

# Science & Practice

Information from SBU – The Swedish Agency for Assessment of Health Technology and Social Services



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## Sustainable Decisions Need Solid Support

Medical treatment must not be based on single studies of dubious scientific quality. To be effective and safe, treatment options must rest on a broad base of well-designed studies.

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### SBU – ASSESSING HEALTH TECHNOLOGY AND SOCIAL SERVICES

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# The Incidentaloma Epidemic

IF THE BRAIN OF forty symptom-free individuals is scanned with MRI, one scan is bound to reveal a pathologic change. Not a trivial change, but a tumour, a cyst, a vascular problem, an inflammation, a silent stroke, or something similar. This is not to say that the person in question would have ever noticed the change, or lived a shorter or less fulfilling life. Probably not. But nevertheless.

“SO WHAT?”, you say. “Who on earth would squeeze into a narrow MRI machine for no apparent reason? I’d rather watch TV, check my mobile, or take a walk. Or have a snack. Big deal.”

Well, unfortunately, this is a big deal. A growing one, too, according to many radiologists. The better the technology for imaging the body, and the sharper the images, the more abnormalities they detect in passing – when the exam is actually aimed at something else. They will find something they weren’t looking for, an “incidentaloma” which could potentially affect health and therefore cannot be ignored.

AN INTERESTING SCOTTISH study (Sandema EM, et al. 2013) using MRI of the skull in 700 symptom-free 73-year-olds revealed pathological findings in as many as one third. The findings led to nine non-acute and one acute referral. The problem, to some extent, involves even younger patients. According to a systematic review of studies on 20 000 younger and middle-aged participants (Morris Z, et al. 2009) such changes in the brain were found in 3% of all symptom-free individuals examined.

The better our imaging technology, the more incidental findings show up in screening and clinical examinations. A small percentage reveal the first stage of a serious condition, but no one knows who is going to be afflicted. Everyone has a right to be informed about the findings and follow-up exams may be needed. Physicians and patients are moving toward an unsustainable situation: either detecting potentially premalignant conditions without taking further action, or burdening the healthcare system with follow-up exams “just to be sure.” This raises the issue of prioritisation. Can we afford to follow up all findings of this sort?

THE KEY PROBLEM is not really new, and is not limited just to imaging. A standard set of blood tests – a type of nonspecific screening – will often include a few outlying values. Some of these indicate an underlying disorder that should be investigated.

In Greek mythology, it was curiosity that drove Pandora to open her box and release the evils of the world. Health care has other driving forces, such as sophisticated technology and well-intentioned ambitions. We cannot put the lid back on, but we can think twice before we lift it.

“The better our imaging technology, the more incidental findings show up.”



Ragnar Levi Editor

MUCH OF PUBLISHED research gives a misleading picture of the benefits and risks associated with different therapies. This is also true for randomised trials. SBU’s assessments show, that to be useful for healthcare decisions, many studies must be better designed and be sufficiently large and long-lasting.

This insight is not really new. When a research group in the 1990s systematically examined the treatments that had been used over the last 30 years against antipsychotic drug side effects, e.g. tardive dyskinesia, they found about 500 randomised studies of 90 different drugs. But none of the trials could provide reliable responses to researchers’ questions. Some studies included too few patients to yield reliable results; others were so brief that the outcome was not relevant.

When the same research group later reviewed 2 000 randomised trials of 600 treatments for schizophrenia – mostly drugs but also, e.g. psychotherapies – many other shortcomings became obvious. Since most trials address hospital patients, it is uncertain which results translate to outpatient settings where patients’ symptoms can differ, as do the opportunities to monitor treatment.

Another problem was that researchers had used many methods to measure treatment outcomes – no less than 640 different measurement methods, of which 369 had been used only once. Discerning patterns and interpreting the results therefore became extremely complicated.

Even in this vast field of research, many studies included too few subjects, or were too short-term, to yield useful results. New drugs were often compared with excessively high doses of drugs with known side effects, despite the fact that patients tolerated some other alternatives better. Hence, the comparisons were clearly misleading.

CONDUCTING A SYSTEMATIC REVIEW that summarises the best studies can provide knowledge that is more reliable. (At times, even more reliable results can be obtained from a large multicentre trial that involves many clinics.) A well-designed and well-executed review can provide more reliable information than a single, small study.

However, quality varies even in such reviews. Different systematic reviews of a given question may yield different



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## Five steps to improve healthcare decisions

1. Understand the need for evaluation. Finding the treatment with the best effects requires high-quality trials comparing different methods head-to-head.
2. Search for all relevant studies. Far from all scientific studies of a given treatment are relevant. They could involve a different patient category, a different disease stage, or irrelevant outcomes.
3. Assess the risk of bias. Many relevant clinical trials are unreliable, e.g. because they are too small, too brief, or too poorly designed to protect against random or systematic errors.
4. Compile all relevant, reliable evidence. Not all reviews are prepared and presented adequately. Sustainable treatment decisions require rigorously conducted and well-reported systematic reviews of the overall evidence regarding benefits, risks, and costs.
5. Assess findings in context. Valid and relevant facts about medical outcomes are not enough. Cost effectiveness must also be evaluated and ethical aspects considered. Research evidence must be considered along with clinical assessment of the individual case and the patient's preferences.

answers. The reasons could be that the questions differ slightly, or that the reviewers proceed differently. Some systematic reviews are inadequately protected against bias. Slight shifts in framing a research question or its objectives, as well as random errors, occur not only in individual studies but also in systematic reviews, for instance, when authors cherry-pick data to support their own opinions and omit others.

**ONE REVIEW OFTEN REFERRED TO** as an illustration of the latter problem concerns treating eczema with oil extracted from a type of primrose. The authors, who had ties to the manufacturer of this extract, arrived at much more positive conclusions than later systematic reviews that included a large study, which did not favour the product and which had been excluded by the first reviewers. Other examples include meta-analyses of different antidepressants that overestimated the impact, mainly due to using a particular form of dropout analysis.

But systematic reviews that are well executed can be very useful. As early as 1974, a Swedish oncologist reviewed studies that compared the results of breast surgery with or without radiation therapy. The overall results indicated that the type of radiation treatment given at the time increased mortality. Later, more detailed analyses based on documentation from individual patients confirmed this finding. The survey paved the way for safer treatments.

**SYSTEMATIC LITERATURE REVIEWS** have become more common. Researchers are increasingly aware that such analyses should be carried out early and then updated. One example is a 2008 meta-analysis of randomised trials conducted since the late 1990s, which assessed the safety of blood substitutes, which do not require refrigeration or cross-matching, in surgical, stroke, and trauma patients. For many years, this was regarded as a good option. But the review showed that artificial blood actually increased the risk

of myocardial infarction and death – a fact that could have been revealed several years earlier.

An important insight is that randomised trials are not the only studies of value for health care and patients. In assessing side effects, other types of studies may be particularly important to consider.

In the case of the drug aprotinin, it proved to be a fatal mistake to rely on randomised trials alone. Although large cohort and case-control studies showed that the drug increased the risk of kidney failure and death, many decisions still relied on a review of small randomised trials that had found no such risk. When researchers chose to continue with a larger randomised trial, it had to be prematurely stopped due to an increased number of deaths. Probably lives could have been saved if other data regarding adverse events had been taken more seriously and if the review had been examined more critically.

**ANY VALID TEST OF TREATMENTS** must consider different types of studies relevant to the context. To obtain an accurate, comprehensive view of known facts, such studies may include in vitro research and trials involving healthy subjects or patients.

Ignoring important facts, or including them in a haphazard way, may have serious consequences. Patients in general and trial subjects could suffer – in the worst-case scenario it could lead to unnecessary loss of life. In addition, resources are wasted; resources that might have been valuable to both health care and research. ♦ **RL**

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# Socioeconomic Health Hazards

People's health reflects their social and economic conditions. Groups with less education report poorer general health and more often die prematurely of heart disease, stroke, cancer, accidents, suicide, and alcohol-related conditions. A Swedish government committee will suggest ways to close health gaps.

Socioeconomic conditions have a strong impact on health, even in a comparatively wealthy country like Sweden. While life expectancy in the country is increasing, differences in health status are obvious and in some cases increasing between the most and the least advantaged.

The gap is evident in almost any category of health problem. Some Swedish examples:

- Premature death is more common in lower than in higher social classes. Remaining life expectancy at 30 years of age is 5 years shorter among people with lower educational levels than among those with higher.\*
- The most common causes of death among people with lower education include heart disease, stroke, cancer, accidents, suicide, and alcohol-related diagnoses, i.e. the same as in the general population.
- People with low education report poorer general health and have more mental health problems.
- Children living in economically disadvantaged families are admitted to hospital more often.
- Children living under poorer socioeconomic conditions are more prone to injuries caused by accidents.

The situation is similar for dental health. Socioeconomic groups differ both in dental health and the number of visits to dental services. Socioeconomically disadvantaged groups more

## Social inequalities in health

Studies of the association between socioeconomic conditions and human health do not use experimental methods. Instead, existing groups are compared and the trends over time are studied. Such comparisons are often methodologically challenging. Different groups and time periods are not entirely comparable, and the results can be uncertain. Many factors can affect the variables under study, and causal inferences can be problematic.

\* Educational level is often used as a measure of a person's general social and economic status, even if educational level in countries like Sweden does not affect health directly.

often avoid visiting dental care even if they need it, and people who report poor dental health more often indicate financial reasons for not seeking care.

Many possible causes underlie health inequalities. Lifestyle explains part of the difference. For instance, smoking is more common among people with low education and low income. Alcohol-related mortality is over three times higher among those with the lowest education than among those with the highest education. Physical activity and dietary habits are other lifestyle behaviours that could contribute to the health gap.

**FURTHER EXPLANATIONS ARE FOUND** in people's working environment and psychosocial context, which are associated with socioeconomic conditions. Many studies have demonstrated, e.g. the correlation between unemployment and various forms of ill health. Even though not all studies can demonstrate the causes and effects, nor how coexisting conditions and underlying disease mechanisms influence health risks, the relationship between unemployment and illness is clear.

For those who have a job, opportunities to influence and control the work environment are important to health. For instance, a recent SBU review shows that cardiovascular disease is more common among people who experience a combination of psychological demands and a lack of control in their work situation. The same goes for people who describe their work as mentally



PIIA KOSKELA

stressful, who lack control, or who experience an imbalance between efforts and rewards.

The same also applies to people who feel they have poor social support at work, who experience injustice at work, who have insufficient opportunities for personal development, or who experience job insecurity, e.g. concerned that their workplace will cease to exist.

The new SBU assessment (presented on page 15) also shows that stroke more often affects groups who report a lack of control over their jobs, people who work shifts, and people exposed to noise at work.

**THE SOCIOECONOMIC GAP** in society is also reflected geographically by where people live. According to the National Board of Health and Welfare's progress report (2015) on the state and development of health care and social services, the share of people receiving income support from Swedish municipalities (and neighbourhoods in urban areas) varies from 0.5% to 18.8%.

The observation that a correlation exists between people's position in society and their health is certainly not new information. Substantial scientific data shows the association between social welfare and public health. The problem of health inequalities has gained international attention by the World Health Organization (WHO) and the European Union (EU). The special commission that WHO set up a decade ago issued three overarching recommendations for closing the health gap:

- improve daily living conditions
- tackle the inequitable distribution of power, money, and resources
- measure and understand the problem and assess the impact of action.

In 2015, the Swedish government established a commission for health equity, stressing that the expected proposals should build on scientifically based evidence about risk factors and interventions. The proposal should be ready by May 2017.

Since July 1, 2015, SBU has been assessing not only health and medical practices, but also interventions in social work; activities that directly affect people's welfare. Hence, the government has expanded SBU's mission. This is a natural step considering, e.g. the strong connection between social conditions and health. Social services and health care combined should lead toward improvements in people's lives.

Such factors also interact – the effects on health by healthcare interventions can also influence people's social and economic situation, which in turn can affect health, e.g. through work environment, home life, and lifestyle. Social service clients often have health problems that may worsen their socioeconomic situation.

To achieve a clear understanding of people's situation and needs, and to offer better help, their socioeconomic and health status should not be considered separately but evaluated as a whole. ◆ **RL**

#### Further Reading

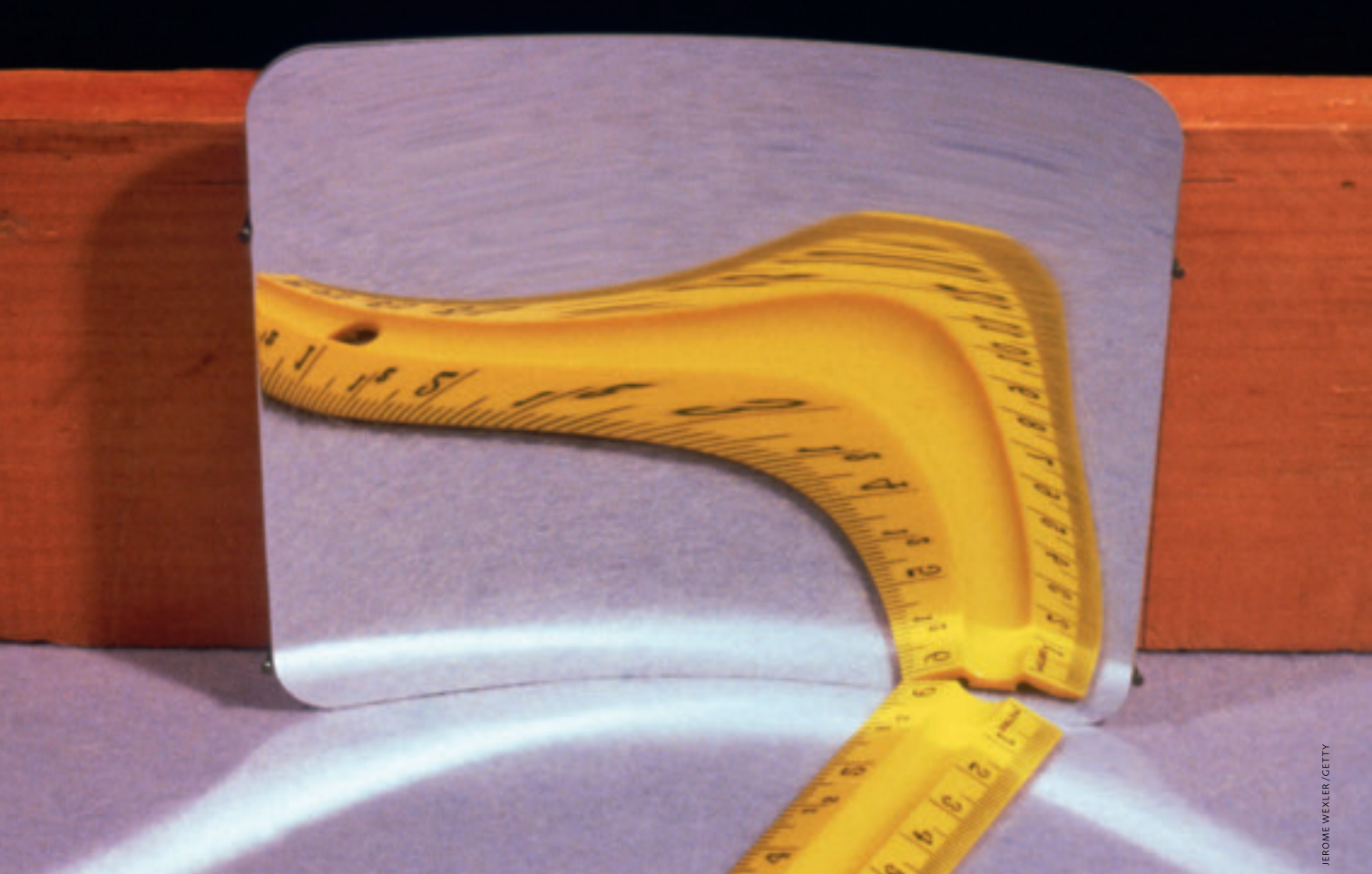
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JEROME WEXLER/GETTY

# Bias Often Skews Trial Results

Randomised trials supposedly compare treatments fairly. But their reliability depends on researchers' success in preventing errors related to randomisation, treatment, analysis, dropout, and reporting.

Unreliable results are common in clinical trials for many reasons. The list of potential sources of error can be long, and avoiding all of them is hardly possible. But effective protection against the most serious problems is a good start for a reliable randomised trial. Such problems are traditionally classified as random errors or systematic errors.

## Random errors

Studies based on few observations involve a high risk that the results are due to chance and that the outcomes would be completely different if the experiments were repeated.

The size of the random error depends on the number of observations. The

greater the number of observations (e.g. the more participants in a clinical trial), the lesser the risk for random errors.

The category of systematic errors includes selection bias, performance bias, detection bias, attrition bias, and reporting bias.

## Selection bias

Randomisation means randomly assigning participants in a trial to a treatment (experimental) group or a control (comparison) group. If the study is sufficiently large, the chances are greater that all characteristics that could influence the outcome, except for the treatment itself, are divided equally between the two groups.

This applies both to such characteristics of participants that are known to potentially influence the outcome (known confounders), and to characteristics which scientific studies have not yet shown to be important to the outcome (unknown confounders).

Stratified randomisation is another method to achieve a fair distribution of confounders in both groups. Before assigning anyone to the treatment or control groups, participants are divided into subgroups (strata) by characteristics thought to affect the prognosis or response to the intervention. Equal numbers of participants from each stratum are then randomly assigned to treatment or control.

The randomisation process must be masked so that assignments cannot be foreseen or manipulated. Hence, allocation usually involves codes or random numbers generated by a computer.

In studies that do not use randomisation, or that use it inappropriately, selection bias may skew the results.

### Performance bias

Expectations among researchers or participating patients, clinicians, and statisticians may influence the outcome of a clinical trial. Hence, no one involved must know who belongs to the treatment or control group until all measurements and analyses are completed.

Masking of this information is called blinding.

Performance bias occurs mainly in unblinded trials, when some trial participants intentionally or accidentally receive some other treatment or type of care than that intended as a result of being assigned to the treatment or control group.

Such an imbalance could arise, for instance, in testing a new drug for diabetes where the treatment group receives greater support than the control group to also change their eating and exercise habits. The groups are then no longer entirely comparable, and the results can be skewed to disfavour the control group.

Ideally, everything should be similar in both groups except for the treatment itself.

### Detection bias

Detection bias relates to measuring effects and analysing results. In an unblinded study, results can be distorted if researchers conduct measurements and analyses differently in the treatment and control groups.

The more subjective the measurement, the more exposed it is to detection bias. For example, in unblinded studies, symptom scales and quality of life measurements often introduce the risk for detection bias. This risk may differ for various outcome measures in the same study.

### Attrition bias

Attrition bias occurs when a certain category of participant is unable or unwilling to complete the study. If the dropout rate is high among all participants, or if this rate differs in the treatment and control groups, results can be skewed. Careful monitoring and analysis of dropout is essential.

### Reporting bias

Reporting bias occurs when the investigators do not report all the results from treatment studies, but only the desired results. Researchers may be tempted to “cherry pick” findings, e.g. by presenting only positive treatment effects and omitting undesired outcomes. This results in reporting bias and a distorted description of the results.

Reporting bias does not necessarily mean that some results were omitted completely. Such bias can also occur through a change of focus. When investigators see their results, they may change their view of what outcomes should be regarded as primary. Outcomes considered to be primary when the study was designed may be inappropriately replaced with entirely different measures or outcomes previously defined as secondary.

One way to prevent reporting bias is to require advance publication of a detailed research protocol that clearly states what investigators intend to measure primarily and secondarily. ♦ RL

## Beware of treatment studies where ...

### • the results are preliminary

Results of pilot studies and preliminary reports of on-going studies, e.g. presented at conferences, can be particularly unreliable.

### • the number of participants is small

The fewer subjects in a study, the more uncertain the results, and the greater the risk to overlook small but important effects.

### • there is no control group

Studies that simply compare symptoms before and after treatment rarely provide evidence that changes result from the treatment. Improvement or deterioration of a condition might have occurred for other reasons.

### • the control group received ineffective treatment

If the control group received placebo, effects in the treatment group should be interpreted in relation to placebo and not to other potentially active interventions. Should two treatments be compared, both should be given in the correct dose/amount.

### • randomisation was not used

If subjects were not randomly assigned to the treatment or control groups, the risk is greater that systematic differences between the groups distort the comparisons. However, the care with which a study is conducted also matters. Other types of studies, if carried out rigorously, may well provide valuable evidence.

### • the study involves a narrow category of patients

If trial participants are atypical, i.e. carefully selected, the results are less generalisable. If, on the other hand, no selection at all has occurred, treatment effects may be obscured by other factors, and the results may be uncertain. To achieve a balanced view, studies of a small subset of patients should be complemented with studies of populations that are more representative.

### • many subgroups have been created retrospectively

The risk is that investigators, in pursuit of a particular result, have performed so many subgroup

analyses that chance alone has brought about a positive outcome in a subset of patients.

### • the risk of side effects has not been analysed

At times – but not always – randomised studies record common side effects. Randomised studies seldom capture rare but serious side effects. Other studies are required.

### • many patients dropped out

If many trial participants are lost to follow-up, the results are dubious. Reasons for dropout should be analysed in detail.

### • blinding was not used

If participants or investigators know all along who receives what treatment, their expectations can affect the outcome. To avoid expectation effects, masking (blinding) should be used.

### • the follow-up period is too short

Follow-up must be sufficiently lengthy to demonstrate whether or not the treatment has the desired effect, and whether or not it persists.

### • unproven methods are used for measurement / analysis

Outcome measures and statistical methods should have been previously described and scientifically validated in other contexts.

### • outcomes are measured by surrogate endpoints

If a treatment targets morbidity, mortality, and quality of life, it is precisely these outcomes that should be measured. At times this is impossible or inappropriate, in which case any surrogate measures used must have been shown to be important to patients' health and quality of life.

### • results are expressed only as relative risk changes

A major change in relative terms – e.g. a 50% reduction in risk – sounds impressive, but may be totally meaningless if the baseline risk is small. Absolute numbers should also be presented.

The list above is not comprehensive, but presents some examples of weaknesses in clinical trials. Further reading in SBU's Handbook, [www.sbu.se/handbook](http://www.sbu.se/handbook)

# Assessing Ethical Implications

A Swedish law from 2010 stipulates that new methods should be ethically assessed before being introduced in health care. Still, a parliamentary committee found that ethical issues are not explored often enough, or in sufficient depth. SBU is developing the methodology.

A study (October 2013) commissioned by the Swedish Parliamentary Committee on Health and Welfare found that the need to analyse ethical consequences of new diagnostic and treatment methods is underestimated. At first glance, clinicians might not realise that a new method might entail ethical dilemmas and conflicting values.

In many cases, we need more comprehensive ethical analysis – which in turn requires both time and special expertise in ethics. With a more thorough ethical analysis, decisions can improve to be more thoughtful and consistent.

The investigation stems from a new provision in the Health and Medical Services Act passed by Swedish Parliament in 2010. It states that healthcare providers should ethically assess new diagnostic or treatment methods of potential significance for human dignity and privacy before they are implemented in health services.

**THE PARLIAMENTARY COMMITTEE** aimed to study how often ethical issues had been considered when new methods were introduced at the clinical level.

The investigators chose eight methods that had been introduced in surgery and ophthalmology that could involve ethical issues, but did not appear problematic at first glance.

For each technology introduced, treat-

ment practices and ethical discussions were surveyed at four to seven clinics in four counties; around 40 introductions in total.

According to the survey, the county councils had not conducted ethical evaluations as intended by the law. Only half had established routines to evaluate new methods, and in practice only a few had included ethical aspects when assessing benefits and risks.

**IN MANY COUNTIES**, few people were aware of the new provision, and for various reasons the requirement for ethical review had received lower priority. Hence, healthcare providers risk introducing ethically controversial practices.

“Ethical reviews are scarce, inconsistent, and rarely comprehensive” conclude Barbro Westerholm and Catharina Bråkenhielm in the Journal of the Swedish Medical Association (*Läkartidningen*), and continue: “This has led to diverging conclusions and in several cases to differing treatment guidelines.”

As an example, the authors mention the choice between eye drops, laser treatment, and surgery for patients with deteriorating glaucoma.

The investigators also found that healthcare providers do not consistently prioritise human dignity before cost effectiveness. But the principle that all people have equal value and equal rights, regardless ▶

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of personal characteristics and functions in society, should override the principle of cost effectiveness, which concerns the balance between costs and benefits in prioritising different interventions. The authors use the example of varicose vein surgery, where they report that patients run the risk of being treated unequally depending on gender and social status.

Another example concerns the choice of drugs for age-related macular degeneration, where different counties – despite

the common ethical platform – have differed in their valuations of treatment effects versus costs.

**SINCE ETHICAL ANALYSIS** involves value judgements, authors must clarify how the analysis was carried out and what factors were actually considered. This is particularly important when the analysis serves as evidence for healthcare decisions, e.g. in SBU health technology assessments.

– That is why we are working to develop SBU methodology for evaluating ethical aspects, says Emelie Heintz, health economist at SBU.

– With the help of experts in the field, we have formulated twelve key issues to identify relevant ethical issues in our health technology assessments.

– In that way, we won't miss significant ethical questions when new technologies are assessed, she says. ♦ **RL**

## Twelve basic questions

### Effects on health

1. Health: How does the intervention influence patient health in terms of quality of life and longevity?
2. Knowledge gaps: In the absence of scientific evidence on the effects of the intervention, are there ethical and/or methodological obstacles to conducting further research to strengthen the evidence base?
3. Severity: How serious is the condition targeted by the intervention?
4. Third party: How does the intervention affect the health of third parties?

Generally, is the benefit-risk ratio of the intervention ethically acceptable?

### Compatibility with ethical norms

5. Equality and justice: Is there a risk that access to the intervention violates the human dignity principle or legislation against discrimination?
6. Autonomy: Are the patients and their families able to give informed consent or participate in relevant decisions concerning the intervention?
7. Privacy: How does the intervention affect the privacy of patients and their families?
8. Cost effectiveness: Is the balance between the intervention's cost and effectiveness reasonable?

Generally, is the use of the intervention compatible with ethical norms?

### Structural factors with ethical implications

9. Resources and organisation: Are there resource and/or organisational constraints that can influence access to the intervention, or that can restrict the availability of other procedures if the intervention is implemented?
10. Professional values: Can values held by the relevant caring professions influence implementation of the intervention, thereby resulting in unequal access?
11. Special interests: Are there special interests that could influence implementation of the intervention, leading to unequal access?

Generally, is there reason to believe that aspects in Q9-Q11 can affect equal access to the intervention?

### Long-term ethical consequences

12. Can application of the intervention have ethical consequences in the long term?

The list above includes the questions, but a full version has been published in Heintz E, et al. *International Journal of Technology Assessment in Health Care*, 2015;3:124–130. The items are based on the work of Norwegian philosopher Bjørn Hofmann, but SBU has also included issues that have been raised in international HTA networks and has adapted the list to Swedish conditions and SBU's working methods.

# STROKE

## BETTER OUTCOMES FROM EARLY DISCHARGE AND HOME REHAB

**The best treatment option after stroke is rapid discharge from hospital to home with continuing, co-ordinated rehabilitation from the same inter-disciplinary team. This improves survival, and more patients can manage daily life unassisted. Few places in Sweden currently use this option.**

Following stroke, rehabilitation is essential for patients to regain various bodily functions and a normal social life. Currently, rehabilitation usually takes place in hospitals or outpatient clinics.

SBU's review shows that early discharge to the home plus on-going structured and co-ordinated rehabilitation in the home environment by a multidisciplinary team yields substantially better outcomes. There are fewer deaths, and the need for assistance with activities of daily living (ADL) decreases without an increase in cost.

**THE METHOD REQUIRES** an interdisciplinary team which has special skills in stroke care and which co-ordinates care through frequent, regular meetings and close collaboration across the disciplines.

The benefits of the method have been demonstrated only in studies where the same team is responsible for continuing rehabilitation in the home following hospital discharge. It is uncertain if outcomes are similar when the team manages rehabilitation only until hospital discharge, and then municipal services or primary care take over this responsibility. Here the evidence is insufficient for conclusions, according to the report.

The model results in better utilisation of healthcare resources – according to SBU's analysis it is probably more cost effective than current practices.

**WITH EARLY SUPPORTED DISCHARGE** and on-going rehabilitation at home the first episode of hospitalisation becomes shorter, but the need for outpatient care, home services, home remodelling, assistive devices, or help from the family



increases. However, research has yet to show the effects on resource utilisation beyond a period of one year.

Rehabilitation at home is uncommon in Sweden and unevenly distributed throughout the country. The extent to which interdisciplinary teams manage the full rehabilitation process, even after hospital discharge, is also uncertain.

Patients receiving post-stroke care

constitute the patient group requiring the most inpatient days in Sweden. Four out of five are older than 65 years of age. ♦ RL

### About the Report

Rehabilitation at home after early supported discharge (ESD) for elderly patients after stroke (2015). Project Director SBU: Jenny Odeberg, jenny.odeberg@sbu.se. Chair: Prof. Lotta Wedén Holmqvist, Department Neurobiology, Karolinska Institutet, Stockholm.

### SBU'S CONCLUSIONS STROKE REHAB AT HOME

- ▶ When the interdisciplinary team is both responsible for co-ordination of the discharge and for the continued rehabilitation in the home environment, fewer people die or are dependent on assistance in their personal ADL. The cost of health care does not appear to increase in short-term follow-ups, which means that the intervention/service is most likely cost effective. Today, most hospitals in Sweden have not implemented this service model.
- ▶ The scientific evidence is insufficient to assess the effects when the interdisciplinary team is only responsible for the discharge but not continued rehabilitation in the home environment for elderly patients after stroke.
- ▶ The initial hospital stay is shorter when an interdisciplinary team is involved as compared to conventional care.

# HIP FRACTURE TEAMWORK IS BETTER AND LESS COSTLY IN REHAB OF ELDERLY

**Elderly persons achieve better activity and functional skills, and experience fewer mobility problems, when an interdisciplinary team manages their rehabilitation after hip surgery. Such outcomes can be key in daily living.**

Frail elderly people with multiple health problems seldom receive co-ordinated help following surgery for hip fracture. Different care professionals are brought in when problems appear – but without a basic geriatric assessment of needs and without joint planning, co-ordination, and follow-up of interventions.

SBU's systematic review of all available evidence shows that rehabilitation managed by interdisciplinary teams enables the frail elderly to function and get around better. They become less dependent on daily assistance.

**THESE ELDERLY ARE BETTER** at handling personal care, dressing themselves, managing personal hygiene, and visiting the toilet unassisted. They find it easier to walk on different surfaces, maintain balance, and rise from a sitting position. However, survival or the possibility to live at home after hospital discharge is unaffected.

– We are uncertain why interdisciplinary teams have better outcomes than conventional care, but a conceivable explanation would be that teams reduce the risk of missing something important in evaluation or follow-up, says Sten Anttila, sociologist and project director at SBU.

– Other reasons could be that the chain of care is stronger – and that care staff become jointly engaged in a way that motivates elderly patients to participate more actively in rehabilitation.

Interdisciplinary teams usually include physicians with geriatric or orthopaedic expertise, physiotherapists, occupational therapists, nurses, and counsellors. Dietitians and social workers may also be involved.

– But what distinguishes this approach from other rehabilitation is not as much about what is offered, but how. Inter-

disciplinary teams build on collaboration, co-ordination, and structure.

– This works better for frail elderly people with hip fractures than does conventional care at orthopaedic or geriatric departments, says Sten Anttila.

**EVERYONE IN THE TEAM** works toward a common goal and meets regularly. They jointly develop a fundamental geriatric assessment and an individual care plan that covers the nutrition, pain management, and mobilisation of the patient as soon as possible after surgery. They practice daily activities and exercise muscles. A discharge plan and follow-up are also important aspects.

From an economic perspective, interdisciplinary rehabilitation teams can lead to somewhat higher personnel costs in the short run compared to conventional rehabilitation. Staff education and costs for necessary changes in work organisation can be added. However, the elderly achieve a higher capacity to function physically, and become active and mobile, which can reduce costs for supportive services in the home. In general, interdisciplinary rehabilitation teams following hip surgery should be able to save costs for society. ♦ **RL**

## About the Report

Rehabilitating elderly people with hip fractures – interdisciplinary teams (2015). Project Director SBU: Sten Anttila, [sten.anttila@sbu.se](mailto:sten.anttila@sbu.se). Chair: Prof. Karl-Göran Thorngren, Department of Orthopaedics, Skåne University Hospital, Lund, Sweden.



SCIEPRO / SPL / IBL

## Background

The Swedish National Registry of Hip Fracture (Rikshöft), a national quality registry covering the full continuum of care for hip fracture patients can provide information on conventional rehabilitation in Sweden.

Prior to fracture, 61% can walk unassisted and alone outdoors. Four months following surgery the figure is 40%.

Prior to fracture, 71% live at home. Four months following fracture the figure is 57%.

## SBU'S CONCLUSIONS INTERDISCIPLINARY REHAB

Regarding the use of interdisciplinary teams in rehabilitating elderly people with hip fractures, the conclusions are as follows:

▶ In rehabilitating elderly patients after hip fracture surgery, interdisciplinary teams outperform conventional rehabilitation in improving patient activity, function, and mobility. The evidence is insufficient to identify a specific interdisciplinary programme that is superior to any other.

▶ The potential for living at home following hospital discharge is not influenced when an interdisciplinary team manages rehabilitation. Likewise, survival is not affected.

▶ Scientific evidence is insufficient to determine the effects on instrumental ADL (activities of daily living), quality of life, cognitive function, depression, complications, cost effectiveness, and impact on the family.

# SUICIDE RISK UNCERTAIN IF ASSESSMENT TOOLS IMPROVE PREDICTION

**No instrument to assess suicide risk has yet been proven accurate. The Sad Persons Scale, a method used by several psychiatric departments in Sweden, often misses suicidal tendencies. SBU calls for research on how different assessment instruments can complement clinical evaluation. To date, such studies are lacking.**

SBU experts have examined all available research on 13 instruments addressing the risk of attempted suicide, and 9 instruments addressing the risk of suicide. Such tools are intended to facilitate and improve clinical evaluation.

The results of available research are disappointing – no instruments are shown to reliably predict suicidal tendencies. A good evaluation instrument should be sufficiently sensitive to identify as often as possible whether an individual will attempt suicide or commit suicide.

Further, the instrument should yield

as few “false alarms” as possible – it must be specific. In practice it is difficult to concurrently achieve both high sensitivity and high specificity. So far no assessment instruments have been shown to meet the requirements set by SBU experts, i.e. to identify at least 80% of those who have suicidal tendencies and to give a false alarm in no more than 50% of non-suicidal cases. Evaluation forms having high sensitivity may, however, serve as pedagogical support for clinical education, notes SBU.

Existing studies mainly include young people and adults who have either intentionally harmed themselves, or who suffer from depression or anxiety syndrome. ♦ RL

## About the Report

Instruments for Suicide Risk Assessment (2015).  
Project Director SBU: Jenny Odeberg, [jenny.odeberg@sbu.se](mailto:jenny.odeberg@sbu.se). Chair: Prof. Bo Runeson. The full report with executive summary is available at [www.sbu.se](http://www.sbu.se)

## SBU'S CONCLUSIONS ASSESSMENT INSTRUMENTS

- ▶ None of the included studies provided scientific evidence to support that any instrument had sufficient accuracy to predict future suicide with 80% sensitivity and 50% specificity.
- ▶ There is strong evidence to support that the Sad Persons Scale has very low sensitivity. Most persons who make future suicidal acts are not identified.
- ▶ Research is needed to clarify if assessment of suicide risk is enhanced when an instrument is used as a complement to the global clinical assessment. To date such research is lacking.
- ▶ More research is needed to clarify the reliability of the commonly used instruments SUAS and C-SSRS.
- ▶ As of yet there are no studies that assess whether the suicide item of the Montgomery Åsberg Depression Rating Scale (MADRS) can predict suicidal acts.

MICHAEL BLANN / GETTY





# WORK STRESS LINKED TO HEART DISEASE AND STROKE

**Serious cardiovascular diseases more often afflict those having poor control over their work. The same applies to people in noisy workplaces. SBU reached these conclusions after reviewing thousands of studies, closely evaluating the 150 that were relevant and well executed.**

SBU's review of 30 years of international research identifies a range of conditions in the workplace that relate to cardiovascular disease. The agency commissioned leading experts on the subject to review and compile research findings addressing everything from workplace organisation and psychosocial conditions to physical strain, noise, radiation, and vibration.

They were assigned to study the association between these factors and heart disease, stroke, and high blood pressure.

There is clear evidence of an association. For instance, heart disease appears somewhat more frequently in people who see few opportunities to control their work tasks and work environment – particularly if the environment also involves high psychological demands, i.e. stressful

work. The same applies to those who believe that the rewards do not correspond to their efforts, or when the workplace offers little support.

Heart disease is also slightly more common among those who work night shifts, have long workweeks, and work in noisy environments. Stroke occurs somewhat more often in people who feel that they cannot control their work situation. The same applies to those who work shifts, or are subjected to noise or ionising radiation at work.

**THE SBU REPORT** bases its conclusions on 150 cohort and case-control studies of sufficiently high quality that meet the requirements established in advance by the SBU experts, e.g. concerning study design and number of participants.

The cohort studies followed clearly specified groups for longer periods. Then the investigators compared cardiovascular health in categories of people working under different conditions. Most of the case-control studies, however, were based on participants who already had cardiovascular disease (the

cases). The current and previous work environments of those who were ill were then compared with the work environments of healthy control subjects who were chosen because they were otherwise similar to people in the case group.

**MEN OF WORKING AGE** are more often affected by myocardial infarction and stroke than are women. And research disproves the myth that the cardiovascular system in women in this context is more vulnerable than that of men. Among women and men under the same degree of stress in the workplace, it is untrue – contrary to popular belief – that women have more cardiovascular disease than men.

The report addresses current associations, and SBU writes that future researchers should also test research-based interventions in the workplace and monitor the long-term effects on cardiovascular disease. ♦ **RL**

## About the Report

Occupational Exposures and Cardiovascular Disease (2015). Project Director SBU: Charlotte Hall, charlotte.hall@sbu.se Chair: Prof. Emeritus Töres Theorell.

## SBU'S CONCLUSIONS WORK ENVIRONMENT & CARDIOVASCULAR DISEASE

- ▶ People in the following groups more often develop heart disease over time than people who are not subjected to the specified exposure at work:
  - Those with job strain (i.e. experience psychological demands, but lack control of their own working situation); or those who experience work as mentally stressful; or those who lack control; or those who experience effort-reward imbalance
  - Those who experience low social support at work; those who experience injustice at work; or those who have insufficient opportunities for personal development; or those who experience job insecurity
- Those who work night schedules; or have long working weeks
- Those who are exposed to noise.
- ▶ People in the following groups more often develop stroke over time than people who are not subjected to the specified exposure at work:
  - Those who lack control
  - Those who have shift-work
  - Those who are exposed to noise
- Those who are exposed to ionizing radiation at work. People in the following groups more often develop hypertension over time than people who are not subjected to the specified exposure at work:
  - Those who experience job strain (i.e. find their work demanding, but lack control of their working situation); or those who experience effort-reward imbalance
  - Those who have shift-work.
- ▶ Women and men with similar occupational exposures develop cardiovascular disease to the same extent, in relative terms. During the working years, the risk for men to suffer or die from acute myocardial infarction or stroke approximately doubles that for women.
  - ▶ Cardiovascular disease has serious consequences for affected individuals, their families and society. Prevention has the potential to reduce suffering for the individual and to save resources. This report presents research-based knowledge about occupational exposure and cardiovascular disease that is useful for future interventions in the workplace.

**ONGOING**  
**Some**  
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**SBU Projects**



**ALCOHOL SPECTRUM  
DISORDER (FAS/FASD)  
IN CHILDREN**

Monica.Hultcrantz@sbu.se  
Expected publ:  
Autumn 2016

**DIAGNOSING SHAKEN  
BABY SYNDROME**

Frida.Mowafi@sbu.se  
Expected publ:  
Spring 2016

**PREVENTION OF  
CHILDBIRTH INJURIES  
TO THE PELVIC FLOOR**

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Expected publ:  
Spring 2016

**TREATMENT FOR BINGE  
EATING DISORDER**

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Expected publ:  
Spring 2016

**SURGERY FOR GALL-  
BLADDER SYMPTOMS**

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Spring 2016

**HEALTH PROMOTION  
FOR CHILDREN IN  
FOSTER CARE**

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Expected publ: 2017

**ANTISOCIAL BEHAVIOUR  
IN YOUTH: INSTITUTION-  
AL PROGRAMMES**

Sten.Anttila@sbu.se  
Expected publ:  
Spring 2016

**OCCUPATIONAL CHEMI-  
CAL EXPOSURES & CAR-  
DIOVASCULAR DISEASE**

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Expected publ:  
Autumn 2016

**OCCUPATIONAL EXPO-  
SURES & OSTEOARTHRITIS**

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Expected publ:  
Autumn 2016

**SURGERY FOR ARM  
FRACTURES**

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Expected publ:  
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MEDICAL AND SOCIAL

# Science & Practice

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