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Taking Charge of Public Health

Many political decisions affect the health of the population, either directly or indirectly. But such decisions rarely consider medical consequences. Decision-makers are poorly informed about public health impacts.

The media and experts often stress what individuals can do to prevent disease and lead healthier lives.

Denny Vågerö, Professor of Medical Sociology at Karolinska Institutet and Stockholm University, argues that health is not only an individual quality but also collective in nature.

– Health and resistance to disease are also affected by the environment and people's life situation, he explains.

Listen to the Silence

Have you read about the man who collected silences? The protagonist in "Murke's Collected Silences," a short story by German writer Heinrich Böll, is a radio technician who makes an audiotape consisting of pauses during the rantings of self-important thinkers. When the hard-pressed Murke comes home at night, he listens to his spliced tape of "collected silences".

SBU has been assigned to do something similar. The agency is to examine reviews of the literature in different clinical areas and "collect" knowledge gaps. In collaboration with other national and regional agencies and organisations, SBU will construct a database of healthcare areas that have been inadequately researched and that are in great need of additional scientific knowledge about effects. You might call it a collection of scientific silences.

There are two reasons for identifying knowledge gaps. The first reason is to prevent methods whose benefits, risks and costs are insufficiently known from spreading uncontrollably in clinical practice. The second reason is to permit clinical research money to be channelled into the areas where it is most needed.

Whenever knowledge gaps are considered, it is important not to confuse insufficient evidence with insufficient effectiveness. Just because a method has been inadequately studied doesn't mean that it is ineffective. And it would be unreasonable to demand scientific evidence for each and every procedure that the healthcare system performs. Clinical practice would come to a halt if every step taken had to be corroborated by research.

The simplest option would be to allow the unrestricted use of any method that enough experts advocate and persuade healthcare professionals to adopt. A thousand flowers would bloom, effective treatments would no longer be the least bit delayed, and poor methods would eventually be driven out of competition by better options – a kind of natural selection process. It might sound good, but the price would be very high.

First, many patients would fall victim to ineffective or harmful measures. Numerous methods that have been introduced on the basis of expert hypotheses (or hubris) have harmed patients instead of helping them. The adverse effects did not become obvious until clinical trials had been conducted. Despite all of our technological advances, noble intentions do not ensure desirable results.

Second, healthcare resources are scarce. Introducing methods of unclear value inevitably shortchanges other interventions which are effective.

Third, it is often difficult to discard methods once they have been incorporated into routine clinical practice. Traditional approaches linger on even when all the available research refutes their benefits.

Choosing the best documented first-line treatments is not only reasonable, but wholly necessary. Meanwhile, methods that are promising but have been inadequately studied deserve further research.

RAGNAR LEVI, EDITOR

– When many people are exposed to the same risk factor in a common setting, a public health problem emerges.

The culprit can be anything from poor food hygiene and protection against infection to unhealthy workplaces.

BEYOND CONTROL

According to Prof Vågerö, many such health risks are beyond the control of individual citizens. In such cases, society must assume responsibility, either directly or indirectly, for minimising the risks and strengthening people's resistance.

– Public policy decisions, legislation and a number of other tools for improving public health are in the hands of society as a whole. Society can also provide health education and take other measures that target individuals or groups.

What is really known about the results of such initiatives to improve public health? How effective are various methods, and what demands for scientific evidence are reasonable to apply to them?

– Obviously we need to establish clearer criteria for assessing preventive initiatives, even with respect to interventions at the community level, says SBU Director and Professor of Epidemiology Måns Rosén.

SPECIAL PROBLEMS

– But assessing public health initiatives gives rise to special problems. Only rarely can you use the research approaches that have been designed for assessing medical treatments.

– One difficulty is that cancer, cardiovascular disease and many of the other maladies we want to prevent develop over such a long period of

time. Follow-up is tricky. Randomised trials would require very large study populations and decades of follow-up before they could demonstrate statistically reliable effects of lifestyle changes.

Prof Rosén offers an example. Although smoking causes many serious and fatal diseases, randomised trials had great difficulty demonstrating the impact of smoking cessation on cancer, chronic obstructive pulmonary disease, allergies, hip fracture and periodontitis. Cohort and other observational studies were needed to show that smoking cessation reduces morbidity and mortality.

THEIR OWN MOMENTUM

– Another methodological issue is that randomised trials concerning public programmes to affect lifestyles frequently gather a momentum of their own.

– If you try to change the study group's dietary habits, encourage subjects to be more physically active and convince them to quit smoking, the control group is often affected as well. As a result, the efficacy of such interventions is underestimated. Genuine differences between the two groups may also be blurred by general social trends that affect both of them. The problem is aggravated if the interventions target large population groups, says Prof Rosén.

– Furthermore, measures to improve lifestyle can also affect family members who are not participating in a study. The study does not reflect the benefits they receive.

Another difference from the assessment of treatment methods is that researchers may have to use surrogate outcomes.

– If you're evaluating something like smoking cessation methods, measuring the impact on risk behaviour such as smoking habits may be the most reliable approach, given that the effect on morbidity and mortality can be distorted by all the confounders in the social and physical environment.

Prof Vågerö points out that public health is affected by many factors other than initiatives that specifically target it.

– A host of legislative decisions impact public health: labour, education, social, fiscal, agricultural policy, and so on.

UNKNOWN EFFECTS

– But the political pundits forget that anything affecting education, employment, living conditions, family life, personal finances or lifestyle can have medical consequences. The problem is that the effects are unknown, or are ignored. The evidence is weak, and the available knowledge about various correlations has not been properly disseminated.

Arguing that policymakers should give greater priority to the health of the general population, Prof Vågerö calls for a parliamentary inquiry.

– My impression is that there is a tremendous lack of awareness about these issues, even though the Maastricht Treaty committed the EU to evaluate the repercussions of its policy decisions on public health.

– We need an evidence-based discussion between researchers and public officials. In my opinion, too few politicians regard the impact of their decisions on public health as particularly important.

– Keep in mind that we're talking about policies that literally change our lives. [RL]

Additional reading

www.nice.org.uk/Guidance/PHG/Published

Public Health Portal of the European Union http://ec.europa.eu/health-eu/

Swedish Association of Local Authorities and Regions. Vård på (o)lika villkor [Health Care on (In)Equal terms] (in Swedish). Stockholm: Swedish Association of Local Authorities and Regions, 2009.

National Board of Health and Welfare. Folkhälsorapport 2009 [Public Health Report 2009] (in Swedish). Stockholm: National Board of Health and Welfare, 2009.

Commission on Social Determinants of Health. CSDH final report: Closing the Gap in a Generation: Health Equity through Action on the Social Determinants of Health. Geneva: World Health Organization, 2008.

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WHAT IS PUBLIC HEALTH?

- The concept of public health refers to a population's total state of health, measured as both the average and overall distribution.
- Major health inequalities in the population are deemed inconsistent with good public health. One goal of the EU Public Health Programme 2008–2013 is to narrow such gaps.
- According to the National Public Health Report 2009 of the Swedish National Board of Health and Welfare, health is unevenly distributed in Sweden.
- According to the report Vård på (o)lika villkor (Care on [Un]equal Terms) issued by the Swedish Association of Local Authorities and Regions in 2009, healthcare resources are distributed in a way that "is nearly always to the detriment of the socially disadvantaged."
- Public health initiatives focus on both preventing disease and promoting health for the entire population.
- Article 129 of the Maastricht Treaty accords public health a central role in the activities of the EU.
- In 2008, WHO's Independent Commission on Social Determinants of Health urged governments to evaluate the impact of their policies and initiatives on health inequalities.

Gary Chapman / Getty

Evidence: Eight Critical Questions and Answers

What are the scientific criteria to which healthcare methods should be subject? The same questions arise whenever best practice is discussed. Professor Nina Rehnqvist, Chair of the Board of SBU, and Professor Ania Willman, member of the SBU Scientific Advisory Committee, offer their views.

1. RANDOMISED TRIALS AND SUBSEQUENT META-ANALYSES ARE OFTEN REGARDED AS MORE IMPORTANT THAN OTHER STUDIES? IS THAT A REASONABLE VIEW?

AW: The question to be addressed should determine the study design. When the efficacies of various treatment methods are to be compared, randomisation to a study and control group is an appropriate design because it can yield reliable results. But other designs may also be useful – randomisation is unsuitable when examining health hazards and rare adverse effects.

NR: While not all health technologies are amenable to randomised trials, treatment methods nearly always are. But it is important to keep in mind that a study is not necessarily well-conducted just because it is randomised. Only good quality studies should be subject to meta-analysis.

2. LARGE, EXPENSIVE CLINICAL TRIALS ARE TYPICALLY SPONSORED BY THE PHARMACEUTICAL INDUSTRY, GENERALLY THE MOST PROFITABLE SEGMENTS. DO YOU SEE A DANGER THAT ONLY COMMERCIALLY PROMISING METHODS WILL BE EVIDENCE-BASED, WHILE THOSE THAT HAVE NOT BEEN EXAMINED WILL BE BRANDED AS UNSCIENTIFIC?

AW: Yes, there is a clear danger. That's why it's so important that there be other sponsors, such as the government and various foundations. They provide a vital counterweight to commercial interests.

NR: No doubt about the danger. Sponsors like the National Institutes of Health (NIH) at the U.S. Department of Health and Human Serv-

ices make an important contribution in that regard. Europe has no equivalent agency as yet.

3. SOMETIMES YOU GET THE IMPRESSION THAT EVIDENCE REPRESENTS THE ONLY SCIENTIFIC DATA THAT ARE NEEDED. ISN'T THERE OTHER INFORMATION THAT IS EQUALLY IMPORTANT?

AW: Clinical evidence is scientific proof that a method has the intended effect, not a demonstration of how the effect is achieved. The clinical trials that constitute the available evidence are rarely designed to shed light on modes of action. But hypotheses or knowledge about modes of action are frequently the starting point for researchers when they design clinical trials.

NR: As a tool for clinical decision-making, evidence focuses on symptoms, mortality and quality of life, usually in relation to costs. But evidence-based data cannot resolve every issue that comes along. It goes without saying that other information is also required, including research about aetiology, the effect of a treatment on various physical and mental functions, and patient experience of living with a disease. The concept of evidence encompasses benefits, harms and resource utilisation, not modes of action – even though you catch an occasional glimpse of them.

4. IS THE PURPOSE OF EVIDENCE-BASED DATA TO ESTABLISH UNIVERSAL TRUTHS THAT ARE APPLICABLE TO ALL PATIENTS, REGARDLESS OF THEIR PARTICULAR CIRCUMSTANCES?

NR: No, not universal truths, but conclusions that are generally applicable to large numbers of patients. Although all patients are unique, they also share similarities and common denominators. Still, whenever we use evidence in clinical practice, we must consider individual circumstances.

AW: My experience is that authors of systematic reviews of the literature are often more scrupulous than others when it comes to evaluating the contexts to which studies apply and potential selection biases in study populations.

When implementing general conclusions based on observations of many individuals, we must consider variations. Evidence cannot be applied mechanically to clinical practice.

5. SOMEBODY HAS CONTENDED THAT THE CONCEPT OF EVIDENCE HAS BEEN "HIJACKED" BY HEALTHCARE BUREAUCRATS WHO WANT TO CURB THE INDEPENDENCE OF CAREGIVERS. WHAT DO YOU THINK?

NR: Nonsense. Evidence is there for all caregivers, and everyone has the professional responsibility to apply evidence-based data. If the result is standard practice that even bureaucrats can be happy about, so much the better.

AW: Healthcare bureaucrats still prioritise an economic rather than a knowledge paradigm. The purpose of evidence-based data is not to limit caregiver independence, but to provide a more reliable basis on which patients and caregivers can make well-informed decisions about the methods that are likely to be effective in a particular situation. The ultimate objective is to give patients access to effective methods and discard those that may be harmful, unnecessary or exorbitantly expensive.

6. IS THERE A DANGER THAT EVIDENCE-BASED DATA WILL LEAD PATIENTS TO BE REGARDED AS OBJECTS RATHER THAN HUMAN BEINGS WITH PARTICULAR DISEASES?

AW: Quite the contrary. Knowledge of the evidence makes for a more confident caregiver who can bring additional information to bear when helping patients and their families. Any method or treatment is based on a hypothesis about its particular value. In the absence of evidence, we make these assumptions on the basis of our clinical impressions. Such experience-based knowledge proceeds from a hypothesis as well, even if it is not explicit in common parlance.

NR: Any doctor or other professional caregiver who disregards evidence is a charlatan. Only with evidence as your foundation can you take an empathetic, value-oriented and individual approach to your patients.

7. ISN'T EVIDENCE DUBIOUS AND IRRELEVANT WHEN IT CONCERNS METHODS THAT ARE COMPLEX AND COMMUNICATION-BASED, SUCH AS PSYCHOTHERAPY?

AW: Not necessarily. But a clinical setting demands more than just evidence or other scientific information. Experience, a wide variety of skills and abilities, and understanding of a patient's situation and circumstances are also vital. Evidence-based health care is the sum of all these ingredients.

NR: If you are going to allege a positive effect, it's only reasonable that you be required to demonstrate it as well. It may certainly be difficult to pinpoint the most effective components of psychotherapy or another complex method. But the contention that a particular type of therapy is effective calls for credible evidence.

8. ISN'T THERE A LACK OF CLARITY ABOUT THE LIMITS OF EVIDENCE-BASED DATA, SUCH AS THEIR APPLICABILITY TO MIXED POPULATIONS?

AW: Yes, I think that's right. Evidence isn't the whole truth, and it won't take you very far all by itself. Evidence can point in the right direction. It is particularly important when putting together clinical guidelines, mostly to set a standard for good care of as many patients as possible.

NR: Context frequently makes a difference, including the people who use the method, and the way that they use it. For instance, it has been argued that skilful doctors may obtain poorer results in an unaccustomed setting even if they rely on evidence-based approaches. The choice of method is often but not always the key issue.

[RL]

Evidence Can Stretch Your Bucks

An ageing population and tighter health budgets are rendering expensive methods less affordable. So how will healthcare be financed going forward? Evidence is a making our money last longer.

Hard times limit caregivers' options. But if the economy improves, both the Swedish and international healthcare systems will need to set stricter priorities as time goes on.

Evidence has an important role to play in that effort. When health care is built on the firmest possible scientific foundation, resources can be redistributed for more efficient use. Despite financial restrictions, opportunities for employing expensive methods may emerge.

GROWING IMPORTANCE

– Scientific assessment with its emphasis on useful evidence is likely to grow in importance as a way of supporting decision-makers and informing clinical practice, says Egon Jonsson, founder of SBU in the mid-1980s and current Director and CEO of the Institute of Health Economics in Alberta, Canada.

– Evidence both improves healthcare quality and reduces costs, he says.

The most recent economic report of the Swedish Association of Local Authorities and Regions estimates that an additional SEK 15 billion is needed to meet the needs of an ageing population in 2011. According to the Association, ongoing cost-effectiveness measures will be necessary but not sufficient to confront the challenge.

ROUGH TIMES AHEAD

Long-term prospects are even more uncertain. Anders Klevmarken and Björn Lindgren, Professors of Health Economics at Uppsala University and Lund University, have outlined a conceivable scenario that stretches to 2040.

"Healthcare costs will rise by 270 per cent as the baby boomers age. That translates to 36 per cent of total tax revenue, as opposed to 20 per cent currently," they write in a 2008 report.

And Sweden is not unique in this regard. WHO stresses that healthcare systems throughout the EU face a series of challenges posed by higher costs.

Michael Drummond, Professor of Health Economics at the University of York, argues that all countries will encounter the need for cutbacks.

– Healthcare costs will outpace inflation, while national budgets will struggle to keep up with it. If budgetary constraints are to be met, patients will have to be denied some treatments.

According to Prof Jonsson, there are number of options for economising on healthcare resources, but the use of evidence is one of the most humane.

– Evidence never harms a patient, but is just and equitable. Other approaches, such as limiting national healthcare costs to an arbitrary amount, lead to heavy cutbacks that unfairly affect certain groups.

FREEING UP RESOURCES

A number of SBU reports have shown that evidence-based health care frees up resources for more efficient use elsewhere.

Treatment of mild head injury provides an excellent illustration. A 2000 SBU report found that research had been insufficient when it came to determining which of two alternatives was better for the patient: in-hospital observation or a new strategy of computed tomography and early return home.

A randomised multicentre study launched by SBU and published in 2006 showed that the two alternatives produced the same medical results. The report found that the new strategy could reduce total costs by one third. That would free up SEK 40 million

Karl Gabor

annually to be used elsewhere in the healthcare system.

Prof Drummond also believes that health technology assessment will play a greater role in the future.

– Decision-makers rely increasingly on evidence, which is becoming a control mechanism for the system as a whole rather than a valuable but optional tool, he says.

INTEGRAL PART

Prof Jonsson says that evidence will be integral to determining which patients are offered new treatment methods as they become available.

– New technologies are constantly emerging, and nearly all of them are effective, but not for everyone. The patients who stand to benefit the most must be identified. Given that Swedes have grown accustomed to the concept of equality and universal access to the same care, individual assessments will be more important than in many other countries, he says.

MINIMAL BENEFITS

Even if a method should not be as widely used as the manufacturers suggest, may be worthwhile for particular patients, Prof Drummond points out.

– Some methods that are not particularly cost-effective are not covered by the British healthcare system, but patients may still pay for them out of their own pockets. The idea is to use resources more efficiently but not waste them on methods that provide only minimal benefits, he says.

BUDGET CONSTRAINTS

According to Prof Drummond, the industrialised countries fall into different categories. Some of the countries, including the UK and Sweden, draw up a limited healthcare budget for a specific period of time and are bound by those constraints when making policy decisions. Countries like the United States, and to some extent Germany, are more

Image Republic

SWEDISH HEALTHCARE FIGURES AT A GLANCE

- Total expenditure on health, % of gross domestic product: 9.1 per cent
- Pharmaceutical expenditure, % of total expenditure on health: 12.7 per cent
- Acute care beds, density per 1,000 population: 2.1
- Total acute care beds: 19,309
- Care events per 100,000 population: 16,481

Source: OECD Health Data, June 2009
The data is for 2007

Additional Reading

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Thomson S, et al. Financing health care in the European Union: challenges and policy responses. World Health Organization 2009. Download from www.euro.who.int/document/E92469.pdf

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Norlund A, et al. OCTOPUS Study. Immediate computed tomography or admission for observation after mild head injury: cost comparison in randomised controlled trial. BMJ 2006;333:469.

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flexible about how much can be spent during various periods.

– Healthcare costs are skyrocketing in the United States. Funding the system over the next ten years remains an uncertain proposition, says Prof Drummond.

President Obama is trying to reform the system. His plans include a USD 1.1 billion appropriation for Comparative Effectiveness Research (CER).

CER is a new term for the kind of health technology assessment that SBU and other European organisations already conduct.

– The United States will invest a great deal of money in assessment studies. But how the results will be used remains unclear. The U.S. system has no mechanisms for limiting health care on the basis of evidence. My sense is that reform of the system will proceed slowly, partially because lobby groups are so strong there, says Prof Drummond.

AVOIDING DISCUSSION

Prof Jonsson believes that the real purpose of CER is to economise on resources while improving the quality of health care. However, the Obama administration has been avoiding discussion of cost-effectiveness because many institutions and members of Congress do not want to associate cost-containment with healthcare reform.

– CER will be wholly oriented toward clinical effects for the first few years. But policymakers will soon realise that they can't get any further without reviewing the economic repercussions of health care. So resource utilisation will soon be incorporated into CER. The third step will be revamping overall healthcare policy, he says.

Prof Jonsson also stresses the importance of not viewing evidence-based care initiatives as reactionary.

– Evidence must also be used to speed up the dissemination of new methods that offer major patient benefit. The objective of health care is not to save money. Evidence-based care means the use of better and more reliable methods. The result is higher quality, often followed by the more efficient utilisation of available resources. [CW]

Fast Track Speeds Up Emergency Care

Care at emergency departments speeds up if patients are assigned a triage level upon arrival, to ensure that the most urgent cases are treated first. Separating patients into one track for those who require hospitalisation and another track for those with less serious ailments shortens the average time spent both in the emergency room and waiting to see a doctor.

An SBU review of international research on triage arrived at the following conclusion. Immediately categorising the needs of emergency room patients on the basis of medical urgency and adjusting subsequent treatment accordingly has proven to be a profitable approach that improves patient flow.

Studies have shown that patients see doctors sooner and spend less time at the emergency department when urgency levels are assessed by a team of doctors, nurses, assistant nurses and other healthcare professionals. The method, sometimes referred to as team triage, also ensures that fewer patients spontaneously leave the emergency room before a medical evaluation has been performed.

INSUFFICIENT BASIS

However, SBU concludes that assigning a triage level is an insufficient basis for referring patients to primary care. Although the immediate risk of death is very small among patients in the category with lowest acuity, some of them still need to be hospitalised.

Following the initial triage assessment, subsequent care also goes more quickly if broken down into various tracks or flow processes. This has been most clearly demonstrated for fast-track cases – patients with the least serious ailments who are treated by a separate team of caregivers.

There is some evidence that patients leave the emergency room sooner if lab tests are analysed on the spot instead of being sent off, and if referrals for certain kinds of X-ray examinations are written by specially trained nurses rather than by doctors.

The SBU report identifies knowledge gaps as well. More research is needed before any meaningful conclusions can be drawn about the impact of triage and flow processes on patient health. Furthermore, the extent to which a particular patient will be assigned the same triage level by different healthcare professionals remains unclear. Existing research provides no reliable answers.

COMMONLY USED

The lack of suitable studies makes it impossible to determine the relative advantages and disadvantages of the three assessment methods most commonly used in Sweden: the Medical Emergency Triage and Treatment System (METTS), Adaptive Process Triage (ADAPT) and the Manchester Triage Scale (MTS). [RL]

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Behavioural Therapy or Drugs Help Insomniacs

The first-line approaches for insomnia, a common condition, are lifestyle changes or self-care. Short-term medication or psychological methods are the second-line approach. It is crucial that any drugs prescribed are chosen on the basis of proven efficacy.

A growing number of people suffer from insomnia – the inability to fall asleep or to sleep well, or the tendency to wake up early. The condition is most common among women and the elderly.

A frequent approach to treating insomnia is to provide general advice on proper sleeping habits. That may include trying to establish a regular circadian rhythm, avoiding eating and drinking habits that interfere with sleep, and creating an atmosphere in the bedroom that helps you sleep. But such advice is not always sufficient. SBU has evaluated the international research on methods that may prove successful when self-care fails.

FALL ASLEEP FASTER

Psychological methods represent one good option. There is evidence that cognitive and other behavioural therapy helps patients fall asleep faster and wake up less often. If such methods are to be used on a more widespread basis in Sweden, additional therapists will need to be trained.

Drug therapy is another option. Patients who receive short-term treatment with drugs in the benzodiazepine family tend to fall asleep faster and sleep longer during the course of a night. But such treatment is associated with a certain risk of adverse events and – particularly among those who have a dependence or psychological disorder – dependence.

Demand is growing for herbal remedies, acupuncture, yoga and other alternative methods. However, SBU's report found that the research is insufficient to determine whether or not they are effective.

According to SBU's review, one fourth of Swedish adults have difficulty sleeping. One study found that a significant majority of these people suffer from depression or other underlying ailments.

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DOCTORS BELIEVE

To better understand how insomnia in adults is diagnosed and treated in Sweden, SBU sent a questionnaire to a random sample of 600 general practitioners. The results showed that a large percentage of patients are receiving drug therapy even though their doctors believe that behavioural therapy would have better long-term effect-

iveness. Potential reasons include the fact that relatively few therapists can provide such treatment and that they are unevenly distributed throughout the country.

Both insomnia itself and associated drug therapy can increase the risk for falls among the elderly. While short-term medication is usually recommended, studies of prescription patterns show that many patients – particularly the elderly – are given long-term treatment.

SIGNIFICANT IMPACT

Chronic insomnia can have a significant impact on health and quality of life. For instance, those who suffer from insomnia may have difficulty doing their jobs properly or interacting with others. In other words, preventive methods and successful treatment offer important benefits.

SBU identifies several possible improvements to clinical practice:

- Whenever drugs are prescribed, they should be chosen on the basis of proven efficacy.
- Cognitive behavioural therapy and other psychological methods should be more available.
- Planning and follow-up of treatment, particularly in elderly patients, should improve. It is important to review all conceivable causes and consequences, as well as to monitor how treatment affects the individual patient's ability to function during waking hours. [RL]

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Repeated Self-tests Costly, Benefits Unclear

More frugal use of test strips by type 2 diabetics who are not receiving insulin therapy would probably reduce costs without increasing the medical risks.

SBU's systematic review concludes that self-testing of blood glucose levels with test strips costs the healthcare system approximately SEK 130 million every year. But no direct impact on health has been demonstrated for type 2 diabetics who are not receiving insulin therapy and who test themselves frequently.

BASIS FOR GUIDELINES

The report is one of the documents on which the Swedish National Board of Health and Welfare bases its national guidelines for diabetes care.

After six months of self-testing, blood glucose levels, as measured by the HbA_{1c} value, decreased only slightly. The average reduction for study participants was only 0.26 percentage points. The findings suggest that more frugal use of test strips by type 2 diabetics who are not receiving insulin therapy could lower annual costs by SEK 50–90 million without increasing the medical risks.

RAISE AWARENESS

Self-testing with test strips may be indicated when there are symptoms of low blood glucose levels, disease is acute, treatment has been changed or there is a desire to raise patient awareness about the impact of lifestyle. Self-testing with test strips is necessary for patients receiving insulin therapy. [CW]

Intensive Therapy Start Helps Type 2 Diabetics

Intensive initial treatment of type 2 diabetes to lower blood glucose towards normal levels is effective. The benefit of the approach in people who have had the disease for many years is uncertain.

A strong correlation has been demonstrated between long-term elevation of blood glucose levels among diabetics and organ damage. Thus, lowering blood glucose towards normal levels by means of intensive treatment has been considered important.

SBU has reviewed the research on the benefits, risks and costs associated with intensive treatment of type 1 and type 2 diabetics.

COST-EFFECTIVE

The assessment shows that intensive glucose-lowering therapy reduces the risk of cardiovascular disease and serious retinal damage in recently diagnosed type 2 diabetics. The treatment is cost-effective and relatively simple. The risk of adverse effects is small.

The benefits and cost-effectiveness of intensive treatment are uncertain when it comes to people who have had type 2 diabetes for 5 years and longer.

Mikael Rydén is an Associate Professor of Endocrinology at Karolinska Institutet and a medical expert in the SBU project group.

– The earlier belief was that all type 2 diabetics should receive intensive treatment. The report shows that to be an effective approach at the beginning. But individual treatment goals are more important with people who have had the disease for a long time, he says.

INDIVIDUAL GOALS

SBU concludes that the risks of adverse effects and organ damage must be juggled when setting individual treatment goals.

– Some long-time diabetics can be assigned just as ambitious blood glucose goals as those who have been recently diagnosed. But a somewhat higher average level may have to be accepted among those who experience repeated blood glucose falls or who gain a lot of weight and may have serious vascular disease, continues Prof Rydén.

The fact that not all type 2 diabetics benefit equally from intensive treatment and the question of where to set blood glucose goals have spurred a great deal of discussion over the past year . Newly published studies have failed to demonstrate that intensive treatment for 4–5 years reduces the risk of heart disease among patients who have had diabetes for approximately twice that time. The effect on the risk of kidney disease was small.

– Some effect might have been observed had patients been monitored for 10–15 years. So new studies with long follow-up periods are a matter of urgency, says Prof Rydén.

GUILTY CONSCIENCES

He believes that many doctors have always allowed the blood glucose levels of their patients to rise, but that they used to have guilty consciences about doing so.

– The report demonstrates that they weren't acting unwisely. It is far from certain that the benefits would outweigh the risks if all type 2 diabetics were forced to strive for the same goal.

The SBU report found that the choice of therapy and the risk of blood glucose fall vary in connection with intensive treatment.

– In practical terms, intensive treatment may take a number of different forms. Once a long-term blood glucose goal has been set, various drugs can be used to get there. Insulin or combination therapy may be indicated, not to mention physical activity, frequent consultations and self-testing of blood glucose levels.

Intensive treatment of type 1 diabetics for 7 years signifi-

cantly reduces the risk of organ damage by 2–3 cases out of 10. The reduction for type 2 diabetics is 3 cases out of 100 over 10 years.

– Such a large discrepancy is totally logical. Type 1 diabetes develops at a young age without initial complications. The onset of type 2 diabetes usually comes when patients are older and may have already developed atherosclerosis or eye damage. What's more, type 2 diabetes is often diagnosed long after onset, says Prof Rydén.

The SBU report confirms that current clinical practice is effective when it comes to type 1 diabetes. However, there is room for improvement. The National Diabetes Register shows that quite a few patients fail to reach desired blood glucose levels.

Christian Berne, Professor of Medicine at Uppsala University Hospital and one of the experts in the SBU project, emphasises the importance of the SBU's conclusion that the current treatment strategy should be retained.

GREATER RISK

– Treating type 1 diabetes remains a challenge, he says. The risk of a serious fall in the blood glucose curve increases, which limits the options for intensive treatment.

– Few type 1 diabetics have normal glucose levels over the long run. Falls are often the reason that the average level cannot be lowered very much. Intensive treatment of type 1 diabetics triples the risk that blood glucose will drop to a dangerous level, says Prof Berne. [CW]

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Magnets for Depression Need Further Testing

Some patients with depression may benefit from a new method called transcranial magnetic stimulation (TMS). But the method requires further clinical trials on selected patients. The risk of adverse effects should be monitored in larger studies.

An electromagnetic coil placed against the patient's scalp to stimulate electrical activity in the cerebral cortex may have an antidepressant effect. The new method is currently being tested at several Swedish research centres.

SBU's assessment shows that important questions, including the possibility of memory impairment, remain unanswered. As a result, SBU concludes that there are still grounds for regarding the method as experimental.

IMPROVEMENT POSSIBLE

Some scientific evidence suggests that a number of patients improve or recover to a greater extent than with placebo following 2-5 weeks of treatment with TMS to the left cerebral cortex. However, there is a high risk of relapse. The results apply to patients whom drugs have not helped sufficiently and whose depression is not severe enough to require electroconvulsive therapy (ECT).

There is strong scientific evidence that the most common adverse effects are headache and muscular pain, which abate during the treatment period.

The SBU report concludes that larger studies than those conducted so far are needed to rule out the risk that TMS may affect cognitive function.

[JT]

Drug Helps Restless Legs, Long-Term Effects Unclear

According to a new SBU report, dopamine agonists can relieve the symptoms of restless legs syndrome (RLS). Patients sleep better and experience higher quality of life. But some patients stop taking their medication due to adverse effects, and the long-term benefits and risks have not been established.

The majority of people who suffer from the unpleasant or painful symptoms of RLS manage to get by without medication. But an estimated 2–3 per cent of patients experience so much discomfort that a drug may be indicated.

An evaluation by SBU Alert concluded that dopamine agonists can relieve the symptoms in people whom a thorough assessment has shown to have moderate or severe RLS in the absence of an underlying disease or deficiency.

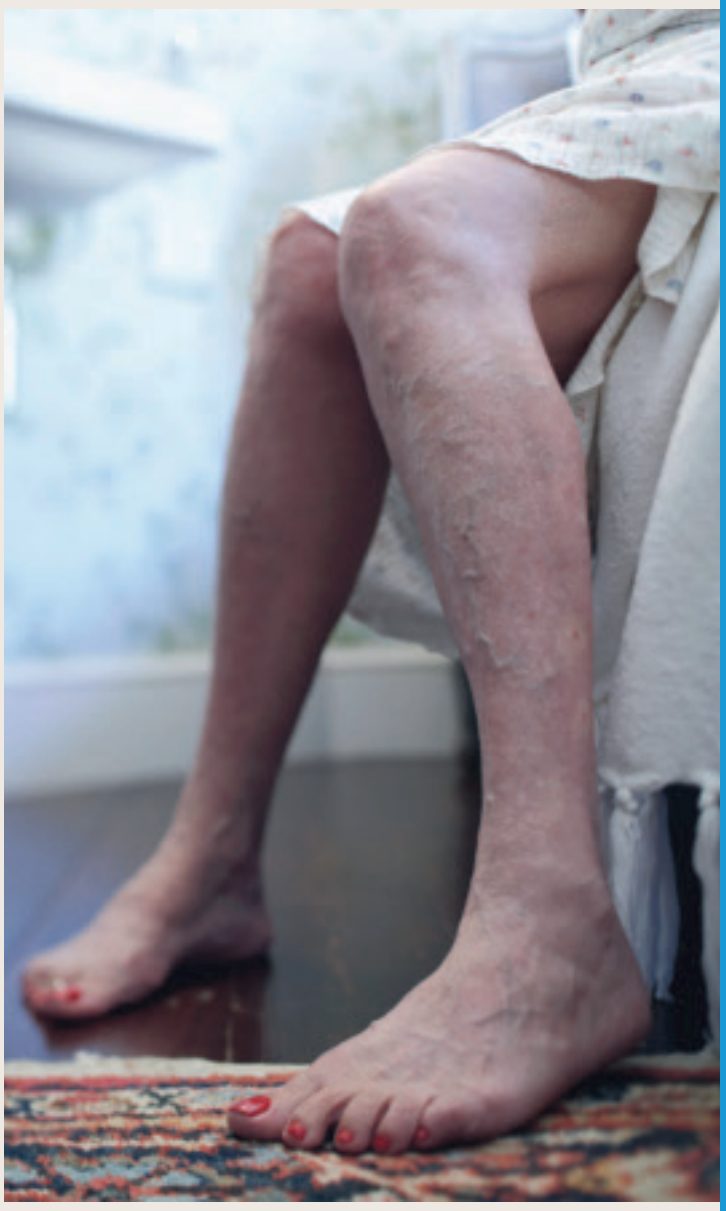
Discomfort in the legs often appears when a person is resting. Patients with moderate to severe symptoms have less trouble sleeping and experience higher quality of life when they take their medication.

ADVERSE EFFECTS

Many patients who start on dopamine agonists soon experience mild or moderate adverse effects, such as nausea. Severe adverse effects may also develop and cause the treatment to be discontinued. No long-term benefits or risks have been established – few studies have lasted for more than three months.

According to the SBU review, levodopa can also improve sleep and quality of life. But the risk of adverse effects is even less well-known than for dopamine agonists. The cost-effectiveness of RLS drugs cannot be assessed either. Too few studies have been conducted.

Initial treatment of mild symptoms includes simple interventions such as avoiding coffee, alcohol and tobacco, or intensive physical exercise right before bedtime. The Swedish Medical Products Agency recommends short-term levodopa therapy for patients who obtain insufficient relief. [RL]



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