SBU – Swedish Council on Health Technology Assessment

# MEDICAL SCIENCE & PRACTICE

# NEW REPORTS SBU Results in Brief | 11-15





# How Can Quality of Life Be Measured?

How do different treatment methods affect patients' quality of life? This question is key in health care. But finding appropriate methods to measure satisfaction with life is a challenge that has eluded scientists for decades.

Health is important for our quality of life. Many people would say that their quality of life is equally important as the symptom level or other signs of disease.

For instance, people who contract a life-threatening disease do not concern themselves only with how many months or years that treatment can extend life. They also want to know what their situation is likely to be during that time – for instance, whether patients are usually able to live life as before.

The question of how different treatments affect quality of life is important to patients, carers, and decision makers.

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# A Pseudo-Informed Physician

With increasing discomfort, I look across the dinner table at B, a know-it-all physician in his prime. He chews energetically on a pasta salad and is obviously proud of his minute – and wordy – analysis of the problems with today's health care.

-You know, evidence and such drivel is the devil's own invention, he finally explains with a smug smile.

– What?

- Yes, a malignant conspiracy amongst a lot of idle bureaucrats and some unsuccessful researchers who couldn't survive the competition. What do they know about care and patients? With their blasted me-e-e-taanalyses they wouldn't last twenty minutes in my clinic!

- Are these sour grapes, or what are you talking about?

- They think they're experts on how to provide this glo-o-o-rious evidence based care, but they've never been close to the actual delivery of care, says B, and then takes such a large swig of beer that I'm able to interject.

- Hey come on, I say. Are you telling me it's unnecessary to review the best available research on treatments? What's the alternative? Where are you going to find your scientific support and benchmarks, might I ask? In some "good old boy" network? Or in 30-year-old textbooks? Or in your own magic formulas?

- Well, it's not my job to mess around with such details. It's your job.

Now I'm getting irritated.

- But please, B, do tell me how you are keeping up with what the research shows, so you are able to deliver that amazingly effective care that you claim to provide.

- Google, responds B contentedly. I don't claim to know everything, so when I need to refresh my memory I use Google. Takes five seconds to pull up the evidence.

OK. And you trust what you find in those five seconds? Amongst one hundred and eighty thousand hits?
Yup. Of course you can see whether it's published

by a professor or some research institute. – Beg to differ. A few scientific articles that you or I

or someone else stumbles over on the Internet do not make up evidence. Evidence is made up of systematically collected, quality-reviewed and evaluated findings from all available research.

- Yah, yah, so it is Ragnar. Like I usually say: Evidence is as important to health care as ornithology is to birds, ha ha. By the way, did you have some problem with your shoulder that I should look at before I have to go?

 Nah, thanks anyway. Suddenly it feels much better. On the way home with my aching shoulder I contemplate the assignment that the Government gave SBU last summer – to investigate ways to establish a national, Web-based library for health services. A site to help healthcare staff find evidence and other useful information all in one place – a resource requested by many. But not everyone. A physician like B might never recognize how much he needs it.







But measuring quality of life is easier said than done – even though the methodology has advanced in recent decades.

JUNGLE OF METHODS A jungle of measurement methods is now available to address health-related quality of life. When researchers in Oxford inventoried these methods they found 1275 different formulas.

One explanation for this multitude of instruments is that they may have been developed for different purposes. Clinical researchers want to compare the effects of different treatments on patients' function and well-being, while public health experts focus on general changes affecting the quality of life of different groups in society. And health economists involved in pricing drugs and prioritising healthcare interventions want to compare the costs of different ways to achieve a particular improvement in the quality of life.

Some questionnaires are general, generic, and can be used regardless of the type of health problem. Others are adapted to different diseases and conditions. The diseaseor condition-specific formulas are more sensitive than the general ones – they provide a more detailed description and can capture several important functions. On the other hand, they can miss side effects and other essential factors concerning other organ systems. The different measurement methods also yield different results.

Another difficulty in research is that our expectations have a strong influence on the quality of life. Jan Liliemark is programme director at SBU, oncologist, and professor of pharmacotherapy.

- In addition to all other measurement problems it's important whether the quality of life is measured directly after onset, or after a period of time, in the course of disease, he says.

# PERCEPTIONS CHANGE

– Many patients can adjust to a serious disease or functional impairment, e.g. cancer. They adapt to their new situation. Even though the quality of life decreases radically at first, perceptions often change later. Researchers need to consider this.

Studies that compare the effects of different treatments on quality of life should also mask who receives which treatment; otherwise expectations influence the outcome.

Since dropout is often substantial, another question concerns how to manage this in studies involving quality of life, says Jan Liliemark.

## **NO FOLLOW-UPS**

 Many of the test subjects are never followed up. The most severely ill are unable to participate through the entire study, which skews the research findings.

But perhaps the greatest challenge involves determining the value of the measured changes in quality of life. How important are they, actually? Does the starting point from which the quality of life becomes better or worse play a role? How much do we think a particular change in quality of life is worth at different levels of health?

In attempting to factor in the public's perspective, health economists use an index, a tariff. This has been calculated using a sample of (mostly healthy) people in the population who have set hypothetical values on different states of health. The researchers asked them to imagine that they had been afflicted by different conditions and functional impairments and appraise how high or low their quality of life would be. Here, methodological problems arise.

 Of course it's difficult to set a value on a state of health that one has never experienced, says SBU's Emelie
Heintz, whose PhD thesis
pursues the topic from a perspective of health economics.

# BRITISH FIGURES

The values, however, differ in different countries. For the EQ-5D instrument alone there are 18 different tariffs.

Nevertheless, an index based on the values of the

Swedish population does not exist. Sweden uses figures based on samples from the British or Canadian populations.

Despite the shortcomings of the tariffs, Emelie Heintz thinks it is good to at least try to consider the public's values regarding quality of life.

Decision makers need to be aware of the functions on which people in general place the highest value, she says. However, she would like to see greater awareness about how to calculate the quality of life.

- For example, you can arrive at totally different results depending on the general formula you choose. One formula might show that a treatment improves the quality of life for patients, while another formula shows no effects at all.

– And this is not a purely academic question. The tariffs and the estimated costs to achieve a certain level of improvement are used in specific decisions about which drugs should be financed with public funds and included among the pharmaceutical benefits.

Quality of life is changeable and difficult to measure. It is reasonable to place high standards on the measurement methods, which must be scientifically appraised for their area of utilisation.

To forgo measuring quality of life is a poor alternative. Then we would most definitely remain in the dark about how patients actually feel. [RL]

## **Further Reading**

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# WHAT IS QUALITY OF LIFE?

Quality of life is a broad measure comprised of an individual's appraisal of their physical, mental, and social well-being. According to WHO, quality of life addresses an individual's perception of their life situation in relation to the current culture and norms, and in relation to their own goals, expectations, values, and interests. By definition, it is a personal experience influenced by changes in one's life situation and which varies with time.

Even though health has a major influence on quality of life, other factors in the environment naturally play a role, e.g. family and friends, work and free time, economics, housing, education, and associating with other people. The concept of health-related quality of life encompasses the aspects of general quality of life that are influenced by health. This is of interest in clinical research when studying the effects of different care interventions on patients' quality of life, and not only on symptoms and survival. Healthrelated quality of life is also measured in population studies for planning and followup of public health initiatives.

Various quality-of-life measures are used for health economic comparisons of different treatments – for instance, comparing the cost of gaining a quality-adjusted life year through different interventions.

The instrument used can be categorised as general and disease- or condition-specific.

The general instruments should make it possible to compare patient groups, while the specific ones aim at a more detailed profile of a particular type of health problem. Specific instruments have become increasingly common.

A general method used in many clinical studies is *SF-36*. Disease- or condition-specific instruments include the *EORTC QLQ* battery of questions for various cancers, *Asthma Quality of Life Questionnaire*, and *St. George's Respiratory Questionnaire*.

The health economic calculations are based instead on information from general methods such as *EQ-5D*, *SF-6D*, and *HUI-3*.

# When are Small Effects Big Enough?

Although the difference between two treatments may be statistically significant, i.e. confirmed by an acceptable statistical margin, it is not necessarily clinically significant. The so-called *p-value* in statistics has no intrinsic value.

Showing statistically significant differences between different interventions often satisfies researchers. If sufficient evidence shows that one treatment has superior effects over another, then they claim that issue is settled.

But the critics argue that this standard – the need to show a statistically significant difference between the methods – is far from sufficient. It does not differentiate between trivial effects and valuable effects.

Before we draw the conclu-

sion that one intervention works better than another, we should decide how great a difference is necessary to play any role for the patient – a type of threshold value. We ought to ask: How small is the minimum difference in terms of clinical importance?

**COINED CONCEPT** More than 20 years ago someone coined the concept of *minimal clinically important difference*, also called the *smallest worthwhile effect*. This refers to the smallest improvement that patients perceive as beneficial and that would motivate a change in treatment strategy – assuming that the side effects and costs for the more effective method are acceptable.

But changing the focus from statistical significance to clinical relevance has been slow, according to Rob Herbert, Associate Professor of Physiotherapy at the Neuroscience Research Institute in Sydney, Australia.

### SOLE FOCUS

 Although the problem has been discussed for decades, we often continue to focus solely on p-values and confidence intervals when we interpret research findings, he says.

- For instance, many readers of the Cochrane reviews look only at whether the diagram shows if one or another treatment option is better. And in fact this is just as uninteresting as reporting the p-value of an individual study. They should also be looking at the differences in size, both in absolute and relative terms.

 Although tempting, it is premature to draw conclu-

# **P-VALUE AND SIGNIFICANCE**

When researchers statistically analyse clinical research results they usually conduct a statistical hypothesis test. This is a test that investigates whether the results measured in a randomised study (e.g. a difference between two groups – treatment group and control group) are statistically significant. The hypothesis tested in the study is called the null hypothesis.

**Further Reading** 

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Levi R Ställer forskarna rätt frågor?

[in Swedish] Vetenskap & praxis nr

clinical trial justified? Brit Med J

The null hypothesis means that the treatment shows no difference compared to controls (e.g. that treatment is no better than placebo). If the null hypothesis is valid, the study is unlikely to show a difference. The p-value indicates the probability that such a difference would have arisen by chance – even though the null hypothesis is true. A p-value of 0.05 indicates that this probability is only 5%.

When the p-value is so low, we usually choose to reject the null hypothesis. We say there is a difference that is statistically confirmed at the 5% level, or statistically significant. But a statistically significant difference between the groups does not necessarily mean that it is clinically relevant. In a study that includes a sufficient number of participants, even a minimal difference in effect that lacks clinical importance can achieve statistical significance.

In contrast, if a study is too small and has too few participants, the opposite problem arises. Not even an effect difference that is actually important would then achieve statistical significance. sions about "winners" and "losers" among treatment methods based only on statistically significant differences. Concurrently, we must always ask: How much better or worse is the respective method? Does this matter?

Preferably, every study that compares different treatment methods should be designed and interpreted from the standpoint of such knowledge, says Rob Herbert.

 It's not really meaningful to commit resources to differences that patients view as having no value.

Together with colleague Manuela Ferreira and other co-workers, Rob Herbert has studied how researchers have addressed the issue in their own area, i.e. treating low back pain.

# **EXPERTS' PERCEPTIONS**

– Most experts have relied on their own – and not the patients – perceptions about appropriate clinical threshold values and reasonable sacrifices to achieve them. For example, many equate "smallest measurable effect" with "smallest important effect". They assume that the smallest identifiable effect is always of interest, says Rob Herbert.

- Instead, it should be the patients themselves who determine what is a reasonable balance between a chance for improvement, on the one hand, and the risk for side effects and costs, on the other.

The patients' values should guide the choice of treatment method.

The constant quest of researchers for low p-values also has consequences for their future research, notes Rob Herbert. Since experts and patients may disagree about the value of a given treatment effect, they might also have different opinions about the value of conducting further studies to improve statistical significance.

# MEANINGLESS QUESTION

- The immediate reaction of many researchers is to conclude that if we do only one more treatment study of sufficient size, we will be able to improve the situation for patients. However, there's no guarantee that the results of a new study, regardless of its size, would benefit the patients.

 In the worst case, it would only provide a more definite answer to a meaningless question.

Clinical research often aims to eliminate uncertainty about the effects of a treatment. But the interesting question is actually whether or not the new study reduces patients' uncertainty about the value of that treatment. [BL]



# Evidence Alone Will Not Suffice for Care Decisions

Evidence has become everyone's catchword – scientists, journalists, and politicians. But evidence does not lead in a straight line to decisions, notes Jesper Jerkert, Teacher in Philosophy.

Many want to cite evidence when they make decisions. The researchers that promoted the concept of evidence based medicine (EBM) explained from the outset that an important goal is to make better healthcare decisions, to offer each patient the best treatment. Thus, EBM is not only about compiling existing evidence, but also about using this knowledge in medical practice.<sup>1</sup> But when it comes to the practical application of evidence, misunderstandings often arise among both the advocates and critics of EBM. People draw a straight line from evidence to decisions. But it can never be guite that simple.

#### ACCEPTED TOOL

The most widely accepted tool for evaluating medical technologies in terms of clinical studies, i.e. GRADE, includes an evidence component and a recommendation component.<sup>2</sup>

The evidence component describes the actual scientific evidence, and the recommendation component recommends the treatments that should be prescribed in concrete cases. The Cochrane Collaboration, which compiles reports on the medical evidence available in different areas, uses GRADE – but like SBU, only the evidence component. Hence, these reviews normally do not present any treatment recommendations. Even if a Cochrane review shows for instance that treatment A has a greater effect than treatment B, this is usually insufficient for making decisions about which method would be most appropriate for an individual patient, or which one should receive priority in health services generally.

## GO BEYOND

The Cochrane Collaboration's instructions for systematic reviews assert that treatment recommendations require considerations that go beyond the actual systematic review.<sup>3</sup>

What are the considerations that lead from evidence to decisions? Two questions are important links in the chain: Is the cited evidence relevant to the decision? Which (possibly implied) values are fulfilled if the correct decision is made?

Exactly what may be considered relevant in this context can be discussed. Jeremy Howick, who is closely associated with GRADE, has listed four criteria for relevance<sup>4</sup>: • The effects must address something important to the patient and not simply a surrogate measure. In other words, one must show a positive effect on well-being and/ or longevity, not simply, e.g. blood values.

• The positive effects must outweigh the possible negative side effects.

• Evidence on treatment effects must address typical patients. In other words, the study must apply to realworld conditions, not only animal experiments or selected groups of people that differ substantially from those who typically present themselves for treatment.

• The treatment must be compared with other options for the condition in question. People cannot make decisions if there are no alternatives to choose from.

# GOAL NOT AS CLEAR

As regards values, an interesting fundamental difference exists between evidence based medicine and other activities said to be evidence based, e.g. evidence based correctional care or evidence based education.<sup>5</sup> In medicine, what we want to achieve with the interventions under review is relatively uncontroversial; everyone agrees that good health is the goal (even though the scope of the concept may differ). In correc-



tional care and education the goal is not as clear – there is political disagreement about the most appropriate aims of these services.

## MAY DISAGREE

Even if everyone agrees about the general goals of health services, people may still disagree on several other values included in the health decision. This becomes particularly apparent when discussing economic aspects.

Assume for instance that there are effective interventions for several diseases, but they are found to be too expensive for preventing or treating all of these diseases in the population. A list of priorities will be needed to appraise which problems are of greater or lesser importance for health services to treat or prevent.

# CONFLICTING VALUES

Conflicting values do not necessarily concern economics, nor do they necessarily mean that different diseases are weighed against each other. Different patients, even those with the same disease, may have different opinions about what they hope to gain from health care.

It is also conceivable that the expected statistical distribution of a treatment effect ought to determine how strongly the method is

recommended. The average treatment effect (i.e. the effect at the group level) is not necessarily the only outcome of interest. Assume that the effect of a treatment is positive on average, but it varies widely among different individuals with the same disease. While some patients improve considerably, others may not improve at all, or might even get worse. If this variation is real (i.e. does not simply reflect statistical uncertainty in the studies) it is not self-evident that the treatment can be recommended generally.

Moreover, patients and health services may view this situation in different ways. The individual patient's view of the possibility for improvement versus the risk of deterioration can differ from that of the healthcare provider.

Necessary elements involving values in care decisions are often forgotten – even though it has long been asserted that evidence-based clinical decisions must combine evidence (systematically collected and quality-graded research findings) with clinical experience and patients' values in each care situation.<sup>6</sup>

### PRESENCE OF VALUES

Some argue that the mix of values and knowledge that care decisions inevitably involve should not be called evidence based. Instead, we should find terminology that more clearly indicates the presence of values.7,8 Personally, I do not think this is realistic. We probably have to accept that evidence based activities are not based entirely on knowledge. Decision making also encompasses questions about relevance and values.

> Jesper Jerkert, Doctoral Student, Adjunct in Scientific Philosophy, KTH, Stockholm Member of SBU's lay panel

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# Studying the Shadows of Psychology

Psychological treatment is often perceived as harmless. But despite examples of unexpected negative effects, research on psychological methods seldom mentions adverse effects. An American article presents reason for concern, writes psychologist Ulf Jonsson, Research Associate at SBU.

Psychological interventions are often an integral part of the services offered through both psychiatric and somatic care. Moreover, psychological methods are used to promote health and prevent ill health in risk groups.

Many well-executed studies have shown the effects of such interventions, as presented in several SBU reports. In pace with the continued expansion of scientific evidence, the potential to assess the effects of these methods is improving. Better information about the advantages and disadvantages of the methods can make it possible to compare them with each other and with other treatment options. This benefits patients since it improves their opportunity to make informed choices.

**COMMON WEAKNESS** Although many studies in this area are of high quality, they continue to have a common weakness – they often fail to mention whether the authors studied adverse or undesirable effects.

The problem is not unique to psychological methods. Inadequate reporting of adverse effects is a general problem that has received attention in research on medical treatments.<sup>1,2</sup> In 2004, a review was published on the reporting of treatment safety in 142 randomly selected treatment studies in the psychiatric field.3 The review, which covered both pharmacotherapy and other methods, reveals major shortcomings generally. Of the 39 studies that addressed pharmacological methods, none were found to have adequate reporting.

# EXCEPTIONAL CASES

SBU is now engaged in reviewing all randomised controlled trials of psychological interventions that were published during 2010. Our preliminary results confirm that only in exceptional cases is it possible to see if the authors investigated the potential disadvantages of treatment.

It is not possible to determine whether the lack of information stems from the intervention's lack of clinically significant negative effects, or if the researchers failed to investigate the issue. Even if we assume that negative effects were studied, but not reported, we do not know how systematically or thoroughly they were studied.

Is it worthwhile to invest research funds, time, and energy on such questions? Can we not assume that psychological interventions are generally harmless? A review article from 2007 speaks against such an assumption.<sup>4</sup>

## HARM OR BENEFIT

The author, Professor Scott Lilienfeld from Emory University (Georgia, USA), lists psychological interventions that have been shown by randomised studies or meta analvses to create more harm than benefit. Examples include interventions for uncomplicated grief reactions, debriefing - group discussion on a single occasion directly after exposure to extremely stressful situations, and so-called boot camp (a method based on disciplinary interventions) for behavioural disorders. All of these interventions appear to increase risks for the symptoms they are intended to prevent or ameliorate. Lilienfeld emphasises that, given the probable deficiencies in reporting, the list must be viewed as incomplete.

## UNDERLINES

It is also noteworthy that, at first glance, several of the interventions mentioned can appear to be harmless. This

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underlines the need to address the issue.

Results that indicate significant post-treatment deterioration are probably unusual. A more likely scenario would be that a treatment has negative effects in subgroups of subjects. For example, psychotherapy research has reported that a small percentage of patients can deteriorate more than those not receiving treatment, while others clearly improve.5 A pattern of this type can be hidden by the mean values often presented in treatment studies. The problem could be corrected by studying the percentage that get worse during treatment, which would require a clear definition of clinical deterioration.6

A broader survey may be important since hypothetically there could be several undesired consequences, e.g. aggravation of specific symptoms, new symptoms, resistance against seeking other treatment, negative effects for next of kin, or even physical harm.<sup>4</sup>

## EASIER

Despite potential negative effects from some psychological interventions, these methods are often easier on the patient than other available alternatives. If this is the case, it must be reported.

The value of clearly showing that a treatment does not involve substantial risk for the individual is illustrated by a current, large-scale study of psychological treatment for chronic fatigue syndrome.<sup>7</sup>

## NOT MORE RISKY

This randomised trial of 641 participants compares standard specialised care complemented by either cognitive behaviour therapy (CBT), graded exercise therapy (GET), or pacing (i.e. a method where patients learn to balance their activity and to avoid over-doing). The reason for the study was that patient associations in Great Britain had conducted studies showing that GET and CBT could be harmful, and therefore pacing was recommended instead. But the results of the randomised trial indicated that none of the three complementary treatments increased the risk for deterioration or serious negative reactions. Both CBT and GET led to better physical functioning and less fatigue than did the addition of usual care alone or pacing. Such information can be decisive for the patient's choice.

Professor David Barlow

at Boston University (Massachusetts, USA) has written an exposé of the past 40 years' research and clinical experience concerning the negative effects of psychological treatment.<sup>5</sup> He asserts that this area of research is surprisingly neglected, and that it is time to systematically collect evidence and develop new methods for this purpose. An increased focus on negative effects can, in the long run, lead to better patient information,"fine tuning" of the interventions, and better individual adaptation to avoid negative effects. This would benefit patients and clinicians alike.

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# **RECENT SBU FINDINGS**

# Demanding Work Increases Risk of Neck Disorders

Scientific evidence indicates that certain types of heavy work – lifting, carrying, pushing, and pulling – increases the risk of disorders in the neck, shoulders, elbows, and forearms. Highly demanding work with a low level of control also increases the risk of neck disorders.

Reliable studies show that the risks for disorders and diseases in the neck and/or shoulders increase in: work involving bending or twisting the torso, heavy work (lifting, carrying, pushing, pulling), combination of highly demanding work and little control, or only highly demanding work or only a low level of control or very limited opportunities for decision making.

The risk for disorders in the elbows and forearms increases with heavy work (lifting, carrying, pushing, pulling) and repetitive work. As regards disorders of the wrists and hands, people whose work requires a combination of repetitive hand motion and exertion are at risk.

Long-term use of a computer mouse also increases the risk for disorders and diseases in the shoulders, elbows, and forearms.

Generally, considerable research has been conducted on work and disorders affecting muscles and joints. However, depending on study design, it is not always certain that the disorders experienced by study subjects were caused by the work specifically, or by other factors. Hence, research is needed where subjects with clearly defined problems are captured early and monitored over time.

An area lacking in scientific studies of adequate quality for drawing conclusions concerns the association between work and the risk of being affected by general pain, e.g. concurrent pain in the neck, lower back, and hips. [JT]



# BACKGROUND

SBU's objective has been to provide unbiased scientific evidence to clarify the impact of work on the onset of disorders in the neck and upper musculoskeletal system.

The project is limited to risks that arise when one is exposed to different factors in the work environment.

The prognosis for various disorders is not included.

The assessment does not aim to make determinations about individual cases or investigations of work-related injuries.

# Schizophrenia Can Improve With New Drugs and More Involvement

# FACTS

Schizophrenia is a serious, usually life-long, disease. The disease may involve hallucinations and distortion in perceptions of reality. Onset of the disease occurs in approximately 15 of 100 000 persons per year. Life expectancy in people with schizophrenia is approximately 20 years shorter than in other people. Common causes of death are suicide, cardiovascular disease, and cancer due to smoking.

Newer drugs for schizophrenia often have better effects than older ones. Hence, current recommendations should be reviewed. So finds SBU in a new report that also shows the important impact on recovery when care involves family members.

The new SBU report focuses on both pharmacotherapy and patient participation in treating schizophrenia.

SBU shows that four of the new antipsychotic drugs, clozapine, olanzapine, risperidone, and amisulpride have superior effects compared to older drugs. Clozapine reduces the risk of suicide and possibly the risk of alcohol abuse compared to most of the other agents. Different forms of abuse are common in people with schizophrenia. The results indicate that the recommendations on pharmacotherapy in schizophrenia should be reviewed.

# SERIOUS SIDE EFFECTS

Although the benefits of the drugs are greater than the risks, the side effects are often serious. Examples of adverse effects include diabetes, stiffness, involuntary movements, and elevated blood lipids. Many of the medications lead to weight increase.

The disease affects both the patients and their families. The report shows that communication and contact between staff, family, and patients should be strengthened. Continuity, respect, and involvement in care are important and help promote recovery. It is also important to provide social support since the disease is often associated with discrimination and exclusion. In working on the report, SBU collaborated with different consumer organisations. [RL]



# Hard-to-Heal Wounds Can Heal Faster in a Vacuum

Wounds that fail to heal after surgery or injury can cause severe, long-term problems. In some cases a special method to create negative pressure around the wound may speed healing, compared to traditional dressings. But for many types of wounds, the method's benefits are unconfirmed.

Pain, odour, infection, or, at worst, sepsis - these are the potential consequences of a wound that fails to heal normally after surgery or injury. Those affected are often already severely ill and require extended hospitalisation for wound dressings and treatment. Vacuum assisted closure therapy is a method that has been used for several years in Sweden. Basically, the method creates a sealed, moist environment around the wound and negative pressure intended to reduce swelling and improve circulation.

**CAN REDUCE MORTALITY** SBU in collaboration with HTA Centre of Region Västra Götaland, Sweden, has reviewed the research available on vacuum assisted closure therapy. The assessment shows that some evidence is available showing that the method can reduce mortality in patients with inflammation in the chest cavity following an operation that requires

separating the sternum (sternotomy). The length of stay in hospital can be reduced for patients who have had a small section of epidermis transplanted from another part of the body (split-thickness skin graft) to a wound that is not"surgically clean". These patients and also diabetic patients with wounds from forefoot amputation may experience faster wound healing. In patients with open fractures, vacuum assisted closure therapy can lead to fewer infections and wound complications compared to usual wound treatment.

# TOO FEW STUDIES

For many other patient groups, findings have not shown whether the effects of vacuum assisted closure therapy are superior to traditional wound treatment since too few studies of sufficient quality are available to draw conclusions.

Vacuum assisted closure therapy costs approximately the same as usual wound treatment. In patient groups where vacuum assisted closure therapy has shortened the length of stay and reduced mortality the method is cost effective. More clinical studies of high quality are needed to determine whether the method could be cost effective in other patient groups. [AB]



# FACTS

Standard wound treatment means dressing the wound once or twice per day. The patient group covered by this assessment consists of adults with postoperative wounds that fail to heal normally.

# Care Managers Improve Care for People With Depression

Specially trained professionals, such as nurses, that link care seekers with care givers could improve primary care for patients with depression. Care managers are cost effective in the United States, but Swedish studies are needed.

A new SBU report assesses methods for promoting evidence-based treatment of people presenting in primary care with mental health problems such as depression. According to the review, scientific evidence indicates that a care manager can improve the situation for patients with depression. A coordinator of this type maintains close contact with patients after their initial physician visit – monitoring symptoms, providing information about treatment, and engaging patients in their treatment. A care manager also serves as a link between physicians and patients, e.g. by arranging follow-up visits, contacting patients that have discontinued treatment, and helping with referrals.

## SWEDISH CARE

Studies of care managers have included other interventions concurrently, e.g. training of staff. The conclusions are based on American studies, and according to SBU it would be important to investigate the effects in Swedish health care.

Demand is growing for health services to provide evidence-based treatment. Concurrently, international research shows that new guidelines are implemented too slowly. Many patients do not receive treatment based on the best available evidence. Hence, there is major interest in finding methods that promote using the evidence in health services. [AB, RL]



# Used Correctly, CT Detects Diseased Coronary Arteries

Computed tomography (CT) is a reliable way to rule out serious stenosis of coronary arteries. For the method to provide optimum benefit it must be used in the right patients.

Coronary angiography involving computed tomography, CTCA, is used to identify narrowing of blood vessels that supply the heart, for example, which lead to angina and myocardial infarction.

SBU has reviewed the scientific literature on CTCA as a diagnostic method in suspected, nonacute (stable), coronary artery disease. The review shows that CTCA can be used to identify those patients who need further investigation - if a practitioner with relevant skills and modern equipment uses the method in appropriate patient groups. CTCA has high sensitivity, i.e. it misses few stenoses that can cause symptoms, when used in individuals with intermediate probability of stable coronary artery disease. However, at times CTCA shows stenoses that have no impact on the patient's health.

The equipment and its use also play a role in the strength of the radiation dose to which the patient is exposed in conjunction with the examination. Since one of the methods often used in further investigation, invasive coronary angiography (ICA), also involves radiation it is important to examine as few patients as possible with both methods. The more patients receiving double examinations, the higher the total cost of the investigation.

SBU's report provides no answer to whether CTCA can predict the risk for serious heart disease or death. [RL]

# BACKGROUND

• Intermediate probability for stable coronary artery disease means between 10% and 85% probability. Probability is associated with, e.g. age, sex, and symptoms.

• A CTCA examination with modern equipment yields approximately the same radiation dose as natural background radiation per year.

• A CTCA examination in Sweden costs approximately half as much as an ICA examination.





# MEDICALSCIENCE&PRACTICE

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