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SBU – The Swedish Council on Technology Assessment in Health Care

MEDICAL SCIENCE & PRACTICE

Edvard Koinberg

Adverse Effects

Before accepting new treatment methods as standard care, health services should check the evidence to see if the new methods actually do more good than harm. Often it is more difficult to find evidence of adverse effects than of benefits.

Adverse effects, or side effects, are among the most common reasons for hospitalization of adults.

Often, clinical researchers fail to thoroughly address adverse effects. The benefits of a treatment tend to generate greater interest than the harm it might cause.

A review published in JAMA suggests there are major deficiencies in the research methods used to measure and report on adverse effects.

The review looks at how 192 randomized trials reported on adverse effects in

Against the odds

Faced with poor health and lousy odds, it is all too easy for patients and caregivers to despair. This only adds to the burden of disease.

Once, when I was a young doctor making rounds, our group approached the door of a woman who was seriously ill. She was dying of cancer. My supervisor, the chief physician, hardened after 20 years of emergency duty, told us to pass by the room. "Let's continue", he said, moving the cart past her door, "there's nothing we can do here." "But shouldn't we at least say good morning?", I asked. "Nope. This is pancreatic cancer. You know the prognosis. Let's move on."

I will never forgive myself for going along with him that day. I can only imagine how she must have felt being skipped over. Today, as Scientific Communications Director of SBU, reading and writing about numbers-needed-to-treat and likelihood ratios, this incident reminds me that evidence and hope can – and should – go hand in hand. We could have helped this woman maintain her hope although her prognosis was poor. We should have.

The evidence may tell us that only one patient in 100 survives a condition, but it does not tell us who that patient is. Whenever we fear a risk, we can also find a glimmer of hope. And hope comes in many forms: for cure, for survival, for comfort, for dignity...

Evidence-based medicine challenges us to build decisions on the best available research concerning benefit, harm, and cost, as well as on clinical skills and patients' preferences.

This challenge, although daunting, is nevertheless too narrow. To fully achieve our goals, health care also needs to build trusting caregiver-patient partnerships – to improve collaboration, compliance with treatment, and a sense of control over the situation.

Maintaining hope does not imply that caregivers should keep grim facts to themselves, or make false promises. To the contrary. Truthfulness – like evidence-based patient information – is key in a trusting relationship. Patients cannot participate in decisions about their health unless they have the facts. If there is a 50–50 chance that a treatment will help, patients have a right to know if they want to.

However, when communicating the evidence, we need to remember that every time we toss a coin, optimists and pessimists have the same odds. Only optimists don't give up. No matter how grim, evidence usually leaves room for some hope.

RAGNAR LEVI, EDITOR

Hugo Samuelsson/Briljans

"Costs in Sweden have been estimated at half a billion SEK"

seven areas: HIV treatment, antibiotic treatment of acute sinusitis, thrombolytic treatment in acute myocardial infarction, NSAIDs for rheumatoid arthritis, treatment of hypertension in the elderly, antibiotic treatment of *helicobacter pylori*, and selective decontamination of the gastrointestinal tract.

DEPLORABLE

According to the review, half of the studies provided inadequate reports on adverse effects. Approximately 10% provided somewhat adequate reports.

– Deplorable, but unfortunately not too surprising, comments Professor Björn Beermann, member of the SBU Scientific Advisory Committee and Director of the Department of Drug Information at the Swedish Medical Products Agency.

– Researchers and the industries that fund many of the studies are usually more interested in describing the desired rather than the undesired outcomes.

Yet, adverse treatment effects are shown to be the main or contributing reason for admission in 2% to 12% of the cases at departments of medicine, geriatrics, and infectious disease.

– Suffering is substantial, and costs in Sweden alone have been estimated at half a billion SEK annually, says Björn Beermann.

– Regarding pharmaceuticals, many events could be avoided through better selection of drugs and drug combinations, more accurate dosage, and better followup and control.

Insufficient research on adverse effects constitutes another problem. For instance, when clinicians start using a new drug, some of its effects are usually unknown.

Prior to approval, new drugs obviously must undergo phase I-III clinical trials. But these studies reveal only part of the truth.

NOT DETECTED

For example, rare side effects are not detected, not even the most dramatic ones. The reason is statistics-related.

– Undesirable effects are

DIFFERENCES IN STUDIES ON ADVERSE EFFECTS

DESIGN	STARTING POINT	OUTCOME	STRENGTHS	WEAKNESSES
randomized, controlled trial	exposure status	adverse event status	internal validity	feasibility, generalizability
cohort study	exposure status	adverse event status	feasible when randomization of exposure not possible	susceptible to threats to internal validity
case control study	adverse event status	exposure status	overcomes temporal delays, may only require small sample size	susceptible to threats to internal validity

Source: Levine M, et al. How to use an article about harm. JAMA 1994;271:1615-1619. See also www.cche.net/usersguides/harm.asp

usually much less common than desired effects so we need larger studies to point them out, explains Björn Beermann.

The studies in trial programs usually include 500 to 5 000 patients.

– This means that side effects which appear in less than 1 per 100 or less than 1 per 1 000 are not discovered before use of the drug becomes widespread.

Since these trials seldom last more than 1 or 2 months, adverse effects that appear only after a longer period are not captured.

– Furthermore, these trials involve mainly adults. Children and the elderly are seldom included.

REMAIN UNKNOWN

The effects on these groups therefore remain unknown until the drug has been in routine use for some time.

Adverse effects should be reported by caregivers to the drug authorities, but this information is often incomplete. Not all cases are detected and reported.

– Rare and unexpected side effects present a particular problem. A great deal of imaginative thinking is needed just to link such symptoms to a particular treatment.

After having collected scattered reports on suspected side effects, further studies must be undertaken.

These often involve observational studies, eg, cohort studies and case control studies, to investigate whether the symptoms are associated with treatment or with something else.

RELIABLE INFORMATION

Professor Paul Hjemdahl, Clinical Pharmacologist at the Karolinska University Hospital in Solna has been involved in the SBU project on hypertension treatment.

– As regards common side effects, the large, controlled treatment studies involving placebo give the most reliable information, but these studies seldom focus on side effects, he says.

– It is common to use several drugs concurrently to treat hypertension, so it may be quite difficult to identify which one causes a particular side effect.

AFFECT THE RESULTS

Another common problem with studies on adverse effects is that you get the answers you ask for – the methods used to measure side effects affect the results, says Paul Hjemdahl.

– Since different researchers use different methods of measurement, it is difficult to compile the results to see how common a particular side effect actually is.

He contends that there should be standard research tools for adverse effects, for instance, a questionnaire with variations – not a patchwork of measurement methods as is the case today.

ROUGH INDICATION

– At the same time, we must remember that statistics on the rates of side effects do not say anything about their severity. The number of trial participants who discontinued the treatment may, however, give you a rough indication.

According to the JAMA review, the percentage of discontinued treatments may be an important piece of the puzzle when assessing the significance of adverse treatment effects.

Ragnar Levi

– We find a lot of preconceived notions about the adverse effects of treating hypertension, influencing our choice of drugs in a manner which is not always good, says Professor Paul Hjemdahl.

Additional Reading

Ioannidis JP, Lau J. Completeness of safety reporting in randomized trials. An evaluation of 7 medical areas. JAMA 2001; 285: 437-443.

NEWREPORT

Dana Edmunds/Taxi

OBESITY

Society Can Curb Obesity Epidemic

The growing problem of obesity can be controlled, but not easily. This is one conclusion drawn from an extensive review of scientific research on preventive interventions. A new SBU report paints a brighter picture than expected about the potential to prevent obesity.

Obesity, once present, is difficult to treat. Hence, effective methods of prevention are all the more important. SBU established this in its first review of obesity in 2002.

Since then, new and important studies have been published on the subject. In a recent review of all scientific research, SBU has found sound evidence that intervention programs in schools and day care centers can reduce weight gain and the development of obesity in children and adolescents.

By encouraging better eating and drinking patterns and more physical activity, society has the potential to control the obesity epidemic, according to the SBU report.

Programs including multiple interventions were often used in the investigations that, in many instances, continued for several years or even longer. Since interventions were combined it is difficult to isolate the specific ones responsible for the best results.

POSSIBILITIES

Although the new report points to the possibilities, it also found that two thirds of the studies on young people failed to show a positive effect on weight. According to the report, this may be due to the difficulty of influencing the lifestyle of children and adolescents through school-based interventions alone. The community at large, and home and leisure-time environments also need to be engaged.

Obesity can be prevented also in healthy, normal-weight adults. Programs that include counseling on low-energy, low-fat, high-fiber diets, greater physical activity, and reduced alcohol consumption have shown positive results in nearly half of the studies. Involvement of adults in actively addressing obesity also has a major impact on their children.

IMPORTANT ROLE

The new SBU report is expected to play an important role in Sweden's strategy for managing obesity. It constitutes one of the cornerstones in the Swedish Government's national action plan for good dietary habits and greater physical activity.

The report Preventing Obesity – A Systematic Review (2005) can be ordered or downloaded free of charge at www.sbu.se.

SBU'S CONCLUSIONS ON OBESITY PREVENTION

Children and Adolescents

▶ In total, there are now 24 studies involving nearly 26 000 participants. Adding the studies found in other systematic literature reviews, but not included in the SBU review, brings the total to 37 studies involving 34 000 participants. From Sweden, only preliminary data are available from an ongoing trial.

▶ The consequences of relatively limited interventions lasting one or more years have been studied. Interventions have been based on programs in schools, day care centers, and other settings to increase physical activity and develop good dietary habits. Usually, a full package of interventions has been used. Based on the study descriptions alone, it is not possible to identify the interventions that have the greatest potential for favorable effects.

▶ Based on the studies in the SBU literature review, the evidence shows that school-based interventions can reduce weight gain and the development of obesity in children and adolescents (Evidence Grade 1). Studies from literature reviews performed in other countries further support this conclusion.

▶ The fact that two thirds of the studies fail to demonstrate a positive effect may reflect the difficulty of achieving lifestyle changes in children and adolescents with school-based interventions alone that do not include the home environment, free time, and the community at large.

▶ Studies have not investigated the extent to which programs that are more long-term and comprehensive (eg, many types of interventions in the community) could be more effective. The extensive changes in society do not facilitate the use of control groups. Effects must be monitored through a reliable registry of weight trends in the population, not least trends among children and adolescents.

Adults

▶ The SBU report now includes 31 studies involving nearly 64 000 participants.

▶ Interventions to improve lifestyle have included counseling on diets that are low in energy and fat and high in fiber. As a rule, recommendations to increase physical activity have been included, and several studies recommend smoking cessation and lower consumption of alcohol.

▶ The previous report presented 11 comprehensive, population-based studies, mainly dominated by North American studies. Recently, another 5 studies have been added. Of these, 2 are Norwegian and one is a Swedish study implemented in smaller regions, but with a longer time frame (5 to 6 years). Favorable weight trends were achieved in half of these studies, which was a better result than earlier reported. The findings give reason for greater optimism concerning the potential to prevent obesity in the adult population. Involving adults is also important considering their influence on the next generation.

▶ Special groups that are now being studied in normal populations include, eg, employees in companies or individuals in age groups at risk. Most of the studies show that weight gain can be prevented in these groups (Evidence Grade 3).

▶ Interventions have had a positive effect on mean BMI in most of the studies aimed at individuals with an elevated risk for cardiovascular disease.

▶ Based on all of the studies involving adults, obesity can be prevented by interventions that improve diet and physical activity (Evidence Grade 2).

▶ The lack of effects in nearly half of the studies may be explained by the difficulty in achieving lifestyle changes, that the interventions have been too limited or they were limited to recommendations focusing only on increased physical activity.

The update on "Obesity Treatment and Prevention" can be found at www.sbu.se

HYPERTENSION

Pressure Still Too High

Three out of four Swedish patients on antihypertensive drugs do not reach their target blood pressure. SBU's systematic review of blood pressure treatment presents this and other findings.

Blood pressure should be lowered further in many patients receiving treatment for hypertension. Also, Swedish health services can do more for those with hypertension and multiple risk factors for cardiovascular disease.

These are key messages from a new SBU report on moderate hypertension. Assisted by a panel of experts, SBU has reviewed and evaluated research published in the field.

Only 20% to 30% of those on medication for hypertension actually reach a blood pressure level low enough to reduce health risks.

CARRIES RISK

– That percentage is much too low, says Lars Hjalmar Lindholm, Professor of Family Medicine at Umeå University and Chair of the SBU Project Group on Moderately Elevated Blood Pressure.

– Long-term, high blood pressure carries certain risks, and effectively reducing it can prevent serious complications.

Solid scientific evidence shows that treatment offers protection from stroke, myocardial infarction, and premature death in men and women with hypertension.

The higher the pressure, the greater the risk for complications. Risks in hypertensive patients are even greater if they are older or smokers, or if they have other risk factors, eg, abdominal obesity or high cholesterol. Even greater risks face people who have cardiovascular disease or diabetes along with high blood pressure.

Achieving a healthier lifestyle is fundamental for treating hypertension. Often, this involves helping people to stop smoking, exercise more, lose weight, modify their diet, manage stress, and drink less alcohol. These measures can improve blood pressure and the health risk profile and even reduce the need for medication.

But in many cases, lifestyle modifications are insufficient, and medication becomes necessary.

Blood Pressure mm Hg

			Hypertension		
	Normal	High normal	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)
Other risk factors and diseases	SBP 120–129 or DBP 80–84	SBP 130–139 or DBP 85–89	SBP 140–159 or DBP 90–99	SBP 160–179 or DBP 100–109	SBP >=180 or DBP >=110
No other risk factors	Low risk	Low risk	Low risk	Moderate risk	High risk
One or two risk factors	Low risk	Low risk	Moderate risk	Moderate risk	Very high risk
Three or more risk factors, organ damage, or diabetes	Moderate risk	High risk	High risk	High risk	Very high risk
Established cardiovascular disease	High risk	Very high risk	Very high risk	Very high risk	Very high risk

SBP = Systolic blood pressure.

DBP = Diastolic blood pressure.

Risk: 10-year risk for fatal/non-fatal stroke or myocardial infarction: Low <15%, Moderate 15%–20%, High 20%–30%, Very High >30%.

Risk factors: High age, smoking, genetic predisposition for cardiovascular disease, abdominal obesity, elevated cholesterol, elevated CRP.

Organ damage: Left ventricular hypertrophy, proteinuria, elevated creatinine, atherosclerotic plaque.

Established cardiovascular disease: myocardial infarction, angina pectoris, coronary artery intervention, heart failure, impaired kidney function, stroke/TIA, and peripheral vascular disease.

Thomas Carlgren/Megapix

Comparisons of various types of drugs for patients with hypertension, but few other risk factors, have not revealed any major differences in treatment benefits, according to the report.

Nina Rehnqvist, Executive Director of SBU and Professor of Cardiology, emphasizes that antihypertensive treatment could be much more cost effective.

EXPENSIVE DRUGS

– Health care needs to economize its resources, and a major problem is the continuously declining percentage of patients being treated with the least expensive, but therapeutically equivalent, drugs. Increasingly, more patients are receiving drugs that often are 10 times more expensive, eg, angiotensin receptor blockers.

– Nevertheless, it is good that we have several treatment options – patients respond differently to the same interventions and it may be necessary to try different combinations before achieving a sufficient drop in pressure.

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Price differences among equivalent therapies are of major importance since antihypertensive treatment is so common.

An estimated 1.8 million adults in Sweden have a systolic pressure of at least 140 mm Hg, or a diastolic pressure of at least 90 mm Hg. About 80% are estimated to run at least a moderately high risk for cardiovascular disease, which, according to current guidelines, motivates antihypertensive treatment.

SBU's Deputy Director, Helena Dahlgren, the Hypertension Project Manager, comments:

– If the guidelines were followed, treatment would be offered to a half million people in Sweden who presently go untreated.

Treating more people and using more medication per person would obviously increase drug costs. According to the report, more value would be gained from the money spent if physicians prescribed the least costly equivalent drug.

GREATER BENEFITS

– We also show that resources will yield greater benefits if we improve treatment for patients at high or moderate risk than if we start treating more people at low risk, says Helena Dahlgren.

For many of those receiving antihypertensive drugs, treatment is not adequately effective. The report shows that only a minority of the patients treated reached blood pressure below 140/90 mm Hg, the target commonly used in various guidelines.

CHANGE OR ADD

One reason may be that patients do not comply with their prescriptions. Also, according to the report, it often becomes necessary to change or add medications to reduce blood pressure sufficiently.

In patients with diabetes or kidney disease, the goal is pressure below 130/80 mm Hg. In these patients, as in coronary heart disease and stroke patients, achieving the target blood pressure is particularly important.

The new report also highlights important knowledge gaps. For example, more studies are needed to assess the effects of lifestyle interventions – the foundation of all antihypertensive treatment.

IN A NUTSHELL
BLOOD PRESSURE

- Hypertension is defined as 140/90 mm Hg or higher, measured on several occasions.
- The patient's overall risk for cardiovascular disease, eg, considering blood pressure, blood lipids, blood sugar, smoking, and genetic predisposition, should determine when to begin antihypertensive treatment.
- Lifestyle interventions constitute the foundation of all antihypertensive treatment – smoking cessation, increased physical activity, weight loss, dietary changes, stress management, and reduction of high alcohol intake.
- Only one in four patients on antihypertensive drugs reaches the goal, ie, pressure below 140/90 mm Hg (and below 130/80 in patients with diabetes or renal disease).
- It is important to reach the treatment target, especially in people at high risk for cardiovascular disease, eg, those with diabetes, renal disease, coronary heart disease, or previous stroke. Often, several medications are needed concurrently.
- No major differences have been found in the clinical benefits of different classes of drugs among hypertensive patients with few other risk factors. Prices, however, differ substantially.
- Low or moderate doses of one or more drugs are usually effective and have few or no side effects. Caution in the choice of drugs is necessary in some patients with other concurrent treatment or health problems.
- Using the least expensive, but therapeutically equivalent, drug to treat hypertension in patients with few other risk factors saves costs in older women and middle-aged and older men.

The report Moderately Elevated Blood Pressure (2004) can be downloaded free of charge or ordered at www.sbu.se.

SBU'S CONCLUSIONS ON HYPERTENSION

Prevalence of High Blood Pressure

▶ An estimated 1.8 million people in Sweden, or 27% of the adult population (aged 20 or older), have high blood pressure (hypertension). The condition is just as common among women as men.

▶ Of the 1.8 million Swedish adults with elevated blood pressure, 60% have mild hypertension (140–159/90–99 mm Hg), 30% have moderate hypertension (160–179/100–109 mm Hg), and 10% have severe hypertension (180/110 mm Hg)

▶ Studies in Sweden find that the number of patients who reach the treatment goal of blood pressure below 140/90 mm Hg rarely exceeds 20 to 30% of those who have been prescribed blood pressure lowering drugs.

Risk Factor for Cardiovascular Disease

▶ Elevated blood pressure is a risk factor for coronary heart disease, stroke, and other cardiovascular disease, including heart failure (Evidence Grade 1). High blood pressure is also a risk factor for dementia (Evidence Grade 3).

▶ An increase of 20 mm Hg in systolic pressure or 10 mm Hg in diastolic pressure above 115/75 mm Hg doubles the risk of death from cardiovascular disease (Evidence Grade 1). The increase is independent of other risk factors for cardiovascular disease, and it is similar for women and men (Evidence Grade 1).

▶ Women have a lower absolute risk of cardiovascular disease than men (Evidence Grade 1). However, blood pressure lowering treatment reduces relative risk equally in women and men (Evidence Grade 1).

Guidelines in Different Countries

▶ The guidelines released in various countries over the past few years for the management of hypertension are largely in agreement. The guidelines are basically the same for women and men. All guidelines:

- stress the importance of reaching the treatment goal of blood pressure below 140/90 mm Hg – below 130/80 mm Hg for patients with diabetes and/or renal disease.
- emphasize the need to consider the patient's total risk of cardiovascular disease rather than treating high blood pressure in isolation.
- recommend a low-dose thiazide diuretic as the first-line therapy or as one of several first-line therapies.

Lifestyle Changes as the Basis for Successful Treatment

▶ With or without concurrently lowering blood pressure, a number of lifestyle changes – including physical activity, weight loss, dietary modifications, stress management, smoking cessation and the avoidance of excessive alcohol consumption – can minimize the risk factors for cardiovascular disease (Evidence Grade 1).

▶ Lifestyle measures can reduce the need for drug therapy and should form the basis for treating people with high blood pressure (hypertensives) (Evidence Grade 1). Smoking cessation measures should also be a priority for hypertensives and can generate major treatment benefits (Evidence Grade 1).

Drug Therapy

▶ Blood pressure lowering treatment reduces the risk of stroke, myocardial infarction, and premature death in hypertensives of both sexes (Evidence Grade 1).

▶ The various groups of blood pressure lowering drugs – thiazide diuretics, angiotensin converting enzyme (ACE) inhibitors, calcium antagonists, angiotensin receptor blockers (ARBs), and beta blockers – ordinarily used in Sweden are equally effective (reduction of approximately 10/5 mm Hg) when administered separately (Evidence Grade 1).

▶ Since the efficacy of different types of drugs can vary for a particular individual, switching to or adding one or more medications may be required in order to lower blood pressure sufficiently.

▶ For people with uncomplicated hypertension, all the major drug groups – thiazide diuretics, ACE inhibitors, calcium antagonists, ARBs and beta blockers – are equally effective in minimizing the risk of cardiovascular disease (Evidence Grade 1).*

▶ Following stroke, blood pressure lowering drugs reduce the risk of myocardial infarction (Evidence Grade 3) and stroke recurrence (Evidence Grade 1). Treatment is equally effective with or without concurrent hypertension.

▶ At least half of all patients with type 2 diabetes also have hypertension. The effect of hypertension treatment on the absolute risk of cardiovascular disease morbidity and mortality is greater with concurrent diabetes (Evidence Grade 1). In people with type 2 diabetes, the impact on relative risk is also greater (Evidence Grade 1).

▶ Patients whose treatment is based on drugs (ACE inhibitors and ARBs) that directly affect the renin-angiotensin-aldosterone system are less likely to develop type 2 diabetes than those whose treatment is based on a thiazide diuretic combined with a beta blocker or on a calcium antagonist (Evidence Grade 2).

▶ In patients with high risk (multiple risk factors) of cardiovascular disease and concurrent type 2 diabetes, drugs that block the renin-angiotensin-aldosterone system can reduce the risk beyond the impact of simply lowering blood pressure (ACE inhibitors – Evidence Grade 2, ARBs – Evidence Grade 3).

▶ Blood pressure lowering treatment counteracts clinically relevant deterioration of renal function (Evidence Grade 1). No difference with regard to the long-term effect on renal function has been shown among the various groups of blood pressure lowering drugs in patients who have mild to moderate hypertension without other concurrent kidney complications. This report did not review treatment of patients with diabetes and impaired renal function.

▶ Hypertension leads to thickening of the heart muscle. Blood pressure lowering treatment reduces left ventricular mass (Evidence Grade 1). The reduction is associated with a lower risk of cardiovascular disease (Evidence Grade 2).

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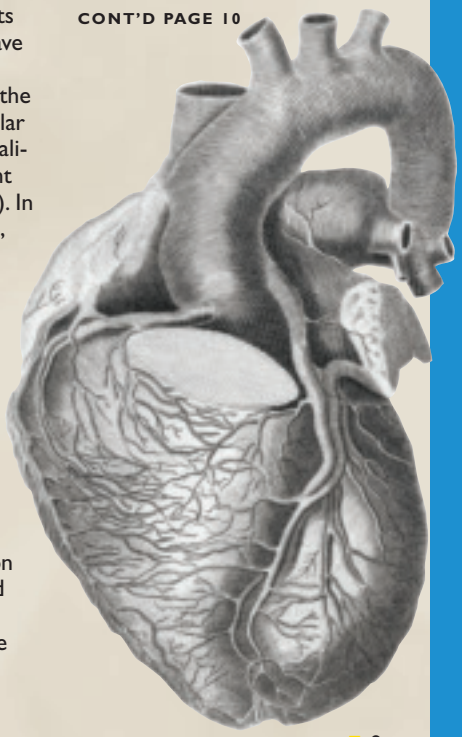

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Economic Aspects

▶ Sales of blood pressure lowering drugs for the indication of hypertension more than doubled from 70 defined daily doses (DDSs) per 1 000 Swedes in 1992 to 155 in 2002. Costs for drug treatment of hypertension totaled SEK 1 656 million in 2002.

▶ Since satisfactory treatment of everyone with hypertension would involve both a larger number of patients and more medications per person, total drug costs would rise (Evidence Grade 2).

▶ Choice of medication has a major impact on both drug costs and cost effectiveness. Prescribing the least expensive equivalent medication whenever possible would reduce drug costs and improve cost effectiveness compared with current prescription patterns (Evidence Grade 2).

▶ Treatment of uncomplicated hypertension with the least expensive equivalent drug entails cost savings for older women, as well as middle-aged and older men. Improving the treatment of patients with moderate to high risk is more cost effective than treating more people with low risk (Evidence Grade 2).

Ethical Aspects

▶ The ethical dilemma of treating an apparently healthy person with drugs for what is likely to be a long period of time should be weighed against the risks associated with withholding treatment that may prevent serious disease.

From Moderately Elevated Blood Pressure (2004), SBU Report No. 164.

Evidence Grade 1: Strong scientific evidence
Evidence Grade 2: Moderately strong scientific evidence
Evidence Grade 3: Limited scientific evidence
Evidence Grade 4: Insufficient scientific evidence

* Regarding atenolol, see Lancet 2004;364: 1684-1689.

Evidence Protects Patients' Teeth

Dentistry must improve its definitions of good versus poor practices, contends Professor Per-Olof Glantz.

– Clearly we can prevent a great deal of unnecessary distress by collectively becoming better at following up treatment results instead of unsystematically testing new methods on patients.

So says Per-Olof Glantz, Professor in Prosthetics at Malmö University, and a strong advocate of evidence based dentistry.

– Consciously and systematically applying the best scientific evidence – allowing the evidence to show the way – is extremely important. In fact, this is only logical considering healthcare's guiding stars – scientific fact, professional skill, and patients' health.

DIVERGENT VIEWS

The role of science in dental care is still too weak, suggests Per-Olof Glantz. Practice varies and dentists have divergent views on what constitutes the best treatment.

– Dentists have always had a tendency to try out new treatment methods on their own, he says, and gives the example of toothlessness. During the 1940s and 1950s, a type of implant was used unsuccessfully. The implant was not adequately anchored in the bone and hence was not stable from the start.

After a few years the bone began to be resorbed, and the implant became increasingly unstable, allowing bacteria from the mouth to enter and spread quickly beneath the entire implant.

PAINFUL

– This was extremely painful for the patients. Nevertheless, it took more than a decade and a lot of unnecessary suffering before we could get rid of this treatment method – some dentists stubbornly persisted in using it.

– Earlier, many dentists worked alone and seldom interacted with colleagues. Now, more dentists sense the need to discuss their routines

with colleagues and examine the scientific evidence. Obviously, acquiring more knowledge is one way to improve.

Historically, however, opinion has ruled over science.

– The use of plastic fillings disseminated rapidly before they had been fully assessed. No one knew, for instance, that this material could cause contact eczema in the staff that worked with it, says Per-Olof Glantz.

At times, the debate about what type of dental care is best for patients has been just as heated as that in other areas of health care, he says.

– For example, look at the amalgam wars that began already in the 1800s. For at least four decades dentists carried on an internal battle as to whether or not amalgam was dangerous.

APPRENTICESHIP

Per-Olof Glantz equates dental care with surgery – in both, apprentices have acquired their skills by learning from older colleagues and have built on their experiences, he says. Usually, the focus was on technical skills.

The problem is that technical aspects and craftsmanship are so complex that patient benefit often is at risk of being forgotten.

– The dentists who focus only on techniques and craftsmanship comprehend only half of their profession. Dentistry is much more than skillful interventions! Although technical skills are demanding, we must also put effort into systematic followup.

– Many believe, for instance, that once a replacement tooth is in place and the dental work is finished, then the patient has been treated fully. But that's when the actual treatment begins!

– It's then we need to follow up and watch what happens, to see if the patient experiences any complications or side effects.

NARROW VIEW

The funding bodies in society that pay for dental care often have a narrow perspective. Often, they view dentistry as some kind of repair kit, asserts Per-Olof Glantz.

– The patient-focused perspective of evidence based care is needed. And I believe there is hardly any field better suited for an evidence based approach than dentistry. Dental interventions are easy to define and the results are relatively easy to observe.

– We already have the terms needed to describe those interventions and to define which results are acceptable and which are not.

– Quality assessment and checking our work against the evidence can become a routine process, without a great deal of extra effort.

Professor Per-Olof Glantz

Adam Haglund

Additional Reading on Evidence Based Dentistry

Introductory Articles & Journals

International Articles

Antczak AA, et al. Quality assessment of randomized control trials in dental research. I. Methods, and II. Results. J Periodontal Res 1986;21:305–14 and 315–21.
Antczak-Bouckoms A. Quality and effectiveness issues related to oral health. Med Care 1995;33:NS 123–42. (suppl)
Antczak-Bouckoms A. The International Cochrane Collaboration Oral Health Group making the results of controlled trials properly accessible. J Dent Educ. 1994;58:820–1.
Bader J, et al. Evidence-based dentistry and the dental research community. J Dent Res 1999;78:1480–3.
Niederman R, et al. Tradition-based dental care and evidence-based dental care. J Dent Res 1999;78:1288–91.

Series of articles in J Can Dent Assoc

Sutherland SE, et al. Evidence-based Dentistry: Part I–VI.
http://www.cda-adc.ca/jcda/vol-67/issue-4/204.html
http://www.cda-adc.ca/jcda/vol-67/issue-5/277.html
http://www.cda-adc.ca/jcda/vol-67/issue-6/320.html
http://www.cda-adc.ca/jcda/vol-67/issue-7/375.html
http://www.cda-adc.ca/jcda/vol-67/issue-8/442.html
http://www.cda-adc.ca/jcda/vol-67/issue-10/582.html

Specialty Journals

The Journal of Evidence-based Dental Practice
http://www2.us.elsevierhealth.com/scripts/om.dll/serve?action=searchDB&searchDBFor=home&id=ed

Evidence-based Dentistry
First issues: http://www.ihs.ox.ac.uk/cebd/ebdsupp.htm
and later: http://www.nature.com/ebd/

Courses & Books

University of Oxford

http://www.conted.ox.ac.uk/cpd/healthsciences/courses/short_courses/Evidence_Based_dentistry/default.asp

Introductory Textbook

Clarkson J, et al. Evidence Based Dentistry for Effective Practice. London: Martin Dunitz, 2003.

Organizations

Cochrane Collaboration & Oral Health Group
http://www.cochrane.org
http://www.cochrane.org/cochrane/revabstr/g080index.htm
Centre for Evidence-Based Dentistry, Oxford
http://www.ihs.ox.ac.uk/cebd/
International Centre for Evidence-Based Periodontal Health
http://www.eastman.ucl.ac.uk/~pdarkins/iceph/nfindex.html
Americal Dental Association
http://www.ada.org/prof/resources/positions/statements/evidencebased.asp
The International Society of Evidence-Based Dentistry
http://www.ihs.ox.ac.uk/cebd/isebd.htm

NEWREPORT

Anders Norderman

TOOTH LOSS

Antibiotics and X-rays Often Unnecessary in Periodontitis

Antibiotics, as used today, are ineffective in treating chronic periodontitis. Radiographs are not needed for regular dental check-ups unless the gums have been examined. X-ray exams are unnecessary unless the gums bleed easily, or the gum crevice has deepened, according to a new SBU report.

Gingivitis, inflammation of the gums, is common, although often reversible and harmless. But gingivitis may precede chronic periodontitis – progressive loss of tooth-supporting tissue.

Although severe forms of periodontitis affect between 7% and 20% of all adults, scientific evidence in this field is incomplete. SBU's systematic review of relevant research – 450 scientific articles, each appraised by at least two reviewers – shows there is still uncertainty about the best way to prevent periodontitis and tooth loss.

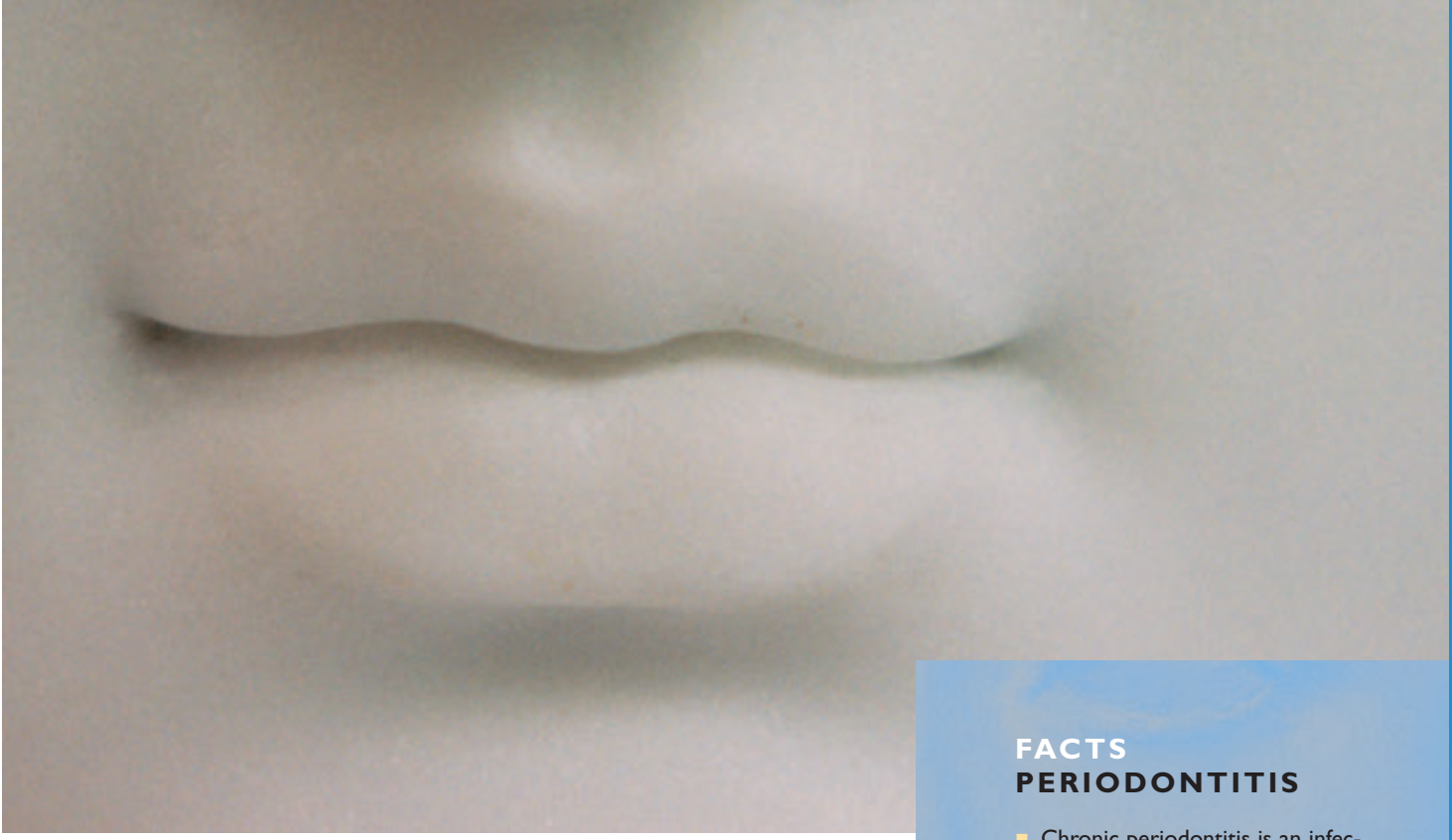
GUMS BEGIN TO BLEED

When checking for periodontitis, the dentist visually examines the teeth by inserting a probe into the gum pocket to see if it bleeds. The dentist also measures the pocket depth around each tooth and often orders radiographs.

– But neither repeated radiographs nor measuring the depth of the gum pockets are reliable ways to diagnose minor changes around the teeth, says Madeleine Rohlin, Professor at the Faculty of Odontology, Malmö University, and Chair of the SBU Project Group.

IN A NUTSHELL PERIODONTITIS

- Gingivitis may be a precursor to periodontitis – but not always. Although gingivitis can be prevented, current studies provide insufficient evidence on how to prevent periodontitis and tooth loss. Rigorous scientific studies are needed.
- Electric toothbrushing is more effective than manual brushing at reducing gingivitis. Repeated training, given by professionals, increases knowledge about oral hygiene. However, it is not certain that these measures influence long-term behavior.
- Chronic periodontitis is a clinical diagnosis confirmed by the loss of supportive tissue along with bleeding during periodontal probing. If probing does not cause bleeding, the risk for periodontitis is small.
- Clinical signs of periodontitis can motivate x-ray examination. However, routine x-ray exams are not justified in the absence of such signs.
- In separate bony pockets, adjuvant treatment using reconstructive methods, eg, enamel matrix-derived protein, improves tooth attachment.
- Adjuvant antibiotic treatment is not shown to be superior to nonsurgical infection control alone. Local antibiotic treatment using metronidazole gel provides no additional benefits. Scientific evidence on other local antibiotics is insufficient. The addition of systematic antibiotic treatment is not superior to using mechanical instrumentation alone.
- The extent to which chronic periodontitis increases the risk for general medical disorders, eg, cardiovascular disease, is scientifically unconfirmed.
- Studies are lacking on the cost effectiveness of different treatments and diagnostic strategies for chronic periodontitis.



– Checking whether or not the gums bleed is, however, a good method. If gums that had bled previously no longer do, it's a good sign that things are moving in the right direction. Gums that continue to bleed probably motivate further probing and x-rays.

The aim in treating chronic periodontitis is to prevent further tissue loss and save teeth. Dental treatment involves removing the dental biofilm from the gum pockets and root surfaces. Antibiotics, either local or oral, are sometimes used.

– Giving antibiotics for chronic periodontitis is not shown to be beneficial, whether applied locally in the gum pockets or generally, says Madeleine Rohlin.

MORE EFFECTIVE

Bacterial deposits and inflamed tissue can be removed in different ways. The first type of treatment is nonsurgical. It involves scaling or root planing, where instruments are inserted directly into the gum pocket. The second approach is surgical, for example, cutting away a "flap" to temporarily move back part of the gingiva around the tooth.

– In deep gum pockets, flap surgery is somewhat more effective. Also, scientific evidence shows that tooth attachment can be improved if we also use biologically active substances or membranes, says Madeleine Rohlin.

We also know that treatment results are not as good in smokers as in nonsmokers.

– One more reason for dental clinicians to encourage patients to stop smoking, says Susanna Axelsson, dentist and Project Director at SBU.

EVIDENCE GAPS

The SBU report looks not only at the evidence, but also at gaps in the evidence. One of the most important questions concerning periodontitis – how to prevent tooth loss – remains unanswered.

– Scientific studies on the

FACTS PERIODONTITIS

- Chronic periodontitis is an infection that leads to inflammation in the tissues that attach the teeth to the jawbone, loss of bone and connective tissue, and deep pockets in the gums. Late in the course of the disease the teeth become partially or completely loose.
- People who have lost supporting tissue and also bleed when the gum pockets are probed have periodontitis. A few teeth, or many, may be involved.
- The process is usually gradual. Periodontitis is classified as severe when the gum pocket depth is 5 mm or deeper, and as moderate at 3-4 mm depth. People with periodontitis always have gingivitis, inflammation in the gums. But gingivitis also occurs without tissue damage.
- Chronic periodontitis with mild tissue loss occurs in up to 40% of adults. More extensive tissue loss affects between 7% and 20%.
- Total tooth loss is socially debilitating and influences dietary habits, affecting a person's quality of life.
- Tissue loss caused by chronic periodontitis is often permanent. Treatment is aimed at slowing tissue loss and reducing the amount of bacteria in the gum pockets to prevent further harm to the tissues.
- The most common method for cleaning the gum pockets and root surfaces involves using various instruments – manual or automated.

CONT'D FROM PAGE 13

benefits of preventive methods have focused on the effects of gingivitis, not on tooth loss. Consequently, we don't have a reliable answer to this question, explains Susanna Axelsson.

Methods for treating both periodontitis and gingivitis aim at reducing the bacterial deposits on the teeth and in the gum pockets.

Some findings indicate that electric toothbrushing is superior to manual brushing in treating inflamed gums.

Triclosan and stannous fluoride are additives in fluoride toothpaste that reduce gingivitis.

– But the use of these additives is not without controversy, emphasizes Susanna Axelsson.

TOXIC FOR ALGAE

– Toothpaste with stannous fluoride can miscolor the teeth and triclosan is classified as an environmentally hazardous substance. It's toxic for organisms that live in water, particularly algae.

New research also suggests a connection between triclosan and antibiotic resistance. The SBU report emphasizes how important it is to weigh the expected benefits of triclosan additives in fluoride toothpaste against the environmental risks and the risk of developing antibiotic resistance.

There has been concern in recent years that chronic periodontitis may exacerbate other diseases. Again, there is no definitive evidence, according to SBU.

The same applies to potential risks for premature childbirth, or low birth weights. Current research findings are conflicting and incomplete.

The report Chronic Periodontitis (2004) can be ordered or downloaded free of charge at www.sbu.se.

– Periodontitis research points to new opportunities to help patients even more, says Susanna Axelsson, DDS and Project Manager at SBU.

Elin Kullerstrand

Preventing Gingivitis

- A powered toothbrush is more effective than a manual toothbrush for reducing gingivitis (Evidence Grade 3).
- Toothpaste containing stannous fluoride, amine fluoride/stannous fluoride, chlorhexidine, or triclosan/copolymer are more effective than conventional fluoridated toothpaste for reducing gingivitis (Evidence Grade 3).
- Mouth-rinsing with a chlorhexidine solution (0.12%–0.2 %) or essential oils as an adjunct to tooth brushing is more effective than tooth brushing alone for reducing gingivitis (Evidence Grade 3).
- Repeated instructions by dental professionals lead to increased knowledge about oral hygiene (Evidence Grade 3). The findings are contradictory as to whether increased knowledge and desired behavioral changes lead to reduction of gingivitis.

Diagnosing Chronic Periodontitis

- Bleeding following probing of the periodontal pocket is a sign of inflammation in the periodontal tissues (Evidence Grade 2).
- Probing pocket depth overestimates the actual depth when periodontitis is present and underestimates it when the periodontal tissues are healthy (Evidence Grade 2).
- The use of electronic pressure-sensitive probes does not improve the reproducibility of periodontal pocket measurements compared to that of manual probing (Evidence Grade 3).

SBU'S CONCLUSIONS ON PERIODONTITIS

▶ Radiographic measurements underestimate alveolar bone loss. The degree of underestimation depends on the extent of bone loss and its location in the dental arch (Evidence Grade 3).

▶ The accuracy of assessing alveolar bone loss from direct digital radiography is comparable to that obtained from film radiography (Evidence Grade 3).

▶ The number of periapical* radiographs can be considerably reduced when a clinical examination, along with bitewing** radiographs of the posterior teeth or a panoramic radiograph precedes a full-mouth radiographic examination (Evidence Grade 3).

▶ The accuracy of bitewing and periapical radiography is low for estimating small alveolar bone changes (< 1 mm) over time (Evidence Grade 3). Thus, performing radiographic examinations at regular intervals for the purpose of assessing changes of the periodontal support over time is not justified.

Predicting Disease Progression

▶ The absence of "bleeding on probing" is a good predictor of periodontal stability (Evidence Grade 3).

▶ Scientific evidence is insufficient for assessing the value of pocket depth as a prognostic method.

Treating Chronic Periodontitis

▶ Mechanical infection control (scaling and root planing) reduces probing pocket depth and improves probing attachment level. Mechanical infection control combined with flap surgery eliminates 10%–15% more pockets deeper than 4 mm than mechanical infection control alone (Evidence Grade 3).

▶ Local adjunctive therapy with 25% metronidazole gel does not result in improved probing pocket depth or probing attachment level compared to mechanical infection control alone (Evidence Grade 3). Scientific evidence is insufficient for determining the efficacy of other local antibiotics and antiseptics.

▶ Systemic antibiotic therapy as an adjunct to mechanical infection control does not improve probing pocket depth or probing attachment level compared to mechanical infection control alone (Evidence Grade 1). Scientific evidence for the benefit derived from using anti-inflammatory drugs is insufficient.

▶ Adjunctive therapy with guided tissue regeneration (GTR) or with enamel matrix derivative (EMD) in individual angular bone defects results in improved probing attachment level and bone level. An improvement in probing attachment level by more than 4 mm can be expected twice as often with GTR or EMD as with flap surgery alone (Evidence Grade 1).

▶ Adjunctive therapy with coralline calcium carbonate in individual angular bone defects improves bone level more effectively than flap surgery alone (Evidence Grade 3). The outcomes are contradictory regarding probing attachment level. Scientific evidence for the efficacy of using other filler materials is insufficient.

▶ Adjunctive therapy with GTR and EMD appears to result in less improvement in smokers than in non-smokers.

▶ Scientific evidence for assessing and designing programs of supportive periodontal therapy is insufficient.

Economic Aspects

▶ Scientific evidence is lacking for determining cost-effectiveness and patient-perceived quality with regard to the various methods of prevention, diagnosis, and treatment of chronic periodontitis. The studies that were included are too limited regarding quantity and assessed quality.

Chronic Periodontitis as a Risk for Other Diseases

▶ Scientific evidence is contradictory as to whether individuals with chronic periodontitis are at increased risk of developing coronary heart disease or stroke.

▶ Scientific evidence is lacking as to whether individuals with chronic periodontitis are at increased risk of developing diabetes mellitus, chronic obstructive pulmonary disease, or rheumatoid arthritis.

▶ Scientific evidence is insufficient and contradictory as to whether women with chronic periodontitis during pregnancy have an increased risk for preterm birth. Scientific evidence of a relationship between chronic periodontitis and low birth weight is also insufficient.

IBL

From Chronic Periodontitis (2004), SBU Report No. 169.

The figures in parenthesis indicate the strength of the scientific evidence for drawing conclusions.
Evidence Grade 1: Strong scientific evidence
Evidence Grade 2: Moderately strong scientific evidence
Evidence Grade 3: Limited scientific evidence

*Complete images (crown and root) of several teeth and surrounding bone tissue.

**A single x-ray image that shows the crown and bone tissue adjacent to the tooth neck and the part of the root nearest the crown in both the upper and lower jaws.

Feri Fazeli

Same Diagnosis – Different Treatment

Variations in treatment routines can be hazardous to patients' health. Even the use of potentially life-saving interventions varies among hospitals.

Clinicians frequently differ in the way they treat the same type of medical problem. However, as far as the patient's health is concerned, not all methods are equivalent.

For example, care given at special stroke units has been shown to be effective in stroke patients. Yet, in some parts of Sweden only about 50% of stroke patients receive such care, while in other parts nearly all patients do.

Rational explanations can be found for certain variations in practice patterns – for example, the population in a particular region may be older, or the disease profile might not be similar.

Other explanations may include variations in the availability of resources – for example, medical staff, hospital beds, or operating rooms – or ease of accessibility by patients to certain hospitals and community health centers.

Patient demand – the tendency to seek care and the expectations from treatment – may also have an impact on practice patterns.

TRADITIONS VARY

However, many times variations among caregivers are also due to differing treatment traditions or work methods. Placed in the same situation, those in the same profession choose different options.

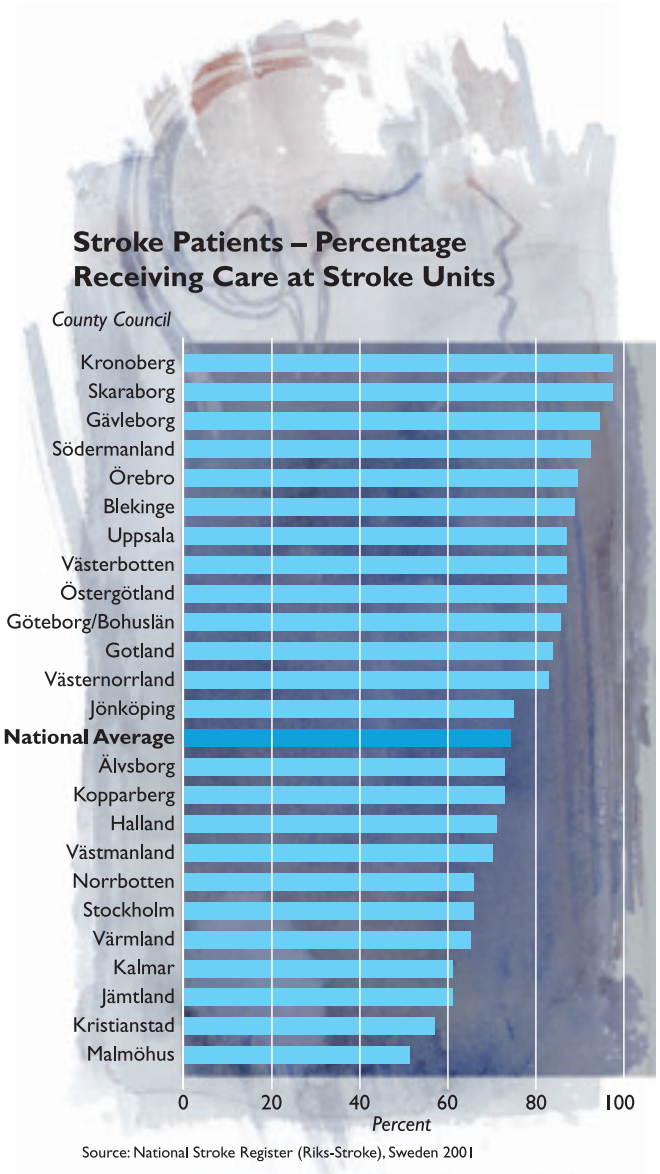
Ingemar Eckerlund, Health Economist at SBU, has investigated the issue of health practice variations in his dissertation from the Stockholm School of Economics.

– One hypothesis is that practice variations are associated with uncertainty, he says.

PRACTICE VARIATION EXAMPLES FROM SWEDEN

- Care at specialized departments, or stroke units, saves lives and improves the prognosis for many stroke patients. However, the percentage of patients who receive care at stroke units varies by county from approximately 50% to nearly 100% of patients.[1]
- The percentage of those with diabetes that also receive cholesterol-reducing drugs varies by county from 6% to 35%.[2]
- Some county councils provide epidural blockade for pain relief during childbirth to approximately 11% of women experiencing their first delivery, while other county councils provide epidural blockade to 44%.[3] This practice varies substantially even in subsequent births.
- Cesarean section rates are twice as high at some clinics in Sweden than at other clinics – 23% versus 10%.[3]
- The use of forceps or a suction device in conjunction with childbirth is three times more common at some clinics than at others – in some hospitals, the rate of instrument-assisted deliveries is 2%, while in others it is 11%.[3]
- Cataract surgery is a routine procedure at every eye clinic that performs surgery. Anesthesia rates in cataract surgery vary from zero percent to just over 11%.[4]
- The percentage of mild brain injury patients who receive CT scans varies among the emergency departments in Sweden from a few percent to 80%.[5]
- Some county councils purchase less than half as many hearing aids per capita than others. This cannot be explained by differences in age distribution or the prevalence of impaired hearing.[6]
- Should a healthy, asymptomatic wisdom tooth that has not broken through in the lower jaw be removed? In a Swedish study, 26 general dentists and 10 oral surgeons evaluated the same 36 cases. The number of cases where the dentist chose to remove a tooth varied from 0 to 25.[7]

1 Health and Medical Services 2002. National Board of Health and Welfare, 2003.
2 Includes 1997-2001. Source: National Diabetes Register, 2002, Citation in reference 1.
3 Includes 2003. Personal communication Feb 2005: Petra Otterblad Olausson, Center for Epidemiology, National Board of Health and Welfare.
4 Personal communication March 2005: Klas-Göran Brege, Mälar Hospital, Eskilstuna.
5 Mild head injury. Hospital observation or CT scanning and discharge? Report 153. SBU, 2000.
6 Hearing problems in adults. Report 164. SBU, 2003.
7 Knutsson K et al Community Dent Oral Epidemiol 1992:20:347-50 and 2001:29:308-14.



– Some studies suggest that practice is less uniform in areas where caregivers are uncertain about which method can offer the best results.

QUESTIONED MODEL

This explanatory model has been questioned by other researchers.

– In contrast, an alternative hypothesis focuses on beliefs – many caregivers may be convinced that their approach is superior, even if it deviates from standard practice.

Probably, examples of both phenomena can be found. Clinical decision-making is a complex process.

– Variations in caregiver judgement may be a result of different professional experience. Clinicians have formed their opinions based on the cases they have handled personally.

Some might have been influenced by marketing claims, or could have been convinced by local entrepreneurs who enthusiastically push their ideas about the best treatment option.

– Caregiver training and experience also varies, which may lead to different views on an issue. Knowledge conveyed through lectures and medical textbooks can quickly become obsolete.

– Not everyone has the opportunity, or the time, to keep updated about the most recent research results and to evaluate them critically. The ability to review and assess the findings may play a role.

What we know for certain is that practice variation affects all specialties and all levels of care – differences exist among countries, among regions in the same country, among care institutions in the same region, and among individual physicians in the same clinic.

For example, in the past 30 years, researchers have documented wide variations in hospital admission rates, the length of stay in hospital, the duration of sick leave, and surgical rates for various disorders.

VIEWS DIFFER

Professional views differ on what is the adequate length of stay, treatment method, and level of care. Views diverge concerning what should be done, by whom, and at which level in the continuum of care. The variations are not always trivial. On the contrary, various treatment options have often been shown to differ in medical benefits, risks, and costs. Eckerlund offers an example.

– In the 1980s, when we discussed routines for treating venous leg ulcers, the district nurses reported incredible patterns of practice. For example, some put whipped cream on leg ulcers, hoping to promote healing!

Prenatal care for twin births is another field where practice varies widely.

– In some clinics, the routine was to admit a mother to the hospital 8 weeks prior to the expected date of birth. Others believed that early admission was completely unnecessary.

– When we eventually conducted a systematic analysis on maternal care we also found other variations, eg, that the rates of outpatient dilatation and curettage varied widely, and cesarean section rates were quite different in different parts of the country.

Furthermore, wide variations were found across the country as regards hysterectomy motivated by bleeding that was not related to cancer.

NOT ALWAYS POPULAR

– Although practice variations generate a lot of interest, it is not always popular to point them out, says Ingemar Eckerlund.

He recalls meetings of clinical directors that were heavy on accusations, arrogance, and indignation, and light on professional interest in causes, or the desire to learn from each other to improve care delivery.

The information was regarded as too sensitive by some when the discussion came around to clinics that deviated in their practices.

– When routines in health care vary we cannot take for granted that everything is equally as good. Rather, we must question why practice varies, what consequences it can have, and if the situation can be improved, says Ingemar Eckerlund, Health Economist at SBU. His dissertation examines the causes and consequences of practice variations.

Ragnar Levi

– There seemed to be an underlying fear that the findings could be misinterpreted, alarm the patients, and lead to unmotivated resource cutbacks, suggests Ingemar Eckerlund.

His feeling today is that these suspicions have subsided, and it has become more accepted to scrutinize one's own organization and review standard practices.

EQUIVALENT METHODS

Many administrators have also realized that different routines in health care are not necessarily a problem. When several therapeutically equivalent methods are available to treat a given disease, then practice variations may be expected.

Without scientific knowledge about the effects of different treatment options we cannot determine which is best. Knowledge gaps are a warning signal, but the consequences of practice variations cannot be judged and should not automatically be viewed as a problem.

– We cannot take for granted that standard practice should be considered as some kind of a benchmark – the vast majority could be wrong. We can't assume that a clinic that uses a particular treatment method more than other clinics overutilizes the method, or that very little use is a sign of underutilization.

Determining what constitutes overuse and underuse must be considered in relation to the evidence available about benefits, risks, and costs.

WASTE OF RESOURCES

– Ineffective methods waste resources, leaving less money for interventions that have been proven effective, says Ingemar Eckerlund.

For every patient to receive equitable care, it is important to apply the research results on medical benefits, costs, and risks systematically throughout the health services.

It is in society's interest to achieve the greatest possible benefit from the resources allocated to health care. It is also in the interest of the patient and the health services. Ultimately, the objective is to provide patients with the best possible care regardless of where they live in Sweden or which caregiver they happen to meet.

Patients should rest assured that the treatment option is based on science rather than on special traditions that are based more on opinion than on fact.

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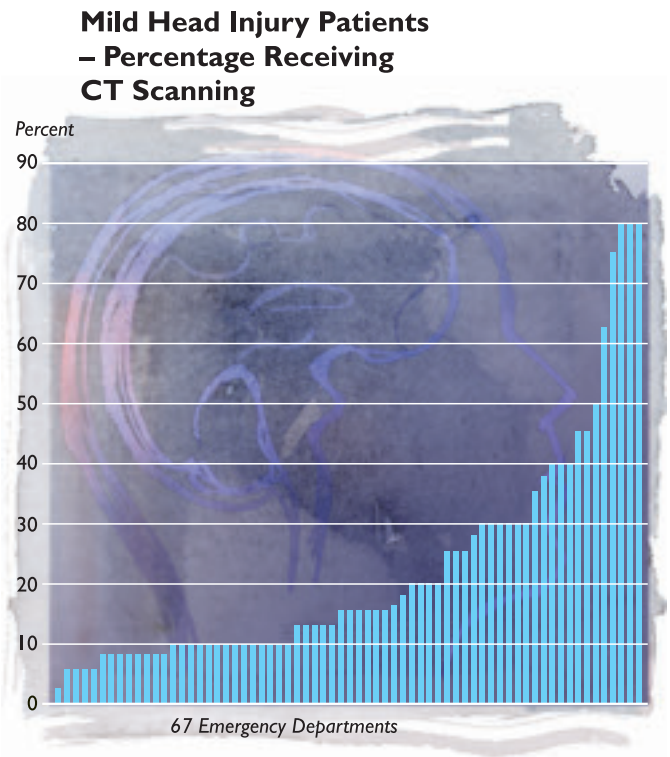

What's the Truth Behind the Headlines?

Factual content in medical news is the focus of a British project. By critically evaluating the promises and warnings reported by the press, CRD (SBU's British counterpart) hopes to offset unrealistic expectations and unwarranted anxiety generated by medical news.

"Breakthrough: First drug that actually reverses Alzheimer's", reports the British press.

Within 48 hours the Centre for Reviews and Dissemination (CRD) critically evaluates the news article and publishes its findings on the Internet. "Although laboratory experiments involving fruit flies have been successful, the drug has yet to be tested on people", write reviewers in the project "Hitting the Headlines".

RESPONDS TO NEWS

"Asthma danger in aspirin", report six newspapers. CRD responds that the articles are actually based on a well-designed, systematic review of 21 studies. Although the review had some weaknesses, its findings suggest that asthma attacks triggered by aspirin are more common than previously believed.

– Are research results reliable? Is the news reported accurately? These are key questions when we comment on news articles, explains Julie Glanville, Associate Director of CRD in York.

The project grew out of the confusion caused by exaggerated health warnings and lofty promises reported in the media about new cures for various diseases. Unrealistic expectations and unnecessary anxiety affect not only patients, but also the caregivers whose job it is to console and comfort.

– The original idea for the project was that health care should offer a rebuttal when the press spreads inflated information.

– But we didn't feel it was interesting to simply look for errors in the news, it would be better to review the content behind the headlines, says Julie Glanville.

– So that is what we do – we comment on one or two news items per week. Not only do we point out deficiencies in the news reporting itself, but also we assess the studies on which the articles are based.

QUICK COMMENTARY

Dr. Ben Toth at the National Health Services Information office in Birmingham is one of those responsible for "Hitting the Headlines", and describes his views on the aim of the project.

– Both caregivers and patients should receive quick commentary on medical news – knowledge that enables them to evaluate the news, he says.

"Hitting the Headlines" was first published on the Internet in 2000 and currently has 28 000 visitors per month. Dr. Toth is satisfied with the response, even though he had hoped to reach an even wider audience.

PATIENTS' QUESTIONS

The project has yet to be appraised, but he believes that physicians are among the beneficiaries of this free service since they are expected to answer patients' questions about the news.

– At the same time, we also hope that journalists will be more careful in their reporting, adds Ben Toth.

The reviewers and CRD comment on selected medical news articles from the 10 national British daily newspapers. The comments are placed on the Internet within 2 days after the articles have been published.

– The flow of medical news is enormous, but we select only articles that address the effect of intervention, tells Paul Wilson, a researcher, reviewer, and communications official at CRD.

– We prioritize reports that appear in more than one newspaper and deal with issues important to British health services, he says.

HALF ARE ACCURATE

From an audit of 100 stories, about half of the articles reviewed by CRD were found to be accurate, according to Paul Wilson. The rest contain minor to major errors, or are based on research results that have yet to be published and are not available for review. Many articles reveal insufficient criticism of the sources.

– A common problem is that the media actually cites the articles correctly, but misinterprets the importance of findings from animal studies or unreliable investigations. Or they uncritically cite misleading press releases.

– Up to now, the project has been positively received for the most part, even by journalists. We have received a few complaints, and one of the newspapers threatened to sue us for being too critical – but that was an exception.

Additional Reading

Read more about Hitting the Headlines at www.nelh.nhs.uk and www.nelh.nhs.uk/hth/help.asp

Kenneth Karlsson

MEDICAL NEWS
COMMON PITFALLS

- Facts are not distinguished from opinions. It is word against word and expert against expert. Scientific evidence to back up the assertions is not included.

- Case descriptions are substituted for scientific evidence. Isolated cases are presented as evidence for general statements.

- Only the benefits, or the adverse effects, of an intervention are reported, even though information exists on both. Rates describing the occurrence of one, or both, are not reported.

- Specific findings are generalized without critical scrutiny, eg, from the laboratory environment to routine health care, from animal trials to humans, or from one group of patients to another.

- Concurrent events are interpreted to have a cause-and-effect relationship. When two phenomena appear together, the first is assumed to cause the second. Example: When someone is exposed to a suspected risk factor and becomes ill, the risk factor is assumed to cause the disease. Alternative explanations are not offered.

- Risk factors are equated with diseases. Interventions that have an effect on the risk factors are automatically assumed – even in the absence of scientific evidence – to provide better health.

- Effects on surrogate outcomes are equated with effects on health – effects on various intermediate endpoints and laboratory tests are taken as evidence for effects on morbidity, mortality, and quality of life.

- Numbers are presented with misleading exactness (eg, unnecessary decimals), giving a deceptive impression of precision. Or they may be presented too vaguely, eg, reporting benefits and risks in percent (50% increase or 20% reduction) without giving the absolute numbers.

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"Use the Evidence!"

If the healthcare sector systematically applied the best available evidence, then current resources would stretch farther, giving citizens both more and better health services, writes Nina Rehnqvist, Executive Director of SBU.

Stockbyte

Sir Archie Cochrane, a pioneer in evidence based care, envisioned in the 1930s that all effective health care should be free. This vision seems utopian today. Nothing is free, and the gap between what is technically possible and what is economically feasible continues to widen in public-financed health care. In Sweden, public resources no longer cover all interventions having a documented, positive effect.

Hence, it is necessary for health care to use the best available scientific evidence to attack our major problems: scarce resources, poor accessibility, geographic variations in outcome, safety risks and disrupted continuity, deficient care of elderly people with multiple disorders, and the rising average number of sick days. A set of possible goals for evidence based care might be the following:

1. AFFORD THE ESSENTIAL

Current healthcare resources cannot cover everything that is technologically possible. Applying evidence in health care would allow resources to stretch farther. Ineffective methods could be identified and retired, freeing resources for interventions documented to be effective, essential, and the most cost effective. Clarifying the scientific basis for healthcare priorities allows the public to judge whether or not resources are being used appropriately. Then we can gain public support for painful, but necessary, proposals for priority setting decisions. Examples of priority setting processes based on scientific evidence can be found in Östergötland County and in the work of, eg, the Swedish Society of Medicine, the National Center for Priority Setting in Health Care (Linköping), and the National Board of Health and Welfare.

2. IMPROVE ACCESSIBILITY

Current problems involving poor access to care in some communities cannot be blamed solely on insufficient resources. Although organizational research in health care is relatively new, documented examples are emerging on ways to improve collaboration and solve logistical problems, thereby increasing accessibility. For instance, there are various ways to lower the risk for disruptions in continuity. This cuts down on idle time for both patients and staff, and increases efficiency.

3. RAISE THE QUALITY

Numerous examples point to major geographic differences, often two- or three-fold, in care utilization and care outcomes. In some cases, gender differences can be found in outcomes of certain disorders. Such differences are contrary to the intent of the Swedish Health Services Act, stating that health care should be provided on equal terms, and that priority should be given to those in greatest need. If we are to level out these differences, evidence based care is probably the only path accessible.

4. IMPROVE SAFETY

Accidents and deviations in care more often stem from system errors than from individual errors. Sufficient evidence is available for effective systems, eg, to avoid hospital infections or falls. But the evidence must be applied. At the same time, further knowledge is needed, eg, on how different healthcare environments influence recovery, or the best way to ventilate and clean operating theaters to avoid postoperative infections.

5. MULTIPLE DISORDERS

Elderly people with multiple disorders constitute a large group that does not always fare well in health care. Further scientific evidence is needed on how to avoid problems in managing drugs, and how to achieve a holistic, patient-centered perspective. Again, it is a matter of applying existing knowledge, eg, to avoid inappropriate drug combinations – a common problem in care of the elderly.

6. REDUCE ILL HEALTH

The economy improves when the number of sick days declines. The rising average number of sick days is not only a problem for public health, but also for the national economy – a problem that health services can help to reduce. Several statistical associations are recognized, but knowledge about the underlying mechanisms is limited. Taking a multidisciplinary approach and systematically applying the results would offer good opportunities to use the total resources of society in a better way.

The advantage of using evidence is clear: if the healthcare sector systematically applied the best available evidence, then current resources would stretch farther, giving citizens both more and better health services.

Nina Rehnqvist
Professor
Executive Director, SBU

Like Seeds in the Wind...

Conclusions from SBU Alert regarding technologies that are currently being disseminated in health care.

CT Colonography (Virtual Colonoscopy)

This new application for computed tomography produces images from a perspective within the intestine that corresponds to the view obtained from usual fiber-optic investigation of the colon (conventional colonoscopy). Potential target groups consist mainly of patients suspected of having malignant tumors as well as asymptomatic individuals at greater than average risk for developing colon cancer in whom the treatable early stages of cancer can be detected. SBU's evaluation shows that scientific evidence on the diagnostic reliability of CT colonography is not fully conclusive. The differences in results from different studies can be due to differences in equipment, procedures, and experience. Scientific evidence for assessing the cost effectiveness of the method is lacking. Studies should be conducted on expected effects and costs under ordinary conditions before applying the method more generally in routine health services. **NOV 2004**

Fondaparinux

Fondaparinux (Arixtra®) is a drug that inhibits the formation of blood clots, intended to prevent deep vein thrombosis (DVT), eg, following orthopedic surgery. SBU's assessment shows that fondaparinux therapy for 5 to 9 days shows a lower risk for DVT, as diagnosed by lower extremity venography, compared to low-molecular-weight heparin (Evidence Grade 1)*. The patient benefit of this is, however, uncertain. Studies of cost effectiveness in short-term treatment are limited to analytical models that build on the premise of an association between DVT (as detected by venography) and serious events. There is some documentation showing that extended prophylaxis (up to 4 weeks) with fondaparinux – as with low-molecular-weight heparin – reduces the risk for venous thromboembolism compared to no treatment (Evidence grade 2)*. No studies have been published on the cost effectiveness of long-term prophylaxis with fondaparinux. **JUNE 2004**

QF-PCR in Fetal Diagnosis of Chromosomal Abnormalities

This is a recent method of chromosomal analysis to detect chromosomal abnormalities in the fetus. In contrast to karyotyping, the standard method, not all of the chromosomes are analyzed in QF-PCR. Results can be obtained within 2 days, but abnormalities are only detected in chromosomes selected for analysis. SBU's assessment shows that there is strong scientific evidence for the capacity of QF-PCR to identify chromosomal abnormalities in the five chromosomes 13, 18, 21, X, and Y with good accuracy (Evidence Grade 1)*. The documentation is insufficient to assess the cost effectiveness of the method. It is important that health service providers discuss the ethical implications and the economic consequences of the method before it replaces karyotyping. **JUNE 2004**

Natriuretic Peptides in Diagnosing Heart Failure

The intention of measuring the concentration of BNP or NT-proBNP peptides in the blood is to facilitate diagnosis of heart failure. The method can be used in primary care provided that the analytical equipment is available, giving the results within 15 minutes. SBU concludes that there is moderately strong scientific evidence (Evidence Grade 2)* showing that BNP or NT-proBNP can be used, with good reliability, to rule out heart failure. However, evidence remains insufficient concerning the cost effectiveness of the method relative to other methods of diagnosing heart failure (Evidence Grade 4)*. **FEB 2005**

Catheter Ablation of Atrial Fibrillation

Catheter ablation therapy to suppress atrial fibrillation involves several different techniques. Heat energy is delivered, via a catheter, to the area of the heart involved in generating or maintaining atrial fibrillation. SBU's assessment shows that the method remains in the development phase. There is insufficient scientific evidence for drawing conclusions about benefits for patients and the methods cost effectiveness (Evidence Grade 4)*. Results from randomized controlled trials are necessary to assess fully the positive and negative effects of the method and its cost effectiveness. **JAN 2005**

For full SBU Alert reports and definitions of evidence grades, please see www.sbu.se

Cecilia Levy

SOME CURRENT SBU PROJECTS

ANXIETY
Contact person: Agneta Pettersson, pettersson@sbu.se
Expected publ: Fall 2005

CHRONIC PAIN
Contact person: Susanna Axelsson, axelsson@sbu.se
Expected publ: Fall 2005

DEMENTIA
Contact person: Anders Norlund, norlund@sbu.se
Expected publ: Fall 2005

DENTAL CARIES
Contact person: Susanna Axelsson, axelsson@sbu.se
Expected publ: Spring 2007

DYSPEPSIA (UPDATE)
Contact person: Anders Norlund, norlund@sbu.se
Expected publ: Fall 2006

GLAUCOMA
Contact person: Ingemar Eckerlund, eckerlund@sbu.se
Expected publ: Fall 2006

MEDICATION IN OLD AGE
Contact person: Juliette Säwe, sawe@sbu.se Expected publ: Spring 2007

MILD HEAD INJURY
Contact person: Jean-Luc af Geijerstam, geijerstam@sbu.se Expected publ: Spring 2006

PERIPHERAL ARTERIAL DISEASE
Contact person: Juliette Säwe, sawe@sbu.se Expected publ: Spring 2006

PROMOTION OF PHYSICAL ACTIVITY
Contact person: Ingemar Eckerlund, eckerlund@sbu.se
Expected publ: Fall 2006

ORTHODONTICS
Contact person: Susanna Axelsson, axelsson@sbu.se
Expected publ: 2006

SLEEP APNEA
Contact person: Bengt Brorsson, brorsson@sbu.se
Expected publ: Fall 2005

VACCINATION DURING CHILDHOOD
Contact person: Juliette Säwe, sawe@sbu.se Expected publ: Spring 2006

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EXECUTIVE EDITOR: *Ragnar Levi, levi@sbu.se* • PUBLISHER: *Nina Rehnqvist*
MAIL ADDRESS: *P.O. Box 5650, SE-114 86 Stockholm, Sweden*
PHONE: *+46-8-412 32 00* • FAX: *+46-8-411 32 60* • *www.sbu.se* • *info@sbu.se*
ENGLISH ADAPTATION: *Ron Gustafson* • DESIGN: *Nilla Westin*