

MEDICAL SCIENCE & PRACTICE

NEW REPORTS SBU Results in Brief | 10–15



Patient Involvement Is a Must

Although patients have legal rights to information and influence, several SBU reports reveal problems of exclusion and poor participation.

It should be self-evident that patients influence their care and treatment, and participate in decisions affecting their health. Section 2a of the Swedish Health and Medical Services Act stipulates that care should be founded on respect for the patient's self-determination, and the patient should receive individualised information about methods available for treatment. Care and treatment shall as far as possible be designed and conducted in consultation with the patient.

The key question is how. A commonly accepted prerequisite is that to participate effectively in decisions about their health, patients need access to reliable knowledge and evidence. Clearly, patients who

Levi/Nyberg

The Curse of Incidental Findings

Give some 40 symptom-free individuals an MRI brain scan, and one of them will reveal a pathological change. Not trivialities, but a tumour, a cyst, a vascular change, an inflammation, a silent cerebral infarction just to mention a few possibilities. That's not to say that the individual in question would have ever noticed the change, or lived a less fulfilling or shorter life. Probably not. But even so...

OK... and? you ask. What healthy-feeling person would beg to squeeze into a tight MRI machine? Wouldn't you much rather watch TV, or check your mobile phone, or take a walk. Or eat a hot dog. So what's the problem?

Well, unfortunately there's a problem, a growing and rather tricky one, as many radiologists point out. The better the methods for imaging the body, the sharper the images we get, and the more outliers we find – often in passing as we are being examined for some other problem. Hence, it's all about incidental findings that could actually affect health and simply cannot be ignored.

A recent Scottish study (Sandema, EM, et al, 2013) of MRI imaging of the skull in 700 symptom-free 73-year-olds revealed pathological findings in as many as one third. These led to nine non-acute referrals and one acute referral. Even younger people are affected. A systematic review of studies totalling 20 000 young and middle-aged participants (Morris Z, et al, 2009) found such changes in the brain in 3% of all symptom-free individuals examined.

Surgeon Åke Andrén-Sandberg and radiologist Peter Aspelin recently addressed the problem in the Swedish Medical Journal. The better the imaging technology we have, they write, the greater the number of incidental findings from clinical examinations and screening. In a small proportion of people with such a finding, this is a first stage of a more serious medical problem, and no one knows who will be affected. Everyone has the right to be informed about the findings and may need follow-up visits. Hence, according to the authors, physicians and patients are headed towards a precarious situation. "We either find potentially premalignant conditions without taking steps to intervene, or we weigh down the healthcare system with examinations and follow-up for safety's sake." The authors raise the question of prioritisation. Can we afford to follow every such finding with regular check-ups – for instance cysts in the pancreas that happen to be detected during CT imaging of the abdomen?

The basic problem of incidental findings is nothing new, and not limited to imaging diagnostics alone. If one orders a large battery of blood analyses – a type of non-specific screening – several of the findings will be outliers. Some of these might not be incidental, but point to an underlying disorder that ought to be investigated.

According to Greek myth, it was curiosity that drove Pandora to open her box and release bad things. When it comes to health care other driving forces are at play, such as refined technology and lofty ambitions. We cannot close the lid, but we can think twice.



RAGNAR LEVI, EDITOR



José Luis Palaez

are uninformed about the treatment options available and what they involve cannot participate meaningfully in decisions concerning their own care.

DISINFORMATION

Already at this point we find substantial shortcomings. While the Internet has dramatically increased opportunities for the average person to acquire medical information, it has also increased the flow of disinformation – biased, misleading, and inaccurate claims. Most people find it difficult to know which of the many claims are true.

Suggestions have been offered that could improve the situation. In April 2013, SBU submitted its investigation commissioned by the Government to study how an open,

web-based national health library in Sweden could improve access to research findings and evidence, not only for health professionals but also, at a later stage, for patients. Similar services have been available in Norway, Denmark, and the UK for several years, providing high-quality health information free of charge to anyone with Internet access.

INFLUENCE

Better knowledge, however, does not automatically increase participation. Some critics argue that it would be difficult to integrate greater patient influence and evidence based care. But Alexandra Barratt, researcher at the University of Sydney, Australia, disagrees:

– Objections to evidence

based medicine have much in common with objections made to shared decision-making, she explains. In both instances opponents argue that this is unrealistic, too time consuming, and that appropriate resources are not available.

CRITICAL QUESTIONS

– Perhaps this reflects some of the similarities between them in terms of the challenge they present to traditional practice, continues Alexandra Barratt.

She admits that problems would arise if physicians were forced to treat all patients in exactly the same manner without considering the individual patient's situation and preferences.

But those who ignore the individual use evidence in a dogmatic and erroneous way, as pointed out by David Sackett, one of the prominent figures in evidence based medicine. Early on he asserted that a "bottom-up approach that integrates the best external evidence with individual clinical expertise and patients'

choice" is required, which could never lead to streamlined cookbook medicine.

Sackett and several others suggest that evidence clarifies both the advantages and disadvantages of different treatment alternatives, which the patient and the carer can use as a point of departure for their discussion.

UNDERESTIMATE

Health services appear to underestimate the patient's potential to participate in many contexts, not least in psychiatry. Schizophrenia is one example – a current SBU report shows that participation, continuity, and respect are decisive for patients with this diagnosis in their contacts with health services.

Today many suffer from discrimination and alienation, which SBU identifies as something that health services must actively counteract.

During the spring of 2011, as part of the International Health Policy Survey, 4800 telephone interviews of "sicker adults" were conducted in

Sweden. When patients in Sweden were asked if they felt encouraged to ask questions, 44% responded "always" or "often" – compared to 80% in the UK.

The national patient survey conducted by the Swedish Association of Local Authorities and Regions (SALAR) in 2012 also showed that the participation of individuals in care planning must improve. The same applies to information about possible side effects of drugs and warning signals related to disease or treatment.

– The patient's right of self-determination is a fundamental ethical principle in Swedish health care, says Måns Rosén, Executive Director of SBU.

– If this is to be realized, then not only the health services but also the patients and their families must have better access to scientific knowledge. [RL]

Further Reading

Barratt A. Evidence based medicine and shared decision making. *Patient Educ Couns* 2008;73:40712.

Trevena LJ, et al. A systematic review on communicating with patients about evidence. *J Eval Clin Pract* 2006;12:1323.

Docteur E, et al. Patient centeredness in Sweden's health system – an assessment and six steps for progress. *Myndigheten för vårdanalys: Stockholm*, 2012. http://www.vardanalys.se/Global/Rapporter%20pdf-filer/2012/R3_2012_Patient_centeredness.pdf

Nationell patientenkät [National patient questionnaire] via SALAR website <http://npe.skl.se>

Sackett DL, et al. Evidence based medicine: What it is and what it isn't. *Brit Med J* 1996;312:71-2.

The International Patient Decision Aid Standards (IPDAS) Collaboration. <http://ipdas.ohri.ca>

Centre for Person-Centred Care, University of Gothenburg, GPCC, www.gpcc.gu.se/

Patientlag. Delbetänkande av Patientmaktutredningen. [Swedish government study on patient empowerment] SOU 2013:2. Stockholm: Elanders, 2013.

Hälsa- och sjukvårdslagen [Swedish health and medical services act] (1982:763), www.notisum.se/rnp/sls/lag/19820763.htm

HOW TO INVOLVE PATIENTS MORE

In their role as patient and user of health services, people must have the opportunity to understand the reasons behind their illness and contribute towards maintaining and improving their health. Patients should be given the opportunity to participate and choose appropriate interventions for acute health problems and find different ways to manage chronic disease.

This is an active consumer role that health services and society must support – in part because it is a right, and in part because it can improve health care. Although not every patient wants to, or can, actively participate in choosing treatment, most feel that health services should provide information and pay attention to their wishes.

Three important building blocks that enable patients to participate are knowledge, shared decision making, and self-care of chronic conditions. Examples of tools for achieving this include:

- written information that complements discussions
- personally adapted, computerised information and support
- communication training for healthcare staff
- encouraging and inviting patients to ask questions
- pedagogically designed decision support for patients
- programmes for patient education and self-care

An important prerequisite is health literacy, i.e. an individual's ability to acquire, understand, and apply information intended to maintain or improve their health. This requires cognitive and social skills, but also access to easily accessible, relevant, and reliable information.

Also essential is the ability and attitude of staff to communicate with the patient. This can be improved through education, training, and support from management and the health service organisation as a whole.

The Swedish government study on patient empowerment (*Patientmaktutredningen*) is proposing a new law.

Too Much Medicine?

Medical diagnosis and treatment are a double-edged sword. Concern is growing that overtreatment of minor problems could have harmful effects and increase human suffering.

Are health services investigating and treating the right problems? Are the methods chosen effective? *No* say many scientists, authors, and critics.

Three authors of an article in the British Medical Journal [1] assert that it is becoming increasingly difficult to use the impressive arsenal of medical technology judiciously. They write: "Screening programmes are detecting early cancers that will never cause symptoms or death, sensitive diagnostic technologies identify 'abnormalities' so tiny they will remain benign, while widening disease definitions mean people at ever lower risks receive permanent medical labels and lifelong treatments that will fail to benefit many of them."

RISK MARKERS

The authors suggest that health services are driven, and to some extent aim, to identify and treat new diagnoses or milder forms of well-known conditions. An increasing number of risk markers, diagnostic findings, or related findings of uncertain significance are being examined and treated. Several examples appear in the international literature:

- New criteria for gestational diabetes include nearly 1 in 5 women. [2]
- A study from Canada shows that 30% of those diagnosed with asthma could be wrongly diagnosed, of which two thirds might not require treatment. [3]
- A broader definition of osteoporosis in the United States could mean that millions of women at low risk for osteoporotic fractures might experience more harm than benefit from treatment. [4]
- A controversial definition of chronic kidney disease would label 1 in 10 as sick, and lead to overdiagnosis in the elderly. [5]
- More sensitive diagnostic methods detect even small pulmonary emboli that might not require anticoagulants. [6]

CONFERENCE

The British Medical Journal (BMJ), which published the article, is arranging an international conference later this year at the Dartmouth Institute for Health Policy & Clinical Practice in collaboration with an American consumer organisation (Consumer Reports) and Bond University in Queensland, Australia.

The phenomena of overdiagnosis and overtreatment are perhaps most apparent and most discussed in the United States. Several books published in the US in recent years have addressed the problems. But apprehensions date far back and reach

beyond the American health services system.

CULTURAL INFLUENCES

In Sweden, a group of Nordic general practitioners calling themselves the Nordic Risk Group raised the issue several years ago. [7] In the 1990's Lynn Payer, a medical journalist, described how cultural values in different countries influence the choice of medical interventions, at times more so than facts. Although Payer coined the concept of disease mongering [8], two decades earlier Ivan Illich, philosopher and social critic, had pressed the controversial argument that the medical establishment was medicalising life itself. [9]

Consequently, the problem is nothing new – but it is becoming increasingly acute. Although a tighter economy and an aging population are putting pressure on many health systems in our part of the world, our expectations for perfect health are growing, and hence so are overtreatment, overdosing, and overdiagnosis. It is becoming increasingly problematic that many interventions, despite highly legitimate aims to prevent disease and reduce suffering, can also harm people and waste health resources.

Several of the changes that have been under way for some time in Swedish health services aim to increase the role of public demand in determining the care offered

Further Reading

1. Moynihan R, et al. Preventing overdiagnosis: how to stop harming the healthy. *BMJ* 2012;344.
2. Cundy T. Proposed new diagnostic criteria for gestational diabetes – a pause for thought? *Diabet Med* 2012; 29:176-80.
3. Aaron S, et al. Overdiagnosis of asthma in obese and nonobese adults. *CMAJ* 2008;179:1121-31.
4. Herndon MB, et al. Implications of expanding disease definitions: the case of osteoporosis. *Health Aff* 2007;26:1702-11.
5. Winearls C, et al. Classification of chronic kidney disease in the elderly: pitfalls and errors. *Nephron Clin Pract* 2011;119 (suppl 1):c2-4.
6. Prasad V, Rho J, Cifu A. The diagnosis and treatment of pulmonary embolism. *Arch Intern Med* 2012; 172:955-8.
7. Brodersen J, et al. *Skapar vården ohälsa?* [Do health services create ill health?] Lund: Studentlitteratur, 2009.
8. Payer L. *Disease-mongers: How doctors, drug companies and insurers are making you feel sick.* New York: John Wiley and Sons, 1992.
9. Illich I. *Medical nemesis: the expropriation of health.* London: Calder & Boyars, 1975.

by society. Many suggest that this is an important part of the objective to strengthen patient participation. However, this requires that the people who demand care should be well informed – not misinformed or uninformed.

If demand is based on vague, biased, or incorrect information that scares people by false alarms or attracts them with empty promises, then medicalisation of society will gain ground. Then even more resources will go towards interventions that sound attractive, but have no proven effects on health – leaving even fewer resources for interventions that actually help.

MUST KNOW

Providers and patients alike must be made aware of the benefits and risks connected with different treatment options. This information must be evidence based – an objective that SBU has worked towards for more than two decades.

Placing higher standards on scientific information is probably the best cure for the medicalisation malady, at least in the long run. [RL]



James Porto

OVERDIAGNOSIS: POTENTIAL DRIVING FORCES

- Technological advancements that enable detection of minor anomalies
- Commercial and professional self-interests
- Dissenting expert groups that expand illness criteria and write guidelines
- Control systems that penalise underdiagnosis, but not overdiagnosis
- Healthcare systems that favour more tests and more treatment
- Cultural notions that "more is better"; belief in early detection without considering the risks

First Divest, Then Reinvest

Given the limited budget for health services, ineffective routines must be phased out to make way for better alternatives. The problem is that adding a new method is often easier than removing an existing one.

Changing entrenched care routines may be difficult. Researchers in sociology and psychology have investigated possible reasons. Sociologists have described organisational inertia, and report that changes occur only after the organisation as a whole has accepted a new model. Psychologists, on the other hand, have studied resistance to change as cognitive and emotional phenomena. We

hold on to what we have because we don't know what we will get.

Cary Cooper, professor of organisational psychology and health at Lancaster University, UK says that the challenge lies in shifting attention from the old to the new.

MUST MAKE ROOM

Instead of focusing on eliminating established routines, we should think more about actually making room for better methods that should replace old ones, he emphasises.

– We shouldn't be looking only to cut things but to ensure that funding is focused on healthcare interventions and technologies that optimise health outcomes, he says.

This is about economising. Internationally, it is called disinvestment when health services cease to offer an intervention so as to free resources that can be used for a better purpose.

The concept of disinvestment is problematic, notes Cary Cooper, since it makes us think only of cutting back and getting rid of something. But moving resources towards interventions that provide the greatest benefit, individually and collectively, is actually not cutting back.

We need to set a positive agenda when it comes to freeing up health resources to maximise returns on investment in health care, rather than implying that cost reduc-

References

Cooper C. Disinvestment in health care. *BMJ* 2010;340:c1413.

Garner S, et al. Reducing ineffective practice: challenges ... *J Health Serv Res Policy* 2013;18:6-12.

Henshall C, et al. Using health technology assessment to support optimal use of technologies. *Int J Technol Assess Health Care* 2012;28:203-10.

SBU. Kortikosteroidinjektioner vid tennisarmbåge (lateral epikondylit). [Corticosteroid injections for tennis elbow (lateral epicondylitis)]. SBU Kommentarer, 2012. www.sbu.se/tenniarmbage

SBU. Perifer venkateter (PVK) – regelbundet byte eller byte vid klinisk indikation? [Peripheral venous catheters (PVC) – regular exchange or changing on clinical indications]. SBU Kommentarer, 2013. www.sbu.se/2013_02

Socialstyrelsen [National Board of Health and Welfare]. Robotassisterad laparoskopisk kirurgi i Sverige. Utbredning, omfattning och tillämpning [Robot-assisted laparoscopic surgery in Sweden. Distribution, scope, and applications]. Stockholm: Socialstyrelsen, 2013.

Socialstyrelsen [National Board of Health and Welfare]. Nationella riktlinjer för rörelseorganens sjukdomar [National guidelines for musculoskeletal diseases] (2012). <http://www.socialstyrelsen.se/nationellariklinjer-for-rorelseorganenssjukdomar/sokiriktlinjerna/artrosikna>

THREE QUESTIONABLE METHODS

Regular changing of peripheral venous catheters

According to the Swedish Handbook for Healthcare, a peripheral venous catheter (PVC) should be inserted for the shortest possible time and changed every 48 to 72 hours. But according to a Cochrane review this plays no role in the incidence of superficial thrombophlebitis (inflammation of superficial veins due to blood clots), bacteria in blood, or local infections if the interval between changes is 72 to 96 hours, or based on clinical indications. Catheters become obstructed more frequently, but resources are better used and needle insertions are fewer.

Cortisone injections for tennis elbow

A systematic literature review evaluated by SBU shows that corticosteroid injections reduce pain and improve function in the

short term. But after some months, and even after several years, the condition deteriorates substantially compared to other treatment, or no treatment. Clinical routines do not take adequate account of the harmful effects over time.

Laparoscopic surgery for knee arthrosis

The procedure involves flushing the knee joint with saline solution and removing loose and damaged fragments of meniscus and cartilage. But according to the National Board of Health and Welfare, the method is no more beneficial than placebo. The Board indicates that other interventions that more effectively treat knee arthrosis should be used instead. Recommendations to forgo laparoscopic surgery are based on systematic reviews and randomised studies.

tion is the objective, emphasises Cooper.

Obviously if we improve health services with new methods, but do not increase total costs, we must concurrently phase out the less desirable alternatives. It's unreasonable to focus solely on the things we eliminate.

At times it's not the treatment or diagnostic method per se that's ineffective, but its area of application – perhaps it's used too much or inappropriately. Perhaps the technology in question has a place in health services, but it should be used in a different way. What needs to be changed are the indications, reasons.

PRACTICE INFLUENCED
SBU's assessments serve as an important foundation. The very first report published by SBU assessed preoperative routines and showed it was not beneficial to routinely perform radiography of the heart and lungs, ECGs, or clinical chemistry testing in healthy individuals with no previously relevant diseases. The conclusions from this report quickly altered practice and directly saved health services approximately 235 million Swedish kronor (SEK) per year.

Going from a systematic review to recommending against utilisation is not always easy. Researchers at NICE in the UK recently



Larry Washburn

studied how the Cochrane reviews could be used to find ineffective interventions that should probably be eliminated in favour of others. But they concluded that it's a big jump from a Cochrane review to concrete decisions. Despite the efforts of the British, very few methods have been proposed for phase out.

SHOULD FORGO

Sweden has had no lack of suggestions. For instance, national guidelines from the National Board of Health and Welfare have listed interventions that health and social services should forgo since they are judged to be ineffective or can put patients at risk. Their guidelines on musculoskeletal diseases alone list 47 "do not do" recommendations.

Several county councils have established priorities in an attempt to eliminate certain methods, but with varied success.

SBU is studying how scientific assessments of healthcare methods can be used systematically to support prioritisa-

tion – an orderly phasing out of interventions proven to be ineffective or harmful in favour of effective methods. A conceivable scenario would be that health services opt to wait before introducing a new method whose benefits and risks are uncertain and whose costs are high.

The project is being coordinated by Pernilla Östlund at SBU.

– We are starting from three bodies of evidence: cortisone injections for tennis elbow, which is documented as harmful in the long term; regular exchange of peripheral venous catheters, which is no better than changing on clinical indications; and endoscopic surgery for knee arthrosis, which is shown to be ineffective while generating high costs.

LONG LASTING

– The reason for a planned phase out is to help health resources stretch further while concurrently maintaining or improving quality, says Pernilla Östlund.

The connection be-

tween planned phase out and planned introduction of methods in health care is a key issue pedagogically, agrees Harald Gyllensvärd, health economist at SBU.

– If all decisions concerning phase out were followed by concrete proposals for alternative use of the resources, they would command greater attention, he says.

MUST FORCE

Refusing to use poorly documented and less effective methods could be perceived as stingy and unfashionable. Professor Nina Rehnqvist, Chair of SBU's Board, emphasises that healthcare leaders must force the issue nevertheless.

– Of course, it might feel less exciting to phase out than to introduce something. But one is obviously a prerequisite for the other, she says.

– Unless healthcare leaders free resources, there won't be enough to cover the innovations that are actually effective. [RL]

Even Promising Methods Should Be Questioned

Small, single studies often prove to be faulty. Even promising results must be challenged. Critical thinking can prevent unnecessary harm and waste of limited health resources.

A lesson that can be learned in nearly every area assessed by SBU is that we must always be critical of new research findings. Many studies of health risks and treatment methods draw too heavily on too few observations and weak evidence. The researchers' own data might not support their conclusions, and new studies are designed to confirm the previous hypotheses of the research group, instead of testing them.

One of the harshest critics is John Ioannidis, Professor of Health Research at Stanford School of Medicine, USA. He goes as far as to claim that most published findings in biomedicine are false. This includes modern molecular medical research, clinical studies, and epidemiological investigations.

MISLEADING

In an oft-cited article in the journal PLoS Medicine, John Ioannidis describes why erroneous conclusions are more common when the studies are small, when the effects shown are small, and when isolated statistical associations

appear among a large number of variables where different relationships are sought nonselectively.

Using statistical simulations, he shows what happens when conclusions are based on isolated studies and statistical significance (e.g. a P value <0.05). Like many others, he remarks that significance alone does not mean that a result is correct.

The probability that a claimed finding is correct also depends on the nature of the research area and the statistical power of the study, i.e. whether or not the study is large enough for its purpose. Statistical power indicates how great the chance is that a study can detect, with reasonable accuracy, a difference between the groups compared.

When researchers plan a new study they should calculate how many participants are needed for the study to show a difference of a particular size. The calculations should show the desired level of significance, the presumed variability of the findings, and how great the difference is expected to be – or how small of a difference is clinically relevant.

A study with too few participants has too little statistical power and yields results that are too uncertain. The greater the effect, the fewer participants the study needs

to achieve sufficient statistical power.

HOT AREA

In new, hot research areas, e.g. genetic research, the subject matter invites a rich flora of hypotheses. When only a few are correct, and when the effects of each individual genetic factor are small, the risk for false conclusions is great, according to John Ioannidis.

The risk of error is also greater in research areas with wide latitude for varying the design, definitions, effect measures, and analytical methods, and where there are substantial commercial or other special interests.

SKewed

Intentionally or unintentionally, studies can be skewed when they are designed, implemented, and presented, i.e. when researchers recruit study participants, manage dropout, collect data, and perform analyses. John Ioannidis notes that errors in study design can lead to apparent associations and effects that can be elevated to facts.

Selection bias means that research subjects are chosen in a way that is not representative of the group that potential conclusions refer to. Such errors are best avoided by randomly choosing participants from the group.

Dropout occurs, e.g. when



Gary Waters

a certain category of research subject cannot, or does not want to, participate in the entire study, which can skew the results of the study. Careful follow-up and analysis of dropout is important. If dropout is too high, general conclusions cannot be drawn.

Observational errors stem from the collection of data itself. Preferably both the research subjects and the researchers should be blinded, i.e. unaware of which participants belong to the experimental and control groups, otherwise expectancy effects can influence the results.

Analytical errors appear when researchers do not analyse all factors suspected of influencing the results, but only certain ones.

The effect measures of a study must also be chosen to reflect outcomes that are actually important to the patients – mortality, morbidity, and quality of life. Instead, many clinical studies are targeted at surrogate endpoints, e.g. a laboratory value whose implications for human health are highly uncertain.

ODD METHODS

Other studies can use odd, homegrown measurement methods. These could include rating scales that have not been sufficiently validated, or composite outcome measures that include nonessential

components and where the effects on key outcomes are obscured.

In research areas connected with strong financial and other special interests, the risk for misleading research results is high. In biomedicine, conflicts often arise between the self-interests of researchers or financiers and the scientific standards of objectivity.

POWER AND STATUS

But it's not only about economic advantages. Strong personal beliefs and the pursuit of power and status in the research community can lead to skewed results and interpretations.

The situation can be exacerbated if every research team engages solely in trying to confirm its own pet hypotheses. Instead of testing whether or not the primary finding actually holds, they conduct and publish small and skewed studies that strengthen their prior hypothesis.

When some prestigious journal publishes these findings, strengthening their status, other researchers look after their own interests by overthrowing the competitor's hypothesis and skewing their own findings in the opposite direction. Such spurious questioning in the shape of rapidly alternating, extreme research claims is ineffective as knowledge development,

and journals are filled with extreme hypotheses and small, misleading studies. According to John Ioannidis this occurs, for instance, in molecular genetics research.

Generally he asserts that the majority of published biomedical findings are rooted in studies which are too small or poorly designed, and that most published research results are exaggerated or misleading.

Even if there are research areas and publications where quality problems are not quite as serious as in others, there are strong reasons to always apply critical thinking when turning biomedical research into clinical policy and practice.

For this reason SBU does not place much weight on small, isolated studies, but often emphasises the collective body of knowledge. [RL]

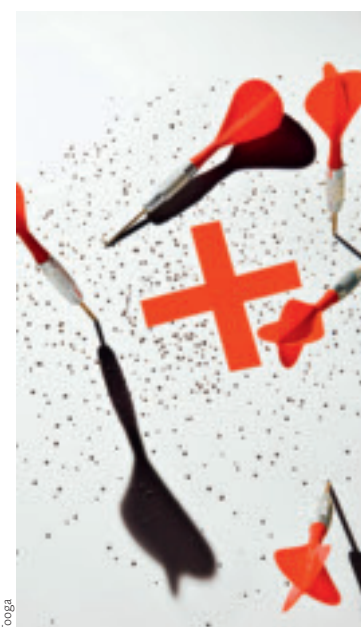
References

Ioannidis JP. Why most published research findings are false. *PLoS Med* 2005;2: e124. doi:10.1371/journal.pmed.0020124

Ioannidis JP. Why most discovered true associations are inflated. *Epidemiology* 2008;19:640-8.

Cordoba G, et al. Definition, reporting, and interpretation of composite outcomes in clinical trials: systematic review. *BMJ* 2010;341:c3920.

SBU. *Utvärdering av metoder i hälso- och sjukvården: En handbok* [SBU's handbook: Evaluation and synthesis of studies using qualitative methods of analysis]. Version 2013-05-16 Stockholm: Statens beredning för medicinsk utvärdering (SBU). From www.sbu.se/metodbok 2014-02-01.



Trooga

RESEARCH IS MORE OFTEN FLAWED WHEN...

- ...studies are small
- ...the expected effects are small
- ...many hypotheses are conceivable, but only a few are studied
- ...the possibilities to vary study design, definitions, effect measures, and analytical methods are great
- ...the area includes strong economic and other special interests or dogma
- ...many research teams attempt to confirm their own hypotheses

Personal Preferences Can Guide Dietary Advice on Obesity

In obesity, the effect of dietary advice on morbidity is largely unknown. But for cardiovascular health, it is better to recommend a Mediterranean diet over a low fat diet. Several types of dietary advice can help obese people reduce their weight or waistline, and the long-term results on weight are similar. But in the short term, advising a low carbohydrate diet over a low fat diet yields more weight loss.

Opinions among health professionals differ when it comes to the best dietary advice for people with obesity. SBU's comprehensive literature review shows that several types of advice can help reduce weight. As regards prevention of cardiovascular disease, intensive advice on a Mediterranean diet is superior to advice on low fat diets. In the long term, advice on low carbohydrate, low fat, and high protein diets have similar effects on weight. Since many people have difficulty in complying with dietary advice over a longer period, there may be reason to offer a broad range of advice options that can be adapted to individual preferences.

About the Report

Dietary Treatment of Obesity – A Systematic Review (2013). Project Director SBU: Jonas Lindblom. Chair: Nina Rehnqvist, rehnqvist@sbu.se. Contact: Måns Rosén, rosen@sbu.se. Find the full report and summary at www.sbu.se.

no negative effects on blood lipids, assuming that weight remains lower. Currently in Sweden, obese individuals are often advised about food with low fat content, low glycaemic index, moderately low carbohydrates, and the Mediterranean diet. However, health services seldom recommend a strict low carbohydrate diet. The studies reviewed by SBU did not show the degree to which fats in a low carbohydrate diet should be saturated or unsaturated. Taking a cautious approach, advice on low carbohydrate diets could mean restricting saturated fat, as long as documentation on the long-term effects is so limited.

Since high intake of saturated fat appears to carry risks for cardiovascular disease, this raises the question of whether low carbohydrate diets would, over time, increase risks, e.g. for coronary heart disease and stroke. Research to date has not provided a clear answer. The long-term effects on morbidity and mortality in people with obesity have not been sufficiently studied. However, many studies are in progress, and better information about long-term safety will be available in the future.

SWEET DRINKS

The body of literature offers some guidance on advising obese people about beverages. Cutting back on sweet drinks leads to weight reduction.

However, the evidence is not sufficient to show whether or not drinking large volumes of water is beneficial for weight, as is often claimed.

People with obesity have a much higher risk of diabetes. The dose-response relationships for both coffee and alcohol show a reduced risk of diabetes in people with obesity. Hence, there is no reason to advise them against coffee or alcohol.

PERSONALISED

Advice regarding alcohol needs to be personalised and adapted to the individual. The energy level in alcoholic beverages must be considered. Some people may need to be advised against alcohol for other reasons, e.g. pregnancy, risk of abuse, or genetic predisposition for alcoholism. Some people are at risk of violent behaviour and other psychosocial problems.

The value of tailoring dietary advice is poorly studied in general. But it is reasonable to consider the individual's experiences and preferences when giving advice. Often obese individuals who seek help for weight problems have tried to lose weight during adult life. Hence, it can be important for health services to be aware of an individual's experience. What methods have they tried, for how long, and with what results? Pursuing a method that previously failed is hardly meaningful; it may



FROM SBU'S CONCLUSIONS | DIETARY TREATMENT OF OBESITY

SBU's systematic literature review focuses on advice concerning the daily diet of people with obesity. The project does not assess the methods of providing dietary advice.

SBU's conclusions address the association between food and weight, morbidity, or mortality in people with obesity (defined as BMI ≥ 30 kg/m² or waist size of ≥ 102 cm or ≥ 88 cm for men and women respectively).

► In the short term (6 months), advice on strict or moderate low carbohydrate diets is a more effective means of achieving weight loss than advice on low fat diets. In the long term, there are no differences in the effect on weight loss between advice on strict and moderate low carbohydrate diets, low fat diets, high protein diets, Mediterranean diets, diets aimed

at achieving a low glycaemic load, or diets containing a high percentage of monounsaturated fats. Advice on increasing the intake of dairy products (primarily milk) or reducing the intake of sweet drinks may also lead to weight loss.

► Advice on increasing the intake of dairy products (primarily milk) may lead to weight loss among obese children and adolescents. There is insufficient scientific data to assess whether other dietary advice that is effective in obese adults is also effective in people under 18 years of age.

► When obese individuals have lost weight, they can maintain their weight more effectively with advice on low fat diets with a low glycaemic index and/or high protein content rather than low fat diets with a high glycaemic

index and/or low protein content. No data are available to assess whether advice on low carbohydrate diets and Mediterranean diets, for example, is effective in preventing weight increase after weight loss.

► For obese individuals, intensive advice on Mediterranean diets (with extra olive oil or nuts and almonds) leads to a reduced risk of onset of cardiovascular disease or death caused by cardiovascular disease, compared with advice on low fat diets. People who drink a lot of coffee also have a lower mortality rate, regardless of cause.

► Obese individuals run a greatly increased risk of diabetes. The risk of falling ill with diabetes is lower among people who drink alcohol and people who drink a lot of coffee, while it is higher among

people who drink sweet drinks. However, advice on low fat diets does not lead to a reduced risk of falling ill with diabetes compared with advice on diets with a standard fat content among obese post-menopausal women.

► It is not possible to assess whether other types of diet or drink are of significance to morbidity or mortality among obese individuals. The scientific data is insufficient. The data is also insufficient to assess the effect of the foods studied – fruit, vegetables, wholemeal products, legumes, potatoes, soya products, meat, and processed meats – on mortality, morbidity, or weight loss among obese individuals.



Kevin Summers

be more reasonable to try another approach.

MANY QUIT

People often fail to follow the advice of health services. Individuals may have poor motivation, become frustrated from not losing weight, or feel that the new diet does not suit them for some reason – it is unappetising, they feel worse, the ingredients are expensive or difficult to find, or the new diet differs too much from the one they are used to.

Price is one of the factors that influences our food purchases. Since obesity is more common among people of lower economic means, problems can arise from offering dietary advice that would increase food costs. For instance, according to SBU's

calculations, low carbohydrate diets are more expensive than low fat diets.

Obesity has become common, particularly in groups of lower social and economic means. In Sweden, self-reported obesity is more than twice as common among those with low education compared to those with high education; 17% versus 8% in women and 16% versus 7% in men in 2011. According to Statistics Sweden (SCB), self-reported obesity is also more common among the unemployed than among working professionals, among labourers than among mid- and high-level administrators, and among people with narrow margins for handling unexpected expenses.

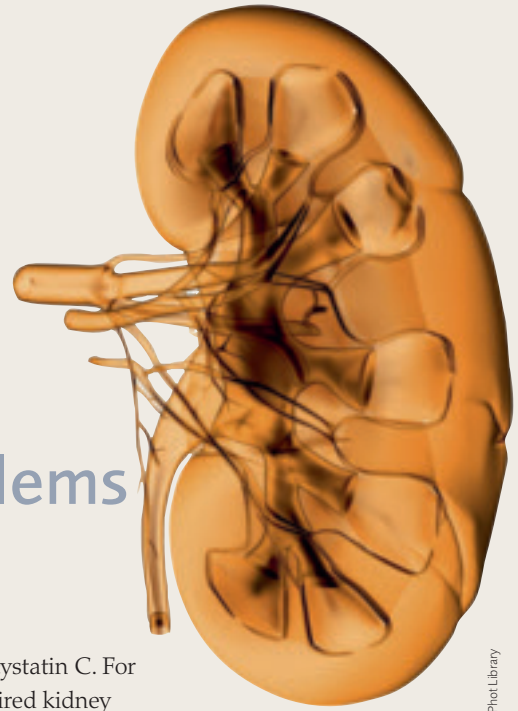
DOUBLED

The prevalence of obesity among adults in Sweden has more than doubled since the

1980s. The most recent information suggests that this trend is not abating. Similar trends can be seen in children, even though some studies suggest that the prevalence of childhood obesity has levelled off in recent years.

A diet that has received much attention recently is 5:2 intermittent fasting where dieters sharply lower their energy intake two days per week, but eat normally the other five days. The aim is to reduce total energy intake, assuming that people do not eat more than usual on the days they are not fasting. The principles of the 5:2 diet can be combined with any of the other diets that SBU studied. SBU did not find any long-term studies of obese people on the 5:2 diet that met the same standards as other studies in the report. [RL]

Combined Test Accurately Targets Suspect Kidney Problems



SciencePhotoLibrary

Testing either creatinine or cystatin C in blood usually gives an adequate estimate of kidney function. If greater accuracy is needed, both substances can be analysed. This is particularly useful in children and in adults suspected of having impaired renal function.

Kidney function cannot be measured directly. Instead, the concentration of different markers in blood must be analysed. But the most appropriate method to use in a given situation is not clear. Opinions differ. Consequently, SBU reviewed the question.

The answer is that creati-

nine and cystatin C usually work equally well. But looking only at the levels in plasma is insufficient. Instead, an equation is needed that uses the concentrations to estimate renal function. When using creatinine, the equation must factor in, e.g. age and sex, and occasionally weight and height, to achieve accuracy equal to cystatin C.

COMBINED TEST

In children, and in adults where there is reason to suspect impaired kidney function, a more accurate estimate may be needed. Then it is best to use an equation to combine the analytical results for

creatinine and cystatin C. For suspected impaired kidney function the combination is probably cost effective.

According to SBU, practices in Swedish laboratories need to be more uniform. For example, test results from different laboratories may need to be compared in the patient's medical record.

Endogenous creatinine clearance is a method that should be phased out since it overestimates renal function. [RL]

About the Report

Methods to Estimate and Measure Renal Function (2012). Project Director, SBU: Ingegerd Mejäre, mejare@sbu.se. Find the full report with conclusions and summary at www.sbu.se.

FROM SBU'S REPORT | ESTIMATING RENAL FUNCTION

► Equations based only on the plasma concentration of creatinine or cystatin C generally estimate kidney function with sufficient and equal accuracy, but are underutilised.* Equations based on cystatin C alone are generally accurate, while creatinine-based equations, to be equally accurate, must include, e.g. age and sex and at times even weight and height.

► The mean value of estimated

glomerular filtration rate (GFR) based on both creatinine and cystatin C is more accurate than equations based on either, which is not widely known. This applies especially to adult patients with low GFR and to children.

► In people older than 80 years of age, the so-called "revised Lund-Malmö equation" can be used, but it is uncertain whether equations using cystatin C alone or the mean value of both mark-

ers combined offer sufficiently accurate estimates.

► When impaired kidney function is suspected, combining creatinine and cystatin C in estimating GFR is probably more cost effective than using only one of the methods.

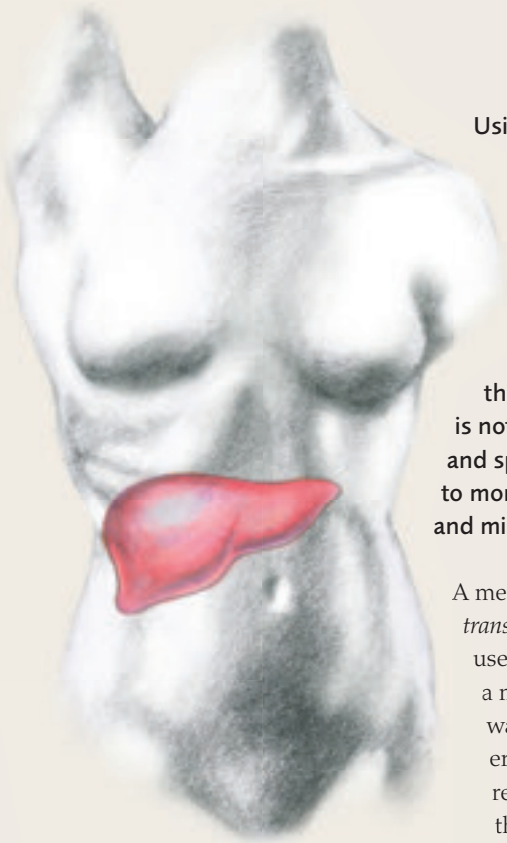
► Laboratories should report estimated GFR, i.e. a measure of kidney function, instead of reporting just the creatinine value.

► Swedish laboratories currently use several analytical methods and equations to estimate GFR. Greater uniformity is desirable.

► Endogenous creatinine clearance is a method that overestimates GFR and should be phased out.

*When creatinine is used, muscle mass and meat intake should be considered, and when cystatin C is used, medications with corticosteroids should be considered.

Liver Damage – New Method Less Accurate but Less Painful



Science PhotoLibrary

Using elastography to assess the liver is easier, less risky, and less painful than liver biopsy. But the new method is not as sensitive and specific, leading to more false alarms and missed cases.

A method called *transient elastography* uses ultrasound and a mechanical pulse wave to assess liver damage. SBU's review shows that the new method accurately confirms or rules out severe liver damage from chronic hepatitis.

LESS PAIN

Needle biopsy of the liver still yields more accurate findings on which to establish a diagnosis. The disadvantage of biopsy is that it causes pain, and patients must remain in hospital for 4 to 6 hours to enable detection of potential complications. Elastography is easier and involves lower risk and less pain. An advantage of biopsy is that it measures not only excess fibrous connective tissue (fibrosis), but it can also reveal other liver diseases.

Ann-Sofie Duberg, senior consultant at the department

of infectious disease, Örebro University Hospital, participated in the SBU review. She describes elastography as a complementary procedure that makes it possible to avoid some biopsies.

– During the year that we used the new method, the number of liver biopsies at the department decreased. Previously we did several biopsies per week, but now just a couple per month, explains Ann-Sofie Duberg.

Patients with chronic hepatitis can develop fibrosis. Hepatitis C is the most common cause, followed by hepatitis B and alcohol abuse.

EASIER TO CHECK

– Up to now we've used tissue biopsy to follow up on patients every three to five years. The new method makes it easier to check the liver more frequently, if necessary.

Elastography has a lower cost per examination, but the effect on total cost remains uncertain. [AB]

FACTS

- Examining the liver using transient elastography is simpler, less risky, and less painful than taking a tissue sample: liver biopsy. However the method is not equally sensitive or specific, and therefore leads to somewhat more frequent false alarms and missed cases than tissue sampling. This applies to liver disease caused by hepatitis C, hepatitis B, and fatty degeneration of the liver due to alcohol.

No definite conclusions can be drawn regarding the applicability of the method with non-alcohol-related fatty degeneration of the liver. If we disregard that the method is not as sensitive or specific, annual examinations using transient elastography appear to be a cheaper and less painful alternative to a liver biopsy performed every three years. To calculate the method's cost effectiveness, the costs of the examination must be considered in relation to how the accuracy of the method affects survival, quality of life, and future healthcare costs.

About the Report

Transient Elastography With Suspected Fibrosis and Cirrhosis of the Liver (2012). SBU's report has been produced in collaboration with the Centre for Assessment of Medical Methods in Örebro (CAMTÖ). Find the report at www.sbu.se.

Special Teams Better Than Standard Acute Care for Frail Elderly

Improving emergency care for elderly patients is a key issue. A recent SBU assessment shows that geriatric patients benefit when multidisciplinary teams manage emergent care.

When health and social services for the elderly are well-structured, they function better than standard care – given that a multidisciplinary team takes responsibility not only for the acute phase, but also has direct responsibility for ongoing patient care.

This finding resulted from SBU's review of research on the comprehensive geriatric assessment (CGA) model, an approach described in the international literature as early as 1946. Under this type of approach, elderly individuals achieve better basic functional capacity than under standard care. Their potential for remaining at home after hos-

pitalisation also increases. The structured approach is equal to or better than standard care when it comes to avoiding re-hospitalisation, and is equal to standard care when it comes to the ability of elderly people to engage in more complex everyday activities. However, no difference was found in mortality.

COMPREHENSIVE

The care event begins with a comprehensive geriatric evaluation by a team of physicians, nurses, occupational therapists, physiotherapists, and others as needed. The aim is to base care interventions and follow-up on a holistic evaluation – not simply on medical conditions.

The team describes the patient's health history, functional capacity, cognitive and mental condition, and oral and nutritional status. The patient's personal experiences

and perceptions should also be included from the outset, before planning interventions and follow-up.

The process requires ongoing follow-up and regular team conferences, which can be time consuming depending on the complexity of the patient's situation.

COST EFFECTIVE

Analyses by SBU suggest that integrated CGA initially involves an increase in costs, but the model can be cost effective in the long term.

Patients above 65 years of age account for over 40% of all visits to hospital emergency departments, and in many cases the elderly patient remains in the hospital.

Throughout Sweden, various models have been tested to improve the care and flow of elderly patients seeking emergency care. [RL]



Ed Horowitz

About the Report

Comprehensive Geriatric Assessment and Care of Frail Elderly. A Systematic Review (2013).

Project Director, SBU: Sten Anttila antilla@sbu.se. Chair: Sven Oredsson. Find the full report and summary at www.sbu.se.

MEDICAL SCIENCE & PRACTICE

QUARTERLY NEWSLETTER OF SBU • CIRCULATION: 157000 (3000) • ISSN 1104-1250
EXECUTIVE EDITOR: *Ragnar Levi*, levi@sbu.se • TEXT: *Ragnar Levi [RL]*, *Anna Björklöf [AB]*
• PUBLISHER: *Måns Rosén* • MAILING ADDRESS: P.O. Box 3657, SE-103 59 Stockholm, Sweden
• PHONE: +46-8-412 32 00 • www.sbu.se • registrator@sbu.se
ENGLISH ADAPTATION: *Ron Gustafson* • DESIGN: *Nilla Westin*



SOME CURRENT SBU PROJECTS

WORK ENVIRONMENT & BACK PROBLEMS

Contact: hall@sbu.se
Expected publ: Fall 2014

WORK ENVIRONMENT & CARDIOVASCULAR DISEASE

Contact: hall@sbu.se
Expected publ: Fall 2015

SUICIDE RISK ASSESSMENT

Contact: odeberg@sbu.se
Expected publ: Spring 2016

DRUG THERAPY FOR BIPOLAR DISORDER

Contact: nilsson@sbu.se
Expected publ: Spring 2014

DEPRESSION IN THE ELDERLY

Contact: ulf.jonsson@sbu.se
Expected publ: Winter 2014/15

DYSLEXIA IN CHILDREN & ADOLESCENTS

Contact: stenstrom@sbu.se
Expected publ: Fall 2014

PREVENTING DRUG ABUSE IN CHILDREN & ADOLESCENTS

Contact: petersson@sbu.se
Expected publ: Winter 2015/16

NON-INVASIVE PRENATAL TESTS: TRISOMY 21, 18, 13

Contact: arnlind@sbu.se
Expected publ: Fall 2014

DRUGS FOR THE ELDERLY: BENEFITS VS RISKS

Contact: vitol@sbu.se
Expected publ: Spring 2014

FOOD SUPPLEMENTS FOR MALNOURISHED ELDERLY

Contact: anttila@sbu.se
Expected publ: Spring 2014

LOW-LEVEL LASER FOR NECK PAIN

Contact: nilsson@sbu.se
Expected publ: Spring 2014

HARD-TO-HEAL WOUNDS IN THE ELDERLY

Contact: odeberg@sbu.se
Expected publ: Fall 2014

POSTMORTEM IMAGING

Contact: hultcrantz@sbu.se
Expected publ: Fall 2014

SBU Board of Directors

Nina Rehnqvist (Chair)
KAROLINSKA INSTITUTET

Ingrid Burman
THE SWEDISH DISABILITY FEDERATION

Ulrika Johansson
SWEDISH ASSOCIATION OF LOCAL AUTHORITIES AND REGIONS

Björn Klinge
KAROLINSKA INSTITUTET, MALMÖ UNIVERSITY

Kerstin Nilsson
SWEDISH SOCIETY OF MEDICINE

Sven Ohlman
NATIONAL BOARD OF HEALTH AND WELFARE, STOCKHOLM

Jonas Rastad
REGION SKÅNE COUNTY COUNCIL

Sineoa Ribeiro
THE SWEDISH ASSOCIATION OF HEALTH PROFESSIONALS

Måns Rosén
SBU

Håkan Sörman
SWEDISH ASSOCIATION OF LOCAL AUTHORITIES AND REGIONS

Mats Ulfendahl
SWEDISH RESEARCH COUNCIL

Marie Wedin
THE SWEDISH MEDICAL ASSOCIATION

SBU Executive Director

Måns Rosén

SBU Scientific Advisory Committee

Kjell Asplund (Chair)

Kristina Bengtsson Boström
BILLINGEN MEDICAL CENTRE, SKÖVDE

Christina Bergh
DEPARTMENT OF OBSTETRICS & GYNAECOLOGY, SAHLGRENKA UNIV HOSPITAL, GOTHENBURG

Anna Ehrenberg
SCHOOL OF HEALTH & SOCIAL STUDIES, DALARNA UNIVERSITY, FALUN

Nils Feltelius
MEDICAL PRODUCTS AGENCY, UPPSALA

Mats G Hansson
CENTRE FOR RESEARCH ETHICS & BIOETHICS, UPPSALA UNIVERSITY

Sten Landahl
DEPT OF GERIATRICS, SAHLGRENKA UNIV HOSPITAL, GOTHENBURG

Margareta Möller
SCHOOL OF HEALTH & MEDICAL SCIENCES, ÖREBRO UNIV HOSPITAL

Joakim Ramsberg
SWEDISH AGENCY FOR HEALTH AND CARE SERVICE ANALYSIS

Bo Runeson
DEPT OF CLINICAL NEUROSCIENCE, KAROLINSKA INSTITUTET, STOCKHOLM

SBU Alert Advisory Board

Jan-Erik Johansson (Chair)
DEPT OF UROLOGY, ÖREBRO UNIVERSITY HOSPITAL

Christel Bahtsevani
HEALTH & SOCIETY, MALMÖ UNIVERSITY

Lars Borgquist
GEN MED & HEALTH ECON, LINKÖPINGS UNIV

Per Carlsson
DEPT OF MEDICAL & HEALTH SCIENCES, LINKÖPING UNIVERSITY

Björn-Erik Erlandsson
ROYAL INSTITUTE OF TECHNOLOGY, STOCKHOLM COUNTY COUNCIL

Mårten Fernö
EXPERIMENTAL ONCOLOGY, LUND UNIVERSITY

Lennart Iselius
VÄSTMANLAND COUNTY COUNCIL

Eva Lindström
DEPARTMENT OF NEUROSCIENCE, UPPSALA UNIVERSITY HOSPITAL

Ylva Nilsagård
CENTRE FOR HEALTH CARE SCIENCES, ÖREBRO COUNTY COUNCIL

Viveca Odling
MEDICAL PRODUCTS AGENCY, UPPSALA

Jenny Rehnman
NATIONAL BOARD OF HEALTH AND WELFARE, STOCKHOLM

Anders Rydh
RADIATION SCIENCES, UMEÅ UNIVERSITY HOSPITAL

Lars Sandman
SCHOOL OF HEALTH SCIENCES, UNIVERSITY OF BORÅS

Svante Tvetman
FACULTY OF HEALTH SCIENCES, UNIVERSITY OF COPENHAGEN, HALLAND HOSPITAL, HALMSTAD

Reports, news
and more at
www.sbu.se