, general public, and associates), interact with the organisation and complicate the pattern by constituting limitations as well as opportunities for the actors within the organisation.

Health problems of health care workers

One would like to think that health promotion would profit from addressing observed health complaints, if cost effectiveness is an issue. Health profiles resulting from studies of workers' health problems obviously depend on the items or criteria included. *Workers' health problems* (26) may be defined in a broad sense as complaints reported by employed individuals about: a) somatic symptoms and dysfunction; b) fatigue and burnout, whether these complaints were measured by self-report or verified by medical examinations, or c) functional ability (26) or work ability (17, 18, 58). Measures such as sick leave, absenteeism or staff turnover may be seen as health-related behaviour, and indicators of health problems. However, these behaviours may be caused by other factors than ill health and the one should not be substituted, conceptually or in measurements, for the other.

Studies of health complaints among health care workers repeatedly show some stable patterns. For instance, in our study of female hospital staff (5) we found that 82 % of the staff had reported musculoskeletal pains within the last twelve months. Low back pain and neck-shoulder pain, were the most common problems. Also reported were pains in extremities (arms, hands, knees), fatigue, digestive

problems, headache, frequent colds and other respiratory complaints, allergies and skin rash, sleep problems and depressed mood and psychological exhaustion (which is one aspect of a burnout state).

In a recent study of the staff at a residential unit for the elderly we found that musculoskeletal pain, including neck pain, shoulder pain and low back pain was the most serious problem. 61 % of the staff perceived this problem to be so strong that it reduced their working effectiveness. Also related to this group was pain in other parts of the body, although far less common and severe. The second group of problems concerned psychological exhaustion, including symptoms such as sleep disturbances, fatigue, dizziness, depressed mood, anxiety and stress. 44 % of the staff reported that this reduced their working effectiveness. The third group of problems were more diffuse complaints, including headache, migraine, frequent colds, digestive problems, allergenic reactions and skin rash, and sore eyes. 56 % found that this reduced their working effectiveness. Although these problems look severe, they were only slightly higher for this institution compared to a random sample of comprehensive-school teachers. About 20 % of the health care staff had been on sick leave for more than ten days during the last year, while the comparable results for the teachers were only five per cent. Obviously, it is worse to continue working with the above health problems in a residential home for the elderly compared to comprehensive schools.

All of these symptom groups are quite complicated. For instance, musculoskeletal pain has no single documented neurological, inflammatory or other patophysiological cause. The problem is presumed to have a multifactorial aetiology (1), developing from complex interactions between external psychological and physical loads, individual psychological and biological characteristics, and psychological and biological reactions. The causal mechanisms may be even more complex. The experience of pain itself may increase the negative effects of external stressors, or provoke psychological and biological reactions that maintain or even increase the experience of pain. A vicious circle may thus be established (6, 8, 56). No single intervention may contain a cure for all of these types of problems, and some of them may not even be cured by worksite health promotions because of the profoundness of the health problem, or the possible fact that it is not related to workplace obstacles at all. Probably we cannot expect strong effects from narrowly focused programmes, such as training in lifting or working techniques, relaxation skills, or conducting stress- and burnout workshops. Comprehensive programmes should probably be recommended, although they leave the researcher with difficulty in tracing causal relationships between cure and effects.

Relationships between stressors and observed health complaints

We like to think of our interventions as curing the problem, alleviating the pain of the symptoms. This brings up the question as to whether there are relationships between the observed health problems and the observed obstacles and stressors at work and, whether these relations are causal. There is much evidence, though

equivocal, for relationships between musculoskeletal pain and a) physical load, and b) individual non-psychological characteristics. The degree of musculo-skeletal pain variance explained by these models is modest, accounting for no more than 20 % (62). Simple, one-dimensional approaches, that ignore the effect of work perceptions and psychological factors on back-injury reporting, over-simplify a multifaceted problem. Recent research has focused upon relationships between psychosocial factors and musculoskeletal pain for several groups (2, 61, 64). For burnout, recent research has highlighted as risk factors, long-lasting psychological stress and imbalance between the individual's own efforts and rewards (49).

However, evidence is rare on relationships between specific psychological and organisational factors, and musculoskeletal pain for hospital staff. In our own study (5), we found that 82 % of the staff had reported musculoskeletal pains within the last twelve months. Some of the subjective health complaints of hospital staff relate to perception of the working environment, and these relationships vary between different subgroups based upon age and part-time versus full-time appointment. Low back pain and also neck and shoulder pain were the most common problems. Psychosocial and organisational work environ-ment factors related especially to neck and shoulder pain for young and middle-aged full-time and middle-aged part-time working staff. The closest relationships to pain were found for the full-time working staff in departments with high perceived ergonomic load. Relationships were lowest for part-time staff in departments with low perceived ergonomic load. The observed "POW factors" were problems related to "institutional policies", "work overload", "social relations", "lack of professional and social support", "monotonous work", "responsibility" and "work-home overflow" as measured with the RJM-scale.

The POW factors emerged as powerful predictors of musculoskeletal pain for young and middle-aged full-time staff and time part-time staff, although strenuous working positions also contributed with unique variance to this complaint. Like-wise, POW factors predicted depressed mood for young and middle-aged full-time staff, and young part-time staff. POW factors also predicted digestive symptoms and tiredness for elderly full-time staff, and middle-aged part-time staff. Finally, POW factors predicted cardio-respiratory symptoms for the elderly full-time staff. Thus, it may be argued that stress problems at work relate especially to the diffuse health complaints that also account for most of the sick leave from work, and for the compensations paid to staff who have retired from work due to health problems. Accepting both the validity and reliability of our measurements along with our theoretical points of departure, it could be argued that the problems giving rise to the measured POW factors could also be causal in eliciting the health complaints that relate to these same factors.

The importance of personal characteristics for developing health problems

According to our model, personal characteristics will be likely to interact with the stress perception and the coping processes. At least two types of characteristics

are of interest here – workers' age and personality (54). Age has become an important issue, as the demographics of most western populations is changing, with a lower number of young workers and higher numbers of elderly workers (17, 18).

In our study there was a trend for young staff to report more dissatisfaction with psychosocial and organisational factors at work than was the case for the elderly staff. Young staff reported significantly more dissatisfaction due to time pressure, feeling of incompetence, poor leadership and institutional policy. A similar significant trend emerged for reporting of strenuous working postures. These findings could indicate that elderly staff have been able to acquire less taxing jobs, or they are treated with more consideration. They also more often work part-time, and do not have to care for their own small children. Thus, some coping strategies are more prevalent among elderly staff than among young and middle-aged staff. These coping strategies may serve as moderators of the relationships between work-related load and health, and also counteract an age-related linear effect on health variables. They also lend support to the idea of a 'healthy worker effect' that selects the less vulnerable staff for full-time employment, whereas the proportion of more vulnerable staff may increase among part-time staff. For 'the survivors', age relates differently to various ill-health symptoms: Younger staff complain about allergies and frequent colds, while elderly staff complain about sleeping problems and cardio-respiratory problems. The proportion of weekly working hours also relates to perceptions of work-related problems. Part-time staff report a lower level of stress from the POW factors. Exceptions to this were, however, 'competence problems' and 'monotony', which were higher for young and middle-aged part-time staff; and 'poor leadership', which was higher for the young part-time staff. The general trend seems reasonable, and supports the idea that part-time is used as a coping strategy for both the work-related and some non-work-related stress. The exceptions also seem reasonable, since the part-time staff may lose some of the learning processes inherent in the daily work, and also be allocated to do the most boring work.

Personality relates to health and perception of working environment (10, 13, 55). Relationships have been found for instance between personality traits and musculoskeletal pain (42, 57). In our study we found interaction between personality traits, musculoskeletal pain and type of work. "Neuroticism", as measured by the Eysenck EPQ, related to musculoskeletal pain and especially to neck and shoulder pain for staff exposed to high emotional load. The Type-A behaviour pattern, as measured by Jenkins' RAS, also related to musculoskeletal pain, and especially to neck and shoulder pain for staff working under high physical load and time pressure. These working conditions applied especially to the orthopaedic department staff, but not to the laboratory staff (4). We must expect similar relationships between personality traits and other health complaints. Such relationships may reflect individual susceptibility to illness as a part of unique personality profiles, or be mediated by behavioural aspects of other personality traits (10, 16, 53).

According to these results, interventions for health promotion in this working environment, the organisation and society could focus on the POW factors predicting common health complaints, and especially for the young and middle-aged full-time staff, and the middle-aged part-time staff. These POW factors include 'work-home overflow', 'time pressure', 'Monotony', 'competence problems', 'responsibility problems', 'poor institutional policy', as well as 'strenuous working positions'. The elderly staff should be focused on in further research to identify their coping styles over time, since they somehow seem to be able to reveal how health care staff could possibly survive the work-related stress. In addition, one should also focus on a better match between workers' personalities and the demands of the job, i.e. having the emotionally stable working with the emotionally demanding tasks, while the workers who are prone to Type–A behaviour should keep away from jobs with heavy lifting. For this purpose a longitudinal design is preferred. However, reflections and planning of this kind implies that the observed relationship reflects causalities. We cannot take this for granted. The evidence is rather weak with regard to causalities, as the main documentation is still based on cross-sectional studies.

In a recent study of 115 workers at homes for the mentally retarded we conducted an exploratory path analysis to test and validate the causal relationship between some of the variables in the stress model. Stress as a state acted as an exogenous variable, while exhaustion (strain), cynicism, and professional self-efficacy and job satisfaction (outcomes) were regarded as endogenous variables. High positive standardised regression weights were found from stress to exhaustion and from exhaustion to cynicism, while the path from stress to job satisfaction was negative and moderate. The rest of the hypothesised causal relationship had a low standardised regression weight (Fig 2). The total effect of job satisfaction in this model was -. 57 or larger than the direct effect of stress alone, which was -. 48. The percentage of variance explained can be seen at the top of the boxes. However, these results are also derived from a cross-sectional study, and only a strong theory can defend regarding the observed relationships as causal.
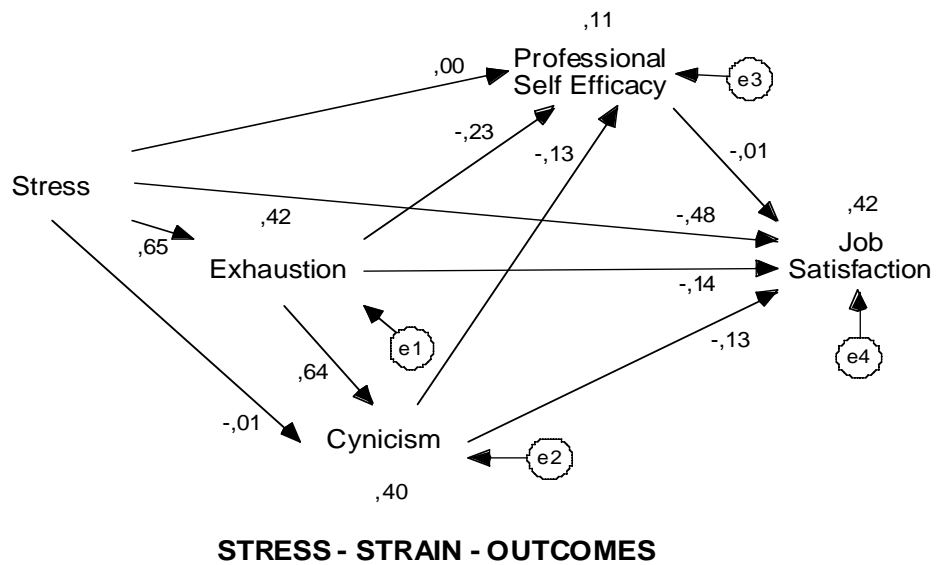
Figure 2. Causal relationships between stress-strain outcomes measured by path analysis. (Adapted from Innstrand , 2000)

Conclusions

The term "psychosocial factors at work" is rather confusing and should be changed to *Psychosocial and organisational factors at work, abbreviated POW factors.* We proposed a model for mapping the POW factors at the workplace, and argued that detailed measurements of such work-related obstacles and stressors are essential for effective interventions to take place. The general model used here is adapted from Sutherland & Cooper (1988), and it also relates stress to health problems. We also argued that characteristics of the person, such as age and personality, should be taken into consideration when designing interventions for better health or working conditions. While POW factors may be removed, or their effect may be moderated if they are impossible to remove, acceptance of personal characteristics will to a greater extent require adjustment of work to the individual, rotation of some individuals to other jobs, and careful selection when new staff are hired.

There is currently a shift in organisational interests in reduction or management of psychological stress at work, but this trend has been hampered by the economic shortcomings. However, POW factors take their toll, in the sense of lower job satisfaction, burnout, pain and ill health, and thus become expensive for the employer. There is a need for workplace interventions to reduce the problem, by either removing the stressors or elevating the problem. Successful interventions depend on adequate conceptualisations of the POW factors, the stress process, and the organisation. Change techniques borrowed from theories of organisational

development may be applied to the intervention process. Interventions in work tasks, social systems and the organisation are to be recommended. However, most interventions are still focused upon the individual, primarily due to low costs and small disturbances in the organisation.

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Assessment of exposure in intervention studies in the health care sector

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Introduction

This chapter focuses on the challenges of assessing the exposure to health risks in the health care sector, especially the problems of assessing exposure over time and changes in exposure level following the implementation of intervention.

In the health care sector, an important part of the occupational exposure to health risks is linked to the patient or client. The time spent together with the patient, the type of work tasks and the relation to the patient depend on the caregiver's job title and function. Working with humans puts morale and motivation on the agenda. The patients can be both physically and psychologically unpredictable.

Two main types of intervention studies have been reported. One type evaluates the exposures before and after the intervention. These studies concern patient-transfer technique, where the outcome of interest is implementation, measured as changes in the quality of the transfer (9,11). The second type introduces different types of intervention such as transfer technique, stress management and physical training, with low back pain, increased endurance or perceived exertion as the primary effect measure (4,5,12,13,18,19).

Exposure assessment can be made in various ways in intervention studies from the health care sector (4,5,9-16,18-21), depending on the scope of the study. In the first type, exposure is assessed by observation, checklists, rating of perceived exertion (RPE) or scores for quality of patient transfer.

In the second type, exposure is assessed as a perception of the psychological load, self-reported information on work technique or RPE. One of the published studies, which includes a programme of individual muscle training, was randomized and controlled (13), which in principle diminishes the need for a detailed description of the exposure. Neither of the two other studies describes external exposure (due to loads put on the body from outside) or change in external exposure (local load on the musculoskeletal tissues of the body) in the intervention period on task level, e.g. number of patients, loads of patients or type of tasks.

The above-mentioned studies all try to modify the physical work load with better coping skills, working technique or enhanced physical capacity. To our knowledge, no study from the health care sector has been published where the number of tasks would be reduced or fundamental organizational changes introduced.

In general, assessment of physical workload in musculoskeletal epidemiology should include information on external exposure, such as level (amplitude), repetitiveness (frequency) and duration of posture, motion and force. These parameters are thought to be decisive for the internal exposure i.e. the forces acting in the body. The relationship between external and internal exposure is primarily influenced by working technique, which depends on both psychosocial and physical factors.

In relation to low back disorders, complex movements including twisting and bending, as well as sudden unexpected movements, are thought to be important. This stresses the relevance of measuring the magnitude, direction and velocity of the single movements, besides assessing the force and duration of the exposure of interest.

Methods to measure exposure

Intervention studies examine the effect of changes, where the exposure of interest depends on the chosen goal and endpoint of the study. In the health care sector this could be changes in the external exposure, e.g. an increased use of helping devices, or changes in the internal exposure by introducing a less demanding working technique. Another approach is to increase the person's capacity by training muscle strength, readiness or coping skills.

When starting an intervention the content of the intervention must be covered by a theoretical framework supported by other disciplines.

This could be a biomechanical calculation, which makes it plausible that the load on the back decreases when a certain transfer technique is used, or experience that working with coping techniques results in a more even work pace, which decreases both the physical and psychosocial exposure.

The advantage of field studies on small populations over a short time (in fixed settings) is that the study is less complicated to randomize, easier to control and it is possible to make direct measurements of the exposure. The problem of small studies is that it can be questioned whether the time window or the population is representative, as far as the problem and the population of interest is concerned. In this respect the health care sector has certain difficulties, because the working day and the working week often vary considerably.

On the other hand, field studies over a long period of time with many participants can have good external validity for the whole "package". However, they can be difficult to interpret, as they may involve multiple interventions, and a low level of control over the confounding factors which occur naturally in the work environment during the intervention period.

The selected exposure measurements should have a sufficiently high sensitivity to describe an expected change in exposure due to the intervention. If laboratory measurements show a 30 % reduction in the range of movement to a given change in the work technique, the observation method must be able to detect this reduction in a true work situation. This means that the need for precision in the exposure assessment depends on what is expected from the intervention.

External physical exposure

Assessment of exposure to physical load when assisting a patient to move has much in common with the exposure description during other types of physically heavy work. However, it is complicated by the fact that the load is not predictable, e.g. a sudden, unexpected loading can occur when a patient loses his/her balance. The weight of the patient is thus not always a valid measure of the needed force, since the patient can help or oppose the process of assisting. The patient´s active movements can thus affect the load of the worker in a positive or negative way. It is important to combine force, motion and posture, because the force has different consequences, depending on the direction of the motion. A given force in a symmetrical position could be beneficial, e.g. in the case of risk factors for low back pain, while the same force with the trunk in an asymmetrical posture could be a risk. A substantial intra-worker and inter-worker variability can be expected both over the working day and the working week.

Another difficulty is the large variation in exposure over time. Most patient transfers only last a few seconds, while a task such as a transfer from a wheelchair to a bed may differ considerably from another transfer, e.g. moving a patient in the bed.

This kind of episodic event is difficult to monitor in epidemiological studies, where the design must be able to capture the time-varying exposure. The challenges in design, statistical models and feedback-bias dealing with episodic event is addressed in a recent paper by Eisen (7).

Amplitude, repetitiveness and duration of motion and force can all be difficult to assess in the health care sector. An overview of different instruments for exposure assessment is given in table 1, focusing on advantages and disadvantages of the different methods.

Table 1. Instruments used in assessment of physical exposure in the health care sector.

Instrument	Measure	Advantages	Disadvantages
Production data	Number and type of tasks in a department. Knowledge of the condition of the patients, number of helping devices.	The data is independent of the investigation.	Lack of precision on individual level. Work schedules can be changed at short notice.
Self-report: Questionnaire Diary	Type of task and number of tasks in categories. Type of task. Number of tasks in repeated measures.	Suitable for ranking exposure in categories. Different risk factors can be recorded in the same way and at the same level. Can be used in repeated measures. Can include major unexpected events.	Lack of precision. Not suitable for assessing absolute levels of physical load.
Observation: OWAS	Frequency of working postures.		Not suitable for registration of single heavy or sudden movements.
Direct measurements: Goniometer Accelerometer Video in combinations with markers and software.	Direction and velocity of a movement, amplitude, repetition, duration. Acceleration, amplitude, repetition, duration. Direction of movements. Amplitude, repetition, duration.	Precise. Possibility of registration of angle velocity. Useful in validating other methods.	Time-consuming. The large amount of data is to be operationalized, with the risk of losing precision. Problems of approval by the patient or relatives.

One of the first steps in the process of designing a relevant exposure instrument for an intervention study is to get acquainted with the available production data.

This makes the questionnaires more relevant. However, there is no need to ask questions of the staff if you can get the answers from the management. Such questions may concern information on the number of patients per department, the condition of the patients, the use of helping devices, the number of patients using nappies, the number of patients who have to be washed in bed instead of in the bathroom, and work schedules. The advantage of this kind of data is that it is normally independent of the aim of the study.

Questionnaires and diaries are examples of self-reported information. They can constitute a part of both baseline and follow-up information, especially in studies including a large sample of persons over time (3). This information is suitable for ranking exposure, but lacks precision and is not suitable for assessing absolute

levels of the physical load for the individual worker. Questionnaires and dairies can contain information on changes in type and number of working tasks, use of lifting devices, and time spent in direct patient contact. Moreover, they can also contain information on the perceived physical and psychological exertion, in relation to a single patient and to the working day as a whole. In addition, dairies can be used to report if anything unusual happens, e.g. heavier load because of extra patients or single sudden unexpected loads; this type of information is, however, especially vulnerable to recall bias.

Observation is a time-consuming method and can only be used for exposure measurement during the actual working situation. It gives no information on past exposure. Since the observations (and direct measurements) are usually carried out only during short periods of time, it is important to choose a measurement strategy, which gives representative results. The choice between a prolongation of the observation period versus repeated observations depends on whether the variation in exposure occurs during the same day or between days.

The most commonly used method is the OWAS (Ovako Working Posture Analyzing System). The method observes the frequency of different categories of working postures, and it has been developed to validate the working postures during lifting. Since patient transfer often consists of a combination of lifting, pulling and pushing, and since the external force is impossible to quantify with the eye, this method is not optimal for exposure assessment in health care. At the moment no validated observation systems exist for assessment of the biomechanical load during patient transfer.

Direct measurements are time-consuming. They can be highly accurate, but seldom cover all factors of interest. The measurement equipment may influence the way in which the employees under study perform their work.

The 3-axis goniometer measures movements in 3 planes at the same time. These registrations provide information on the direction angle velocity and acceleration of a movement. Goniometers can be used in real work situations in combination with a description of working tasks, e.g. video, observation or data logger with task icons.

Video recordings cause certain problems in the health care sector, because the caregivers, the patient and the relatives have to give their approval.

Internal exposure

To assess the internal exposure it is necessary to measure the working method, including the involvement of the patient and the use of helping devices. Inter-worker (and intra-worker) variability in internal exposure (dose) by the same external exposure may be expected, since different workers use different working techniques and equipment.

In laboratory studies biomechanical calculations can be used to assess the internal exposure during different tasks. It is, however, a very time-consuming method and cannot be used in the workplace. The internal dose during a working day for a given worker can theoretically be calculated from a description of the

work task, in combination with the internal load for each task (found in the laboratory study).

High validity of this method implies low inter-worker variation in the load for a given task.

Psychosocial factors

Several epidemiological studies combine psychosocial exposures in the working environment with the occurrence of low back pain (1), although two later reviews (2,6) conclude that the relative importance of the psychosocial factors is uncertain, due to lack of consistency in the findings.

Exposure assessment concerning psychosocial factors is normally based on self-reported interviews, questionnaires and diaries. At present there are no generally accepted observation methods available for assessment of social support, demand-control or coping abilities. It is theoretically possible to make observations on time consumption, planning of work routines and cooperative skills-specified tasks.

The health care sector is a human service organization with other values, goals and work content than an industrial production site. This naturally has an influence on the emphasis of different elements of work demand, where patient relation, own attitude and morale will determine a major part of the perception of the work demands. As discussed by Josephson (17), there is a need for developing extensions of the demand-control model for use in the health care sector.

Most of the time and commitment are spent in relation to the patient. One recent study of staff working with care of elderly people (17) found time pressure and troublesome clients were associated with psychological stress, and a study of Finnish nurses (8) found that time pressure and troublesome clients were the type of job demand which was mentioned most. This implies that the assessment of psychosocial exposure must be able to separate the mental strain due to the contact with the patient from psychosocial work stressors other than those associated with the patient.

Another problem is that in the patient relationship, e.g. in a transfer situation the physical and psychological strain occurs at the same time, which hampers the analysis of the relative contribution from physical and psychological exposures.

A third problem in interpreting the data from an intervention study concerning e.g. transfer technique, is the possibility that the interaction of psychosocial and physical exposure in the patient/caregiver relation can interfere with the way the transfer is performed. On the other hand, those problems stress the importance of including physical and psychosocial exposure assessment, preferably at the same level, in epidemiological and intervention studies in the health care sector.

In intervention studies it is important to assess the baseline of psychosocial exposures, covering the dimensions of demands, job control, job content and social support, tailored to meet the special dimensions of the health care sector. The instruments measuring these dimensions should be sensitive enough to allow detection of changes during the process.

Conclusions

Assessment of physical and psychosocial exposure in the health care sector is difficult, because of considerable day-to-day, week-to-week and caregiver-to-caregiver variation. This may be one of the reasons why only a limited number of intervention effects have been documented in reported studies. It has been possible to establish that the occurrence of low back pain is associated with patient transfer. However, it has not been possible to describe in detail what situations are risk situations.

We must develop exposure measures sensitive enough to measure changes in both external exposure and internal dose following successful intervention. If the intervention concerns methods for patient handling, changes in internal exposure have to be measured by registration of changes in the technique used by the individual workers.

A combination of exposure measures is needed, which, when repeated over time, can provide a reliable assessment of cumulative exposure. This could be complemented with registration of single sudden overexertion situations, where the working conditions, task load and individual modifying factors vary considerably.

One could envisage a protocol in which quantitative measurements, e.g. type of task and distribution of tasks over a working day are collected on a large scale, and "task exposure" measurements are performed to calibrate the proxy measures from the quantitative method. For example, when the performed tasks are principal determinants of internal exposure, detailed internal exposure measurements ("task exposure") could be conducted by measuring a few workers performing these tasks. After this addition, information on the task distribution could be collected at the individual level. Subsequently, the cumulative internal load (dose) of individual workers over a working day can be calculated as a product of the load per task and the duration and frequency of the task on an average working day. A precondition for high validity of this method is low inter-worker variability in the internal exposure connected to a certain task. With respect to the question about episodic events, it is necessary to use laboratory experiments and models in order to be able to estimate the biological relevance of these events, and to establish a design for episodic events.

There is also a need for standardised tools for the assessment of the client's positive/negative effect on the biomechanical workload of the caregiver, tools which can supplement the self-reported mental exposures. Dimensions such as time pressure, effect of organizational changes, elements of client contact and the structure of formalized co-operation should preferably be observed or registered independently of the project participants.

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Challenges in performing work environment interventions for research purposes

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A hypothetical case

A workplace becomes aware of a problem in the work environment and wishes to solve it. The management and the employees agree on the nature of the problem and the possible solution. The benefits are expected to exceed the efforts of both parties, and the necessary resources are available. However, a thorough evaluation of the effects of the intervention is requested. The workplace contacts a group of researchers who are interested in the problem and want to study the effect of making the changes suggested by the workplace. The researchers have considerable knowledge about causes and effects within this field, and they also have valid methods to measure them satisfactorily. Together they find several similar workplaces where there are corresponding work environment problems and where they are ready to invest in corresponding changes. These workplaces agree to participate in the project on the basis of randomisation, which means they will either be intervention or control workplaces.

The project is carried out in positive co-operation; potential conflicts are solved as they arise, and all workplaces support the changes decided upon and the collection of data. The project shows the expected effect and also a positive cost-benefit balance. The gains of the project are higher than the costs. Parallel with the project an evaluation of the change process is carried out, summing up the experience of problems and solutions that arise when making changes. Thus the control units are able to carry out corresponding intervention with fewer problems and with better and faster effect. Consequently, a considerable amount of experience is available, which convinces other workplaces, researchers, and authorities that this intervention is both an effective and a practical solution to the work environment problem.

Everybody with experience in intervention projects will find this example far from reality. The goals of the workplace will normally focus on delivering service or products effectively and competitively, and not on producing scientific research of high quality to benefit other people. Besides, the inconvenience of implementing the changes, the data collecting activities and the presence of "strangers" at the workplace will often be regarded as very inconvenient. Therefore, workplaces will participate wholeheartedly only if they expect to make fair gains themselves.

Involvement of management and employees in the project

Different types of interventions demand different levels of commitment from the management and the employees. Interventions in work organisation and the psychosocial work environment imply the greatest demands, because the aim is to change the interaction between people. It may involve delegation of responsibility, improved feedback, increased social support, etc. These changes can clearly not be carried out successfully without a high degree of participation and support from the employees. Therefore, scepticism or resistance to the intervention from even a small number of the employees can seriously impede the intended changes.

But even with relatively simple technical interventions, such as improving the ventilation, the involvement of employees is crucial. If the ventilation is shut off because it creates a draught and nobody has the responsibility or competence to adjust the machine, the investment is lost. A different, but well-known example is the fact that the "person lifts" in nursing homes are not used if the staff lack confidence in using them.

In "Diffusion of innovations" Rogers (5) describes a series of phases characterising the spreading and adopting of new concepts, e.g. work environment improvements. In the beginning, innovations spread very slowly, but if the innovation is successful, this is followed by a phase of rapid spreading. Spreading finally stops as its limit is reached, or it is replaced by a new innovation.

People react differently to change, and can more or less be characterised by five types:

"Innovators" are the few people who are most eager to seek news and information, and are willing to take a risk to test new ideas. They play the important role of introducing new ideas by importing them from outside the system.

"Early adopters" are more integrated in the local social system and serve as role models for many others, as they are opinion leaders and respected by colleagues – the typical individual to check with when in doubt. The early adopters gain esteem from good judgement on innovations, and reduce uncertainty about the new idea among others.

The "early majority" is a bigger group, comprising about one-third of the population. They spend more time considering before taking the deliberate decision to adopt a new idea. On the other hand, they do not want to be the last ones to stop doing things in the old way.

The "late majority" is also a group constituting about one-third of the population. They are more sceptical about new ideas and do not adopt them until most others in the workplace have done so. Their resources are more limited than the earlier groups, and most of the uncertainty must be removed before they feel it is safe to adopt new ideas. They typically adopt innovations for reasons such as economic necessity or pressure from colleagues.

"Laggards" tend to refer to habits and traditional values, and to be suspicious of new ideas. They have limited resources and must be sure that a new idea will not fail, before they adopt it.

As a general trend, early adopters have a higher social position, longer education, more external contacts, and are greater consumers of mass media than later adopters.

Individual differences alone cannot explain the course of diffusion. Another important factor is the social system. The formal and informal structure of the social system, and the norms and roles in the system also influence the diffusion of innovations.

Both managers and employees can have a tendency to see changes as annoying interruptions of the daily work; as something that has to be dealt with in order to move on. This conception can also include changes that a person himself has initiated, e.g. in order to improve the work environment. However, with the pace of development in the working life of today, change has become a fundamental condition. Therefore, if change is still perceived as something unpleasant that has to be dealt with, at the same time as the need for change increases, this will lead to a vicious circle of growing frustrations.

In opposition to this, attempts have been made to develop models that could promote a "good circle". This has led to concepts like "The learning organisation" (1) and "Developmental work" (2) that try to implement changes in a way that increases insight and motivation for further changes.

Just as different models are discussed in order to carry out changes at the workplaces, different paradigms of research into effects of changes are discussed (see the chapter on research design). Some of the most extensive experience of far-reaching employee involvement has been obtained within projects based on the paradigm Participatory Action Research (PAR). The starting point is that the workplace and the researchers co-operate on the process of change, as well as the process of research. Traditional scientific articles most often refer only to "material and methods" of measurements – not of the change process. Some PAR literature also describes the process and the context of changing the work. This literature contains some very frank and honest discussions concerning the problems of carrying out changes at workplaces. For example, Israel et al. (3) have described the problems from some workplace projects, and summarised the challenging and facilitating factors in an article that also discusses the strong and the weak sides of the various competing paradigms within intervention research (4). Using an article like this for inspiration during the planning of new projects could probably prevent many problems when it comes to implementation of the intervention measures.

This chapter aims at covering those situations that need much commitment from the employees. Some comments can therefore be irrelevant when making relatively simple interventions. Conversely, in some situations the changes demand such extreme commitment by the employees that the project needs experts with comprehensive experience in carrying out changes and dealing with the attitude of the organisations toward changes and with the employees' scepticism or resistance. If the researchers or the workplace do not have people with such experience, it will be advisable to seek guidance from outside during the planning phase and maybe also during the intervention.

The following sections concern how to handle the interests of the parties in the workplace, and problems that could be expected to arise at different phases of an intervention project.

Respect for the parties' interests

Even though the parties at a workplace seem to agree on supporting a project, the motives behind the support will probably differ. The employees can expect that the intervention will provide a better work environment, better well-being, and more interesting work. The management's expectation of the same change can be less absence from work, fewer errors, or other kinds of increased efficiency.

If the survival of the workplace is at stake (e.g. a workplace expecting a merger or increased competition, a public institution subject to tenders) it is important to be prepared for extensive changes from outside during the project period. In such a situation it is important whether there is clear support from both the employees and the management, or if there is a high risk of conflicts concerning e.g. financial matters or manpower which can hamper the project. In long-term projects it is especially necessary to consider if an agreement concerning a common effort can be reached in case of trouble, and also if there is faith in the survival of the workplace in a comparable form until the end of the project. (In addition, the research team must also consider if they can be sure to present a sufficient level of continuity).

When the project is presented at the workplace the researchers will observe the employees' reactions, and often divide the staff into those who are respectively for and against the project. Although Rogers' description gives hope that more people will adopt the change with time, it is not clear whether those against are just passive towards the change, or actively against it. As it is often harder to make the passive people support a change than to change active opponents into supporters, the question of active or passive resistance seems quite important.

If the active-passive axis is combined with a for-against axis it makes up the picture seen in figure 1. (Jørgen Møller Christiansen, 1999, personal communication):

- Group 1. Those who are actively in favour of the project. Typically, this group includes both the "the real enthusiasts" who argue and work eagerly for the adoption and the implementation of the project, and also those who are quieter but make a discreet positive effort, e.g. in task groups.
- Group 2. Those who are actively against the project. They are immediately identified as opponents of the project, as they argue against it and try to undermine it. However, there may also be other people who secretly counteract the project.
- Group 3. The passive people who are in favour of the change. They do not make an independent effort, but act like passengers and swim with the current.
- Group 4. The frustrated passive people, who show passive resistance in the daily work, and vote against if the project comes to a vote.

Resistance is closely connected with insecurity and mistrust. Thus security and confidence are keywords in the understanding of why some people are against change. Insecurity is strongly connected with the co-operation culture of the workplace and with previous experience of changes. At workplaces characterised by conflicts and/or poor experience of co-operation, it can be a very demanding task to promote changes, even when the need for them is obvious to everyone.
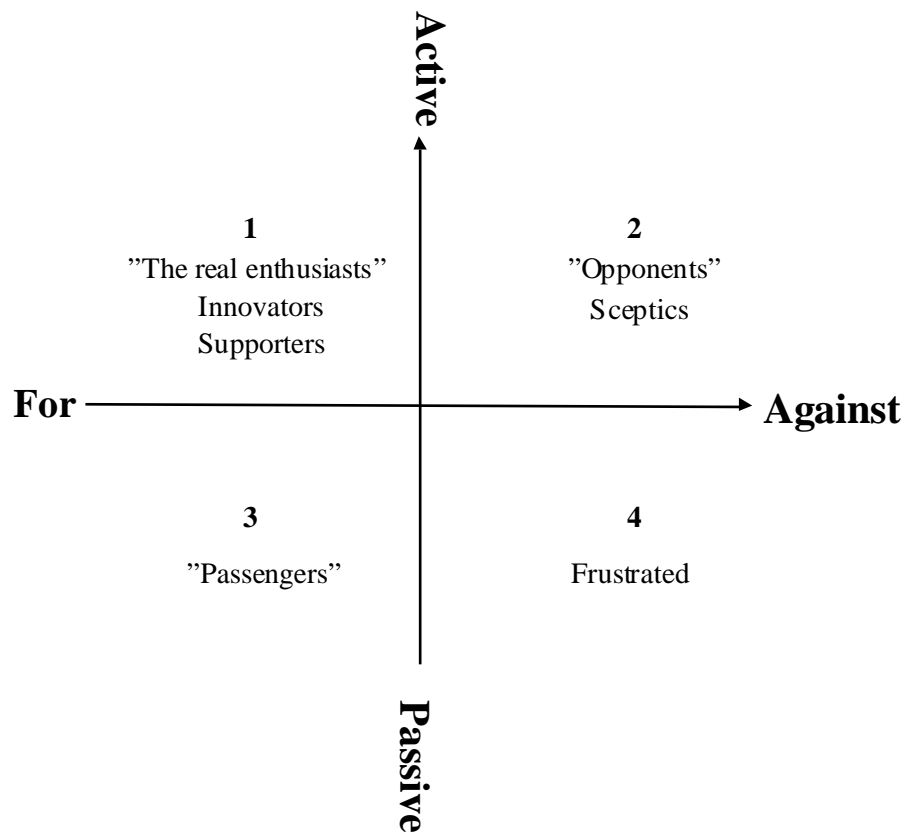

Figure 1. Attitude to the project and level of activity.

The people at the workplace can be classified according to their attitude to the project, and according to their level of activity/passivity. Evaluating the distribution into the four groups and the motivation to be in each group may stimulate the researchers to anticipate and solve potential problems in the project.

It is worthwhile considering that some of the passivity is more based on lack of will to contribute actively than on real disapproval of the content of the project. Thus it is wise to make it easy for less involved employees to participate by trying to increase trust and confidence in the project. Some of the "opponents" may be preoccupied with whether they themselves or their group will be respected and heard. They often give relevant criticism of the project from which a lot can be learned.The criticism can be about things that can lead to inconvenience for them

or create insecurity for themselves or the whole group. Therefore, it is an advantage to take their criticism seriously and try to include these people in the project. If more openness and co-operation is established, this can increase other people´s trust in the project. In addition, the opponents will be less eager to oppose the project if they feel that their voice is heard, and that at least some of their suggestions lead to real improvement of the project.

Normally, the "the real enthusiasts" are an important asset for the project, but they can also create problems. Most people have probably met an "anti-smoking freak" who argues so provocatively that some of the smokers choose to smoke even more, just to protest. Correspondingly, the support of the "the real enthusiasts" can create problems for the project if other people find their arguments provocative, selfish, or an expression of irrelevant interest.

The patients' interests

The health care sector is created to treat and care for people who are not able to care for themselves because of illness, handicaps etc. The inherent primacy of patients' needs has often made the personnel's needs a secondary or even irrelevant consideration. In contemporary health care administration it is sometimes expressed that what is good for the staff is also good for the patients. Obviously, this is true in some cases, for instance in prevention of diseases among the employees. On the other hand, it is clear that some of the strains in working with patients cannot be removed, and should be seen as a basic condition that should be handled carefully, rather than as a problem to be removed. It is inevitable that weak or immobile patients need help to move, and that working with seriously ill or dying patients is emotionally demanding.

Some of these strains can be diminished by technical aids or otherwise, but it would not be in the best interest of patients to avoid exposing the staff to the patients. Instead, it would be wise to handle the strains in a way that causes the least possible harm to the staff and the best possible care for the patients.

As mentioned in the chapter on patient and personnel perspectives, improvements of treatment and care often imply considerable changes in the work, which leads to frustration and stress in the employees. When implementing necessary changes in the care, it is therefore important to consider the wants and needs of the staff. And when improving the work environment, the changes should be planned carefully, so as not to decrease or impede the ability of the workplace to fulfil its primary goal – the care of patients.

In an old people's home the personnel reported very high demands in the work. A closer discussion of the problem revealed that a major part of the perceived demands originated in the individuals' ambition to take care of all the residents' needs every day, no matter how few of the staff were at work. These ambitions often exceeded by far the expectations from management and residents. This caused a continuous feeling of being very busy and a tendency to do everything for the residents, instead of fulfilling the institution's aim: to help and motivate the residents to carry out as many tasks as possible by themselves, and thereby

preserve and strengthen their abilities. By developing consensus on the work tasks, the perceived demands decreased and satisfaction increased. Some residents considered the changed attitude of the staff as "poorer service" and were dissatisfied. Others appreciated doing more by themselves and experienced greater self-esteem and satisfaction.

The employees' interests

Improvement of the working conditions often leads to increased efficiency, and this may lead to fewer employees. If the employees perceive the project as a way of making cuts and layoffs, it will, understandably, create much resistance. In order to avoid serious conflicts it is advisable to discuss such problems in advance. Some workplaces have chosen to make an agreement, stating that if the project leads to cuts then the money saved will be of benefit to all employees, e.g. more work environment improvements. This can cover the project period or a suitable period of time after the project, in order to see if the effect lasts. Correspondingly, some have agreed that if there are to be staff reductions in the future, then this will only be through natural wastage or by helping the employee to find another adequate job.

A certain group of staff is reduced in seven similar divisions in a public institution. At the same time one of the divisions is included as an intervention workplace in a research project. The staff group concerned chooses to boycott the project, as their demands for being exempt from the general reduction are not met.

Even though it can seem easier, at first sight, not to hold this kind of discussion during the preparation of the project, it is necessary to remember that the problems will be harder to deal with if they are not recognised until things have come to a head.

If representatives from the project group do not handle such problems on their own initiative this could be because of perceived or real problems, representing diverging interests of their group. It can also be due to lack of trust in the co-operation, e.g. if the workers´ representative is worried about the reaction of the management. Therefore, it can be necessary for the researchers to initiate discussion of problems, e.g. by asking for the parties' expected reaction if the problem should arise. For this purpose it is necessary to think through which conflicts can be expected at the workplace.

Interests of the supervisors

In many traditionally organised companies the supervisors have only limited managerial training, and often primarily perform control tasks. If the intervention is aimed at creating a modern organisation by delegating responsibility and by a dialogue- and value-based management style, the supervisors risk becoming redundant in the process, because the control and administration tasks are minimised. Furthermore they often lack competence in the "new" management skills, such as supporting and motivating the staff. It is important to consider how to create positive opportunities for them, in connection with the intervention.

A hospital wanted to put together cleaners, hospital orderlies, assistant nurses, and housemaids in a new, wider work function called service assistants, which had more varied work, and was organised into groups with a high degree of autonomy. It was obvious that the group supervisors in cleaning would be made redundant due to this change. However, they were asked to inform the cleaners about the project and to persuade them to participate in the first attempt to introduce autonomous groups. The result was considerable resistance to the project among the cleaners. A preceding dialogue with the group supervisors could have created more positive solutions for all parties.

Interests of the managers

If a manager (or an employee) takes up some potential problems that may disturb the project, he/she will often be thought of as being critical towards it. In the light of the above it should, however, rather be seen as being responsible, and as an attempt to prevent the project from failing at a later stage.

Just as the employees' trust and support is crucial for carrying out the project, it is important that the management support it. It is common knowledge that projects which are carried out as "grass roots projects" without including the management often do not get very far (3).

Out of consideration for the managers and the employees it should be clearly stated how responsibility is divided between the managers, the project group and other possible decision-making parties, such as co-operation boards and safety boards. If it is unclear who is competent to transact business in a special matter, or what topics the project group can choose to decide on, much of the discussion may be futile.

If the intervention includes delegation of responsibility, or other elements that can cause the leader to lose influence or status, this could easily decrease the manager's motivation. Thus, it is important to consider if it is possible to plan the project so that the managers' contribution to the project and results are clearly recognised.

If the workplace is part of a large organisation, it is important that management at all levels is actively involved in planning and carrying out the project. Even though the project has solid support from the local managers it can run into resistance to changes that need acceptance from "above". This may happen if the superior managerial layers have not been "sworn in" during the planning process and shown that they support the intentions of the project, e.g. by accepting higher degrees of freedom than they normally would.

In practice the manager will often be the one who represents the interest in "the survival of the workplace". If this is threatened, and also during the planning process, he/she may want an explicit discussion of the fact that the running of the workplace comes before the project.

The interests of consultants, sponsors and others

Just as interest in the survival of the workplace is of primary importance, the advisors have more interest in their own financial survival than in research. Some consultants have developed a concept that they routinely carry out, and will have a tendency to stick to that concept instead of complying with the intentions of the research project or the specific needs of the workplace. Many consultants attach great importance to a good result as a matter of professional satisfaction, and as good sales talk to new customers. Unfortunately there are also consultants who go all out for selling themselves to one-off assignments. Therefore it is of great importance to know as much as possible about the consultants one employs in a project, or to obtain information from others who have used the consultants for similar projects.

Trusts, authorities, and others who allocate money for preventive work often have other perspectives than the researcher. In Denmark public authorities may grant money to be used for prevention, but explicitly demand that the money is not used for research. It has been argued that the money could not buy as much prevention if it was included in a research project, and that the researchers would not provide useful recommendations on what works in any situation. Therefore, paradoxically, it can be harder to raise money for projects with a systematic evaluation of the effect of the interventions than for preventive efforts that will not be carefully evaluated. On the other hand, trusts that support research sometimes make demands as to design and methods that are not realistic in this type of research.

Problems and solutions in the various phases of the intervention project

Wording of the problem

Interviews and observations of the practical conditions at a relevant workplace are often a good investment. It might be helpful to formulate the problem in a way that covers the employees' perception of it, as this eases co-operation in the following phases. Employees who are strained by some problem do not always perceive it in the same way as the researchers. Furthermore, they may provide insight into factors that might ease or obstruct the desired change. In this context it is important to consider what problems are preventable and what problems are inevitable dilemmas. It is not possible to remove serious illness and death from the work environment at a hospital. Violent patients cannot be removed from psychiatric wards. And it is always possible to do more for the patients. By focusing on these conditions as causes for stress among the staff, there is a risk that the frustrations will increase. The task must be formulated so that it deals with factors that can be changed. This can also include ways of coping with those dilemmas that cannot be removed.

Design

It is important to consider carefully the real interests and possibilities of the workplace when designing the study, in order to avoid unnecessary conflicts. If already at this point the researcher is in contact with relevant workplaces he can draw on their practical experience and get response on different proposals. On the other hand, it is important for the scientific quality of the study that the design makes it possible to draw well-founded conclusions concerning the problems studied in the project. If the workplace does not accept arguments regarding this, it is doubtful whether a sustainable co-operation can be established.

Recruiting intervention workplaces

When contacting a workplace to discuss participation in a project it is easy to raise false expectations as to how the project will proceed and what the workplace will gain from it. Naturally, it is important to consider which positive results the workplace can gain from the project, and then use them as "sales arguments". But it is also important to be realistic about the costs, such as time spent on the project, resources, and commitment in connection with changes, data collection etc. Otherwise, disappointment and frustrations are created, and this can be devastating for the project. The researchers must also be honest about their own motives and expectations. The primary goal of research is not to help the particular workplace in question, but to obtain knowledge that is of use to workplaces in general. The outcome is of course not predictable, even if the expectations are clear. It is not ethically acceptable to promise results to the workplace which depend on the outcome of the intervention to have the hoped-for effect.

When the researcher gets in contact with interested workplaces, or has persuaded them to participate in a study, the workplaces are often eager to get started as soon as possible, as they are interested in the benefits the project can give them if the hypothesis is confirmed. It is important that the workplaces do not initiate the project until the content has been discussed so thoroughly that they have a sufficient understanding of what it will mean in practice, and they have decided whether they are willing to do what is necessary. Correspondingly, the researchers must have sufficient information about the workplaces, in order to evaluate if the project can be carried out in a scientifically sound and responsible way.

Recruiting control workplaces

It can be difficult to find workplaces for comparison with intervention workplaces (control or reference workplaces), as they often feel cheated of the intervention or feel that the data collection is too demanding when they are not even an intervention workplace. It can be an advantage to try to work for resources to carry out interventions at the control workplace when the project ends. If that is the plan, the following arguments can be pointed out:
- They can see the effect at the intervention workplace before they decide on starting a similar project.

- Thereby they have realistic expectations of what can be gained, or save themselves the trouble if the intervention turns out to be ineffective.
- The control workplaces can also learn from the experience of the intervention workplaces, and thereby later obtain the same or a better result with less trouble.

If it is possible to randomise for intervention or control, the researchers can present the options so that if the workplaces participate, they may be lucky and get started with the improvements as soon as possible, but with the risk of running into unforeseen problems. Alternatively, they may be lucky to get started later, when the researchers and workplaces have more experience to build on, and things will be easier.

Another option is a co-operation between researchers working with different problems. Thereby the workplace is offered a randomisation between the various interventions that they want to carry out, e.g. a course in lifting techniques at one workplace, stress prevention at another, and measuring the development in back pain and stress symptoms at both workplaces so they are controls for each other.

Organisation of the intervention in practice

Based on the wish to improve the work environment as much as possible, the optimal intervention will probably be a continuous process. First the problems in the work environment are described, then solutions are suggested, initiatives selected and carried out. After that, the results are evaluated, uncovering remaining or new problems, and then the cycle is repeated by creating new solutions. On the other hand, based on the wish for a clear research design, it should be possible to study the effect of a relatively well characterised intervention. The tasks for the workplace and the consultants who support the implementation of the intervention should be clear. In practice, it will often be necessary to find a balance between these two points of view. This means that it will be desirable to establish a continuous documentation of the revealed problems and completed changes. This is of great importance to the interpretation of the effects noted at the end of the project (See the chapter on process description).

In order to react properly to the problems and experience arising during the project, the project must be organised in a way that makes it possible to take necessary decisions concerning changes of the plans in an effective way. This requires that the representatives of the management and the employees have good contact with the people they represent, and also a feeling for what might be accepted and supported. Furthermore, it is necessary to reserve resources (qualifications, time, financial means etc.) to deal with the management of the project. Finally, it is important that the researchers and the advisors are willing to participate when a dialogue about the problems is needed.

As mentioned under the paragraph "interests of the parties" the prject management´s decision-making competence in relation to that of other decision-makers should be clear. It is also important to have a discussion about possible conflicts

that may arise and how to handle them during the project. It will often be an advantage to make a written "contract" which states the commitment of the workplace to carry out changes and help in collecting data, and the researchers' obligation to produce and present results to the workplace. The "contract" should clarify the "rules of the game" for all parties concerned.

Presentation of results to the workplace

Feedback from the researchers to the workplace is of great importance in order to maintain motivation and commitment. Furthermore, the results from the first data collection can often contribute to an evaluation of what may be the most relevant effort. Therefore, it must be planned in advance for the feedback to be given as soon as possible after the first data collection. This involves preparing the selection and computing of results to be included, as well as the design of the report, even before the questionnaire data are ready. At the same time, it is important that the workplace experiences ownership of the project of change. The management and the staff should not see the workplace as an attachment to the researchers' project, but rather the researchers as an attachment to their own project. When the final results are available the workplace must be informed thoroughly. The researchers´ insight into the processes behind the results will improve if the workplace is included in the discussion concerning the interpretation of the results. And the workplace may contribute with reservations, or other relevant experience, which could well be presented together with the results.

Summary

Different interventions imply different demands on involvement of the workplace. Before large intervention projects are initiated, reading specifically about implementation of interventions within the field one is going to work in, and seeking guidance from experienced professionals, are recommended.

It is important to consider how the project should be designed in order to promote the motivation for active participation by the personnel at the workplace.

- What the researcher sees as a research project should include what the workplace perceives as their own project of change
- There are different actors and tasks in various parts of the total project, and there are different interests among the various parties at all levels
- The project must fulfil some essential needs for all parties involved – otherwise they will not be motivated to contribute.

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Description of the intervention process

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Abstract

In reports of intervention studies, various processes taking place during the study may be described in order to suggest possible mechanisms behind the results achieved. If the mechanisms are plausible, the reader will be inclined to believe that the reported results were probably due to the intervention. The need to describe processes and the best way of doing it varies from study to study. If there is an explicit theory at the outset of the study this will guide the monitoring of the processes considered relevant to cover. Also without an explicit theory or model, the description of the process(es) going on during some intervention study will reflect the mental models of the researchers, whether they are aware of it or not. With time some kind of guidelines on how to describe intervention processes clearly and concisely will probably be established. As the study of human behaviour at work can never be codified for good, there will, however, always be studies which do not fit into ready-made formulas for reporting.

Introduction

Intervention studies are conducted to find out whether it is possible to affect some outcome variable(s) and if so, by what measures and to what degree. In reports of intervention studies carried out to improve the health of employees in some work-places, the design of the study, the population under study, the methods used and the results obtained are mostly described according to the principles set up for epidemiological studies, concerning the occurrence of diseases and its relation to various risk factors. The "intervention process" is mostly described briefly, if at all. However, a variety of processes take place simultaneously in the work units under study in all intervention studies. The processes reflect the form and intensity of the cooperation between the various "actors" in a study. These actors, either

individuals or groups, never act in some predetermined way, however carefully the intervention is planned beforehand. The processes may thus differ considerably from one study to another. In studies requiring little interaction between the researcher(s) and the group(s) under study, there may be little or no need to describe any "processes" related to the study, while in studies requiring considerable interaction between the various parties participating in the study, description of the processes caused by, affected by, or affecting the study without being caused by it, is of vital importance in order to understand the results.

In some interventions, the "intervention process" may be quite simple. In the case of vaccinating employees who are leaving for tropical countries against hepatitis, the "intervention process" can be described as a series of practical tasks, which together constitute the vaccination process, in the same way as the performance of some specific task in industry can be described in the company´s quality control handbook. In psychosocial interventions in working life it may, on the other hand, even be difficult to decide which events constitute a process, not to mention which processes to cover and which to report. Anything can be considered a part of a process from some point of view. To define where some process begins and where it ends is often a conscious decision by the researcher, reflecting a focus on the question of interest in the study at hand.

An attempt to describe "the intervention process" in some study presupposes that a process takes place because of the study, and that this process runs through the study as some kind of "main thread". In studies where the measures to be taken are carefully planned and carried out as planned, "the process" may not be so difficult to describe. But in studies emphasizing a participative approach, the thread is often very far from straight. Now and then it breaks up into smaller parts, diverging from each other. The parts may converge again later, but they may also end up intertwined with other threads, or break and stop as "dead ends". As an intervention study is by definition not a laboratory study, there are always other parallel processes going on at the workplace at the same time as the study. How to become aware of them and how to evaluate their importance from the point of view of the intervention study are questions which are hard to answer.

Any intervention consists not just of the "treatment" administered, but of everything done to the target(s) as part of the process of administering the treatment. Every aspect of an intervention delivery system can affect the outcome of an intervention, so much so that monitoring the delivery of interventions is generally a necessary adjunct to impact assessment (6).

There is, however, no generally accepted or commonly used way of reporting the process(es) taking place in intervention studies (1). This is understandable, not only because there are many ways to conduct such studies, but also because it is seldom possible to adhere to a detailed plan, drawn up before launching the study, when carrying it out in practice in the field. Even so, some guidelines or recommendations on what to include in the description of a process would be helpful to researchers who want to report the relations between the relevant events that took place during a study.

Structure and process are terms commonly employed in organization theory. The activities in working life can be analysed either from a structural or process perspective. Because of the difficulties in capturing a process, the structural approach has for a long time been the most widely adopted one (3). Activities that are conducted in organized form can be described like a movie. The camera is stopped at regular intervals to provide a series of still shots. The course of events between the shots is complex. The outside observer can only acquire knowledge of what actually happens during the intervals through time-consuming participant observations (8).

In practice it is often difficult to decide what to consider a process. In principle, it may be defined as the chronological order of identifiable events taking place during a certain period of time, and the possible/plausible/probable cause-effect relationships between these events. However, the "causal links" between two variables may work not only in one direction (a causes b), but also reciprocally in the other direction (b causes a).

The description of the process(es) going on during some intervention study is inevitably based on the mental model of the researchers, i.e. their preconceived and continuously developing ideas about the mechanisms behind the change(s) sought for. The model serves to establish the links in causal chains, which seem possible or probable to the researcher. An example of a mental model is presented in Figure 1.
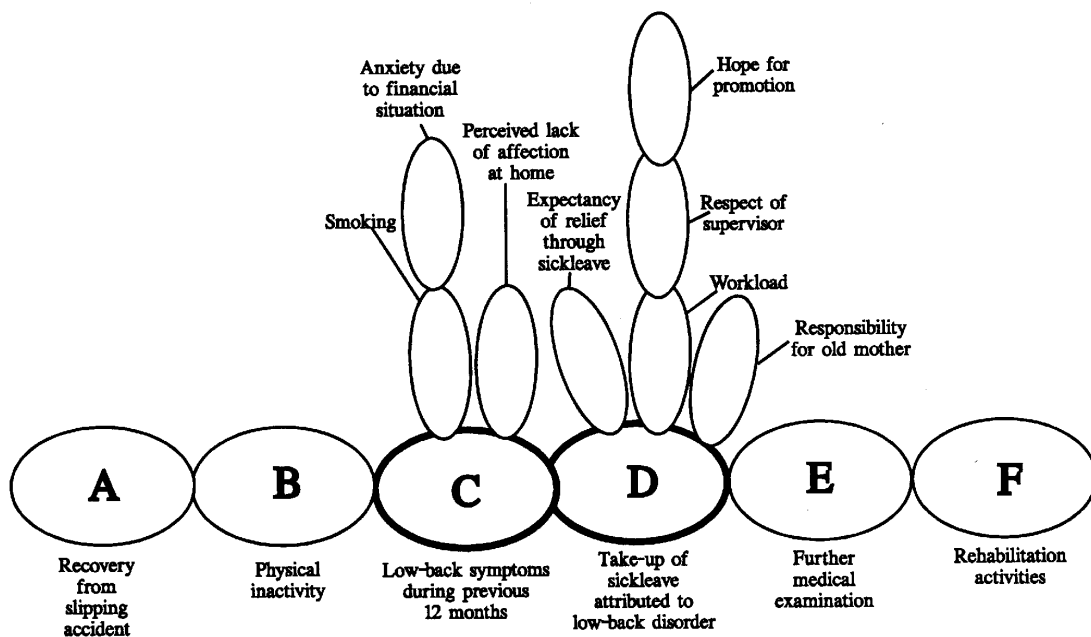

Figure 1. Chains of causal relations in presumed chronological order (A, B, C, etc.) behind changes in the two outcome variables "occurrence of low-back symptoms" and "take-up of sick leave attributed to low-back disorder".

The innovative processes in organizations may be considered to consist of sequences of decisions, actions and events. Reporting the processes observed in intervention studies, one may adhere to the five stages established by Rogers (1995): agenda-setting, matching, redefining/restructuring, clarifying and routinizing. The development from stage to stage can be further divided into sub-processes of implementation at each stage.

The *agenda-setting* process goes on all the time in every system, reflecting the way in which needs, problems, and issues bubble up in an organization. This stage requires an extended period of time. In many cases a shock to the organization is needed in order to reach the threshold for attention leading to action. On the whole, however, innovations seem to be driven less by problems than by solutions. The answers often precede the questions. If one begins with a solution, there is a good chance that an innovation related to it will match some problem faced by the organization.

Matching is the stage at which a problem from an organization´s agenda fits an innovation. This match is planned and designed. The agenda-setting and matching together constitute the initiation of the innovation process. The decision to adopt the innovation marks the watershed between initiation and implementation.

Redefining/restructuring occurs when the innovation is accommodated to the organization´s needs and structure. This often requires some modification both of the innovation and of the organizational structures.

Clarifying is the following step, in which the innovation is put into more wide-spread use in an organization, so that the meaning of the new idea gradually becomes clearer to the organization´s members.

The last stage, *routinizing,* occurs when the innovation has become incorporated into the regular activities of the organization. At this point the innovation process is complete.

The role of the researcher in intervention studies varies according to the aims of the study and the methods chosen to reach these aims. According to Rogers, seven roles can be identified for a "change agent": a) develops need for change, b) establishes an information-exchange relationship, c) diagnoses their problem, d) creates intent to change in the client, e) translates intent into action, f) stabilizes adoption and prevents discontinuances, and g) achieves a terminal relationship.

Referring to adoption of changes in some population, Rogers identifies a small group of "innovators", a larger group of "early adopters", large groups of "early majority" and "late majority", and a smaller group of "laggards". He characterizes the innovators as daring and risky, always eager to try new ideas. The early adopters are opinion leaders, more integrated in the social system than the inno-vators. They follow with deliberate willingness in the adoption of innovations, but they seldom take the lead. The late majority approaches innovations cautiously and sceptically, and does not adopt new ideas until most others in their social system have done so. The laggards tend to be frankly suspicious of innovations, interacting primarily with others who also have relatively traditional values; they may be in a precarious financial position, which forces them to be extremely cautious.

During every intervention study carried out in working life, a great number of various types of processes take place. Some of them are due to the intervention or affected by it. Others are not, but may at times also affect the study. Most of the processes are, however, of little or no interest to the researcher. The reason for describing some of them derives from attempts to understand the relations between factors which are involved in the matter under study, and to identify the factors which are probably responsible for the changes (or lack of changes) observed. In a study aimed at reducing the occurrence of recurrent low back pain in various groups of employees, if the results are positive, one may ask which were the factors that were probably responsible for the decrease in the occurrence of back disorders in the intervention group. What measures can be recommended in order to obtain similar or better results, preferably at lower costs, in other workplaces on the basis of this study?

The two main reasons for describing an intervention process are thus:

a) to strengthen the evidence that an observed effect was due to measures taken in the intervention study, by identifying links in a chain of causes and effects which could lead to the observed outcome, and
b) to recommend what factors/features to pay special attention to in future attempts to achieve similar or better results in other studies.

Describing the intervention process(es) may be looked upon as describing the development of understanding and accepting the goals of a project, as well as the methods for reaching these goals. To be able to recruit active participants, both the goal(s) and sometimes even the method(s) may be decided upon only roughly when initially planning a project aimed at affecting psychological and social factors at work. It is important to be able to modify both goals and methods, at least to some degree, according to the opinions of the participants in the study, in order for them to feel as if they can truly affect the way the project is carried out. Otherwise they may feel as if they are being used as human "guinea pigs" by working life scientists, and decide not to cooperate with the researchers. To secure as active participation as possible of the population under study, consideration should thus be given to the various interests of the potential individuals/groups approached. Respect for their position on questions important to them, as well as fairness in the balance between demands put on them and rewards they may expect, is necessary in order to achieve their active cooperation. This is why a summary of the discussions and decisions during this phase should be reported.

At the start, the situation in one work unit recruited to the intervention study may be very different from that of another. The results to be obtained often reflect in the situation at the beginning. However, the results will vary, not only according to the initial situation of the unit and the attitudes of its staff. They will also depend to a considerable extent on the trust the researchers evoke. In addition, the results will depend on the degree of informal backup from various background "authorities", such as the workers' unions. And of course they will depend on the talent, experience and the enthusiasm of the researchers.

In reports on intervention studies, the intervention measures are mostly described in the section on methods, while various observations made during the course of the study are brought up in the discussion of the results. In general this is a satisfactory way of describing intervention processes, as it brings up the factors considered to be relevant when evaluating the results. It should, however, be clearly understood, that this leaves it up to the judgement of the researchers to decide which observations to report and which not (9). The processes that will be reported are those which the researchers are aware of, and consider worthwhile reporting, on the basis of their mental model of the matter under study. Many processes may have passed unnoticed by the researchers. And of the processes that have been noticed, only a few may have qualified for inclusion in the written report, as they were considered interesting, either because they were in concordance with the researchers´ mental models or because they were in discordance with them. In large intervention studies the number of observations is always so great that a researcher cannot report all of them, nor does any reader wish to learn about them all. However, it should be possible to check the main observations behind all significant conclusions, so that they can be confirmed or refuted in later, independent similar studies.

Griffiths (1999) underlines the need to ask detailed questions about how the intervention was implemented: Did it reach the intended number of people? Did the participants comply with what they were supposed to do? What appeared to be the barriers to compliance? Such information is helpful in trying to understand why an intervention had, or did not have, an impact.

Recruitment of the participants is one of the most important processes in all intervention studies. A report of an intervention study should thus include a presentation of all the individuals/groups approached, why they were chosen as potential participants, how they were approached, what their first reactions were, and whether or not - and if so why - they decided to participate or not to participate in the study. This information may be difficult to provide, partly because people are not always clearly aware of the factors which make them take a favourable or unfavourable stand to some suggestion, and partly because they may not want to report the reasons for their opinion for one reason or another. Questions concerning this topic may be difficult to ask directly at the time of recruitment and, if asked later, memories/opinions may have changed over time. Even so, it is important to try to document the process of recruitment as well as possible, as this will help evaluation of the results obtained.

The participative scheme in activities which are related to work environment is subordinate to the general cooperative climate in a company. In a climate that is characterized as tough by negotiations of demands, it is difficult to establish a participative approach based on joint effort in problem-solving of work environment problems (4). However, to carry out an intervention study in a country like Finland you must nowadays obtain explicit acceptance, not only from the management and the supervisor of the unit(s) to be involved. The study must also be accepted by the staff concerned. If the staff says "no", the answer is "no", no matter what the immediate superior or the administration says. Whether a unit

decides to participate in a study or not often depends on the opinions of a few influential members. Their reasons for speaking for or against participation depend primarily on the aim of the study and their trust in the investigator´s competence and integrity. However, it depends also upon consideration of various possibilities and threats brought up by the project, some of which may be evident to the investigators, while others may be hidden.

It is important that the researcher(s) is/are as aware of her/his/their mental model as possible. If the investigators have an explicit theory, or at least an explicit model of thought, at the outset of the study, this will guide the observation of the processes taking place in the course of the intervention. The theory, or mental model, guiding the planning and carrying out of an intervention study may be explicit and written down at the onset (See Figure 2). This is always the case when a study is carried out in order to find out whether a certain model works as expected or not. Most studies, however, are carried out with the aim of trying to improve something which is considered important to improve, often without much awareness of theories or explicit mental frameworks for the study, at least when the study is launched.
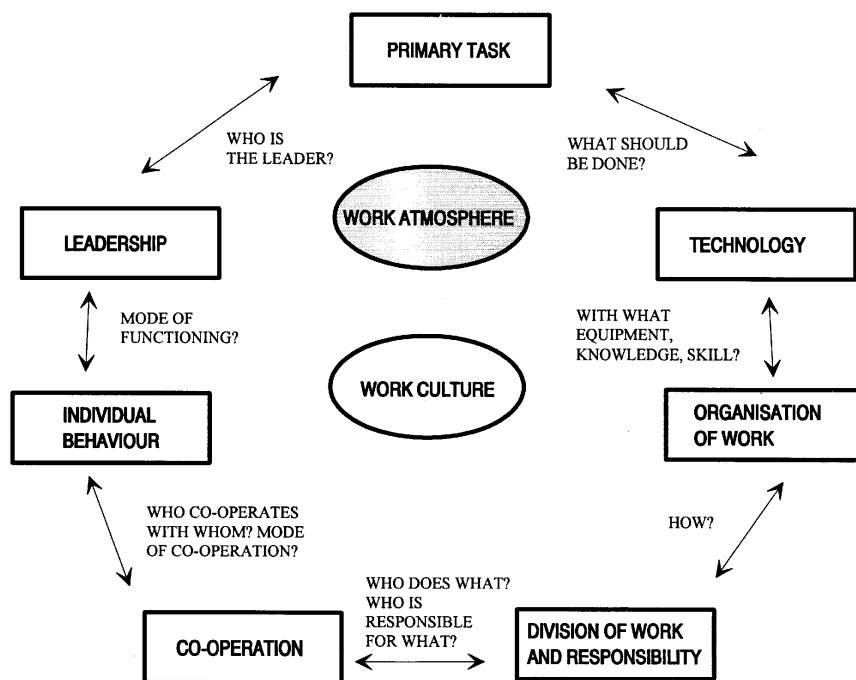

Figure 2. Example of a model, which can be used as a basis for an intervention study (modified after Weisbord).

The data may be gathered according to ready-made checklists or forms, and/or taken down freely in notebooks on the basis of what the researcher/observer at that time considers to be of special interest. When the researcher/observer takes notes on the facts he/she finds interesting, the reason for the interest may be that:

- the observation supports the theory/model, which the study is based on, or is in disagreement with that model, or that
- the observation fits into a different, presently developing personal mental model, or is in disagreement with that model.

The personal mental models often become evident only through writing down observations in support or disagreement with one's expectations. There are many factors which determine not only whether some observation may be made or not, but also whether it will be acted upon in some way. It may be a) actively considered, but not acted upon in any way, b) taken down in written form to be remembered but not yet acted upon, c) verbally fed back to the subject(s) under study, or d) included in the written report of the study. Factors that may be systematically observed are, among others:

- proportion of target group actively participating in the study
- degree of involvement
- conflicts arising among the participants because of questions brought up by the intervention study
- dependency on the researchers.

It may be worthwhile reporting all formal meetings, their agendas and atmosphere (when the meetings took place, where they took place, who participated in them, main themes discussed, nature of the discussion) in order to give an overview of the intervention process. The distribution of meetings over time, as well as the proportion of group members participating in the meetings, may be presented as a diagram (See Figure 3).
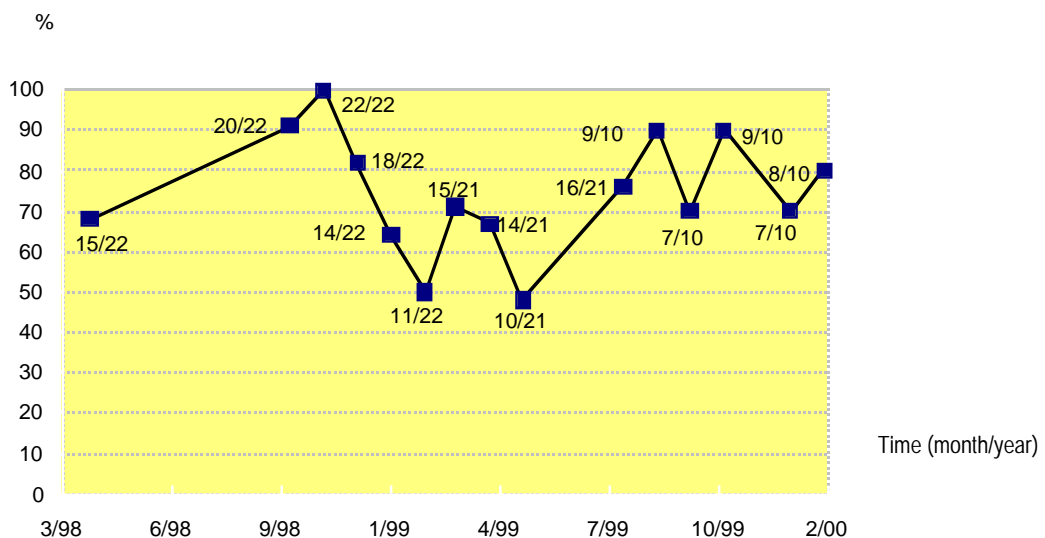

Figure 3. Proportion of group members participating in meetings to advance the intervention during the various phases of the study (absolute numbers also presented).

Other planned and unplanned changes than those initiated by the study always take place during an intervention study (10). To be able to evaluate the results of the measures introduced by an intervention project, all "major changes" during the time of the study should be monitored. Changes in formal organisation should thus always be reported, as should possible changes of persons in key positions. The rate of turnover among the staff of the units under study should also be reported.

At times it is not possible to publicly report all observations of importance for the interpretation of the results, as this could hurt the interests or the feelings of some individual or group that participated in the study. Explicitly bringing up sensitive incidents in research reports might violate promises given when launching the study, and could jeopardize carrying out similar studies in the future. Sensitive themes can, however, often be brought up in an implicit way, by commenting upon the matter in question in general terms and avoiding putting the blame on any special party.

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Ethical issues in intervention research in health care work

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Basic ethical principles

Like all other professionals, researchers must conform to ethical principles in their work. The ethical principles in research are basically the same, irrespective of research field, and can be classified into three basic principles: autonomy, beneficence, and justice (14).

The principle of *autonomy* includes protecting the autonomy and integrity of persons. It means that participation in research projects should be voluntary, and that informed consent is necessary. Important factors are privacy, confidentiality, anonymity, and integrity. Researchers should give those involved in a study the opportunity to receive information on ethically sensitive issues before they are published, and the participants should be offered a summary of the results, if they are interested (14).

The principle of *beneficence* (or the principle of nursing) implies maximising good outcome, while avoiding or minimising harm, risk, or wrong, not only for the individual research participant, but also for science and humanity. Thus, researchers have a moral duty to do good, and not to harm anybody. Those who participate in a study may benefit in different ways; they might gain insight or learning. Organisational changes can also be a consequence of an intervention; however, the individual might regard these changes as more or less beneficial.

The principle of *justice* means that all persons should be treated equally. Two aspects of this principle are the criteria of equality and need. The equality criterion means that respect for the life, dignity and justice of persons in health-care and sick-care should not depend on nationality, race, religion, age, gender, or political or social status. The need criterion implies that the need of a person should decide the distribution of advantages (14).

Ethical research problems

Ethical research problems are principally of two types. The first concerns the aims of the study and how the results are going to be used. The second type concerns how the research is carried out (8). High quality research, focusing on important questions, is necessary for the development of society.

Most researchers have realised that scientific work at times includes ethical conflicts and dilemmas. In medical research history there are several examples of

the dilemma between the urge for an increasing scientific understanding and the need to respect individual rights. For example, in studies on treatment of syphilis, some of the subjects were excluded from effective treatment and not informed of its availability (10).

Nowadays, special ethical committees regularly take the process and progress of a study into consideration. Hence, a study will be stopped if the treatment is found to be so beneficial that also the control patients should receive the treatment. There are several examples of both social intervention studies and medical treatment studies where this has happened (15).

In research on conditions of working life, an ethical conflict between the above-mentioned basic principles is not unusual. Haglund et al. have analysed the dilemma of improving the working environment while maintaining respect for the autonomy of the participants when using individual-based data (6). A distinction was made between no study, a study without informed consent, and a study with informed consent. They concluded that the interest of the exposed workers, present and future, was of primary interest; and that no lack of confidentiality should be tolerated concerning the individuals studied. Thus, the respect for the individuals under study was a main concern. The interests of other concerned groups, for example the community at large, should only be decisive secondarily.

Ethical committees

To protect society from research frauds and bad research (research of low quality and/or importance) most research projects in the Nordic countries must be approved by an ethical committee. Research funds and medical faculties at university hospitals have such committees. Additionally, most scientific papers demand an approval of the study in question by an ethical committee before publishing results. There are also laws and regulations regulating the use of personal data covering privacy, confidentiality, identifiability, and data protection.

When reviewing a research protocol, the focus concerns mainly a) the project plan, b) the ethical justification for the project, and c) the content of the information letter to the participants (19).

a) In the project plan the following factors are scrutinised:
- the research question(s)
- the method(s) used to answer the research question(s)
- the population under study
- the size of the population to be studied

b) When using individual-based data the ethical committees demand a justification concerning the chosen method with maintained respect for the autonomy and integrity of the participants.

c) The ethical committees put great emphasis on the information to the study participant. Honest information about the aims of the research project must be

given and no information about the true nature of the research should be withheld. The participants must be aware of this in order to consider whether or not to participate, and to know what is expected of them. Also the participants must be informed of short-term beneficence from participation, for example increased number of lifting aids on a ward, flexible working hours, treatment and/or rehabilitation through modified work, and/or an individual health check-up. Short-term beneficence from participation can also be education and training during working hours, for example physical training, training in diabetes care or in patient-transfer technique. It is understood that if an intervention is successful, a more long-term aspect of the beneficence from participation is that implementation of the intervention at other workplaces in the health care sector might lead to improved working conditions also there.

The participants must also be informed about their right to leave the project without any negative consequences. Information about who the research leaders are, and where and how to reach them, must also be stated in the letter.

Ethical issues in intervention studies of low back problems among nurses

In the analysis of the study by Haglund et al., ethical dilemmas were scrutinised (6). However, most published studies still lack a discussion about ethical issues, as exemplified by the eleven intervention studies summed up in Table 1. These studies focused on the working environment in the health care sector with the aim of decreasing the occurrence of low back problems. Parameters covered in the table are: comments on quality, focus on the individual or organisation, effect on occurrence of low back problems, and comments on ethical issues. Other parameters, presented in the original report were: follow-up length, intervention studied, outcome measure and main findings.

Regarding the comments on quality in these reports, the categories most frequently used were:
- inadequate method, including lack of control group or lack of randomisation (1, 3, 4, 7, 12, 17, 18, 20), low participation or follow-up rates (17, 12, 3, 4, 20, 18) and
- lack of important information, concerning sample and/or exposure at work and/or participation rates.

As a consequence of these quality shortcomings it could be discussed whether some of these studies should have been carried out using another method, or not at all.

Most of the eleven studies used quantitative methods. Broadening of this perspective by also gathering qualitative data, using participative or interview methods, might identify contributory factors to low back and other health problems in nurses (9). To reach an increased understanding of intervention studies it may be necessary to adopt methods used in research on education (16).

The matter of focus of the intervention is also a quality aspect. Eight of the eleven studies had an individual focus, i.e. the projects aimed at changing the behaviour, attitudes or physical capacity of the employees through teaching or physical activity. Among the eight projects with such an individual focus, five failed to show a decrease in low back problems among the nurses. Four of the eleven projects had an organisational focus or an organisational *and* individual focus, and in all these projects a decrease in low back problems among the nurses was reported. These interventions consisted of, for example, application of technical aids in patient care (4), and modified work for nurses from high-risk wards (20). In several reports it has been emphasized that low back problems among nurses is not only an individual problem, but also needs an organisational solution (17, 18). Thus, the "ergonomic" (and ethical) question could be posed: "Is it right to change the nurse so that she will fit the workplace, or should the workplace change to fit the nurse?" Wood stressed the importance of combining the programmes, as the effects emanating from them could be either short- or long-term (18). When there is evidence of the importance of both organisational and individual measures in projects aiming at decreasing low back problems among nurses, it could be questioned whether it is ethical to perform projects merely with an individual focus.

This emphasizes the importance for researchers to keep updated in their field of interest. This can be regarded as a problem, as the volume of evidence of work-related factors increases every year. The Cochrane Libraries publish systematic reviews of controlled trials in health care. Due to the fact that easily accessible research reports tend to exaggerate the benefits of interventions, such systematic reviews concerning research on working life, irrespective of method, should also be produced.

Ethical issues were mentioned in only one of the eleven studies, and the question of what the members of the control group gained from the study was only raised in one of the studies. In this study the justice and equality aspects were solved by putting the members of the control group on a waiting list, in order to receive the same intervention as the others participants after the study (13).

It must be recommended that researchers actively take up the ethical issues, the principles and the dilemmas of their projects. If a discussion of ethical issues were mandatory, not only in scientific articles but also in other reports, one conse-quence would be an increased awareness of these issues, not only among researchers, but also among the general public. Taking part in doctoral courses is one way of increasing knowledge and awareness of ethical issues in research. However, gaining a deeper insight into these problems is also a matter of personal maturity.

Table 1. Ethical aspects on intervention studies of low back problems (LBP) in nursing work

Reference	Population and data collection	Quality comments #	Individual (I) and/or Orgisational (O) focus	Decrease (D) or No Decrease (No D) in low back problems	Ethical principles/ issues reported
Gundewall et al, 1993 (5)	32 nurses aides & 28 controls with or without history of LBP in a geriatric hospital. Questionnaire, report card, physical tests	Info	I	D	No
Videman et al, 1989 (17)	87 student nurses with extra training & 113 student nurses as controls. Questionnaire, anthropometric measurements, strength and functional tests	Method Info	I	No D	No
Hellsing et al, 1993 (7)	2 nursing schools: 19 student nurses with extra training and 33 student nurses as controls. Questionnaire	Method	I	No D	No
Lagerström et al, 1998 (12)	348 nurses working at physically demanding wards. 4 questionnaires during 4 years	Method Rate	I	No D	Registration was made for all nurses at one ward i e participation was mandatory. Filling in questionnaires was voluntary
Feldstein et al, 1993 (3)	30 nurses and 25 nurses as controls. Questionnaire, transfer forms, physical tests	Method Rate	I	No D	No
Garg & Owen, 1992 (4)	38 nursing assistants at a nursing home. Observation, Borg´s RPE scale, accident reports, biomechanical tests	Method Rate Info	O and I	D	No
Yassi et al, 1995 (20)	250 nurses with back problems and 1,395 controls at the same hospital. Interview.	Method Rate Info	O	D	Participation was voluntary with signed consent. From an ethical viewpoint nurses with back injuries were not randomised to intervention/ control. All injured nurses were allocated to intervention.
Cooper et al, 1996 (1)	40 nurses at high-risk wards and 118 controls. All had earlier had back injuries. 2 scales. 6 months follow-up of (12)	Method Rate	O	D	See Above (12)
Wood, 1987 (18)	Employees at one hospital. 2,035 accident reports (2 projects)	Method Info	I O	No D D	No
Donchin et al, 1990 (2)	142 nursing staff with back problems annually. Questionnaire, physical capacity tests	Info	I	D	Information letter with the purpose of the study and randomisation into groups
Linton et al, 1989 (13)	36 nurses & 30 control nurses currently working, but with history of back problems. Questionnaire, diary.	Info	I	D	The control group was given the offer of intervention after the study

Info= Incomplete information concerning: sample, participation, follow-up rates, and/or physical and psychosocial exposure at work Rate= PR= participation rate<70% and/or FR= follow-up rate<70%;
Method= randomisation not performed and/ or no control group.

Ethical aspects of intervention research – suggestions

The ethical principles stated above are general principles in research. However, in each research field there are problems concerning specific ethical aspects. Below are some suggestions regarding what nursing personnel who participate in research projects to improve their working conditions, might expect:

- The participants should not be persuaded or coerced into participating. The individual employee must feel free to reject participation, even if the project is sanctioned by the management and endorsed by the trade union.
- The method, design, and analyses should be appropriate and correct.
- Information about the research project and the beneficence of participation should be provided, including both the risk for the individual and the usefulness for society.
- The interventions should preferably be both bottom-up and top-down, as the best conditions might develop when the interventions are carried out in dialogue between the employees, who are experts on their work environment, and the management, which is responsible for the effectiveness of the activity.
- Education and training might include employee empowerment, where the goal is to assure nursing personnel a sense of control over their workplace, by encouraging them to participate fully in the improvements at their work.
- Reporting of results should include "negative" results, i.e. risk factors that are not shown to be predictors of the problems under study
- In the feedback given either to the management or to a working group, it must not be possible to identify any participant.
- Ethical issues should be discussed whenever relevant. When using a control group, and if the intervention proved beneficial, the outcome for this group should be considered.
- The collected data should be kept and archived safely, according to regulations and rules. Lists with names must be kept separate from returned questionnaires or other personal results.

Acknowledgement

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