

# MEDICAL SCIENCE & PRACTICE

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## The Art of Saying No

Excessive or exaggerated healthcare interventions must decrease. They risk causing harm and draw resources from interventions proven to be effective.

Patients and healthcare providers often focus on what should be done in terms of diagnosis and treatment. But many times it is equally important to know what should *not* be done.

Several countries have taken initiatives to list unnecessary interventions that health services should stop offering. One of the more controversial examples is the *Choosing Wisely* campaign in the United States. It started in 2009, and 60 speciality societies have each proposed five interventions they feel should be discontinued.

The lists of ineffective and inappropriate interventions have received widespread attention, and similar initiatives have been taken in several countries,

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## The Unbearable Lightness of Opinion

They say we live in an information society, but I often wonder if we're not really living in an opinion society. Opinions first, facts later. In the opinion society, facts are considered supplementary. But everyone is always expected to take a stand, and without hesitation. Immediately thumbs up, or thumbs down – acquit or convict.

This results in a deluge of hasty conclusions, not least when it comes to health matters. I need only mention diets, self-testing, screening programmes, and mental disorders. Show me someone who doesn't have an opinion.

In his book *Thinking, Fast and Slow* the Nobel prize winning psychologist Daniel Kahneman describes the human tendency towards drawing hasty conclusions. If we rely solely on our first impression we are much more gullible than we think. Human thinking, according to Kahneman, takes place via two different principles he calls System 1 and System 2. The first is a rapid, more or less automatic, thought process, while the second is slower and more analytic.

System 1 is always in operation. Like a grid over reality it constantly enables quick interpretations. Fast and false – research findings are entirely too complicated. System 2, however, both understands statistics and can question the interpretations of System 1, but it requires both time and conscious reflection. Hence, System 2 is frequently turned off. We rely on the System 1 autopilot.

Realising this is not always easy. When System 1 intuitively believes something, we are inclined to believe that evidence backs it up.

A medical example: Intervening against diabetes is important in preventing cardiovascular diseases, vision disorders, kidney damage, and impaired nerve function in the feet and legs. System 1 says, "Great! It's needed." But when the American Diabetes Association expanded the concept in 2010 to promote a condition called prediabetes the risk arose that System 1 would quickly draw the conclusion, "Yeah, interventions against prediabetes are also good because they too are preventive." That's when we need System 2. As professor emeritus John Yudkin recently noted (BMJ 2014; 349:g4485) it is not at all certain that interventions against prediabetes reduce mortality and morbidity. "This remains to be proven," says System 2. Nevertheless, the concept of prediabetes has disseminated worldwide.

Kahneman's model is important even if the existence of two such distinct systems could perhaps be questioned. He reminds us that we all, not least the experts, love to reinforce our first impressions and prepare to defend them.

In health care this often takes place under the banner of standard practice. Even when we encounter facts that contradict our views it is not certain that we will change our opinions. Psychologists call this confirmation bias, i.e. the tendency to see only the information that supports our assumptions and to shut out opposing views.

The flood of unshakable opinions that submerges existing evidence does not make things easier. Social media offers an easy path to find followers for any and all unfounded opinions. But endorsement is not evidence.



Martin Barrault / Getty

including Canada and Spain. For years, Sweden's national guidelines have included so-called "do-not-do" lists that identify interventions that should not be conducted routinely, or should be completely phased out.

One strength (among others) in *Choosing Wisely* and similar initiatives is that peers within their own specialties have selected the inappropriate interventions. Since the target groups receiving the message have been represented in the groups sending the message, this adds legitimacy and may promote implementation.

### FACTS

Equally important for legitimacy is the accuracy of the underlying facts.

Here, scientific assessment must guide the choices, i.e. the type of systematic reviews conducted by SBU. Otherwise there is a high risk for arbitrary decisions. This applies not only when investing in

health services, but also when disinvesting.

In this regard, *Choosing Wisely* has been questioned. There is uncertainty about how the lists of unnecessary interventions were actually produced, and the critics suggest that the self-interests of speciality societies have taken precedence.

Nancy Morden, Associate Professor at the Dartmouth Institute for Health Policy and Clinical Practice criticises U.S. orthopaedic societies, for instance, since four of five questionable methods point only to a nonprescription treatment, two simple assistive medical devices, and a minor but rare procedure. The societies carefully avoid mentioning major procedures that generate income for American orthopaedists, claims Morden.

### DARE TO QUESTION

Nevertheless, she notes, American general practitioners dare to question annual general health check-ups –



A stylized signature of Ragnar Levi.

RAGNAR LEVI, EDITOR

even though these comprise a substantial portion of their members' activities.

A group from the Swedish College of General Practice (SFAM) has undertaken a similar initiative in Sweden. One of their suggestions has generated debate since some members have arrived at different interpretations of evidence published by SBU in 2007, e.g. that giving advice to patients in a clinical setting may increase their physical activity.

SBU is now considering revisiting the subject and evaluating new studies or reviews. The question is whether an intervention such as writing prescriptions for physical activity actually belongs amongst the least necessary interventions in Swedish primary care.

#### NOT BETTER

What has sparked international interest in *Choosing Wisely* is that more and more physicians recognise the need to avoid unnecessary practices and use those resources for better, more important interventions. Even in an intervention-oriented health-care system, such as that in the United States, people increasingly see that more care does

not necessarily mean better health. At the same time, it is not readily apparent what the different lists actually show. In some cases the argument for listing an intervention is that it does more harm than good. In other cases it's not viewed to be worth the cost. And at times it's about health services' failure to take patients' wishes into consideration.

Eliminating inappropriate interventions should be high on the agenda of all professional groups in health care – ultimately on the patient's behalf. *Choosing Wisely* and similar initiatives by physicians in several countries will be followed by many other professions and specialties in other areas. Proposals to phase out various healthcare interventions must be based on reliable knowledge, and different types of arguments must be discernable.

#### PRIORITISING

–Eliminating obsolete and unnecessary methods from health services should be viewed as a type of house-cleaning says Susanne Waldau, Strategist for Västerbotten County Council, who has conducted a local prioritisation process on two occasions, in 2008 and 2011.

The aim was to make room for developing the organisation through redistribution of existing resources. Again, systematic reviews were not available to guide all choices, but at least the process was substantially more transparent than *Choosing Wisely*.

#### ASKED MANAGERS

–We started by asking each unit manager, along with their own experts, to list the interventions of lowest priority in the respective units and which collectively corresponded to 10% of their budget.

–Then we asked the unit representatives to evaluate each other's lists, calibrate the interventions' rank, and jointly choose the 5% that could be eliminated.

Politicians did not enter the process until stage three. The political goal in 2011 was to redistribute 3% of the budget, over SEK 160 million. According to Susanne Waldau, after an occasionally difficult process they were able to actually free around SEK 29 million that could be reinvested in urgent areas in line with the national guidelines and scientific evidence. In the previous prioritisation process in 2008 they redistributed SEK 47 million.

SBU is currently conducting a project to develop support for setting priorities based on scientific assessments of healthcare methods. The project aims to offer guidance to health services regarding opportunities to phase out methods shown to be ineffective, harmful, or for other reasons inappropriate in favour of effective methods. For instance, waiting to introduce a new method where the benefits and risks are uncertain and the costs are high.

Evidence is key. One can neither accept nor reject an intervention based on opinion alone. [RL]

## QUESTIONABLE METHODS

SBU is currently working to develop evidence for setting priorities based on scientific assessments of healthcare methods. Examples of potentially questionable healthcare methods which might be reviewed include:

- Antihistamines and decongestants for glue ear (otitis media with effusion, OME) in children

- Birth control pills (combined oral contraceptive pills) for functional ovarian cysts
- Combination chemotherapy for locally advanced rectal cancer

The American project *Choosing Wisely* has questioned many methods, including:

- Antibiotics for urinary tract infections (UTIs) in older people with no specific UTI symptoms
- Antipsychotic drugs for symptoms of dementia (mental or behavioural) in people with undetermined causes behind symptoms of dementia.



# Mission: Improve Care for Frail Elderly

One percent of the elderly account for 30% of all hospital days, but resources are used ineffectively. Care coordinators for the elderly in Sweden advocate better coordination and earlier intervention for the frail elderly.

How can we improve care for the frail elderly? Someone who should know the answer to this question is Eva Nilsson Bågenholm, Sweden's coordinator of elder care. She is a nurse and physician, and since 2011 has been the government's coordinator for elderly issues with SEK 4.3 million at her disposal to improve the situation. As national advisor she has worked with experts to formulate goals and initiate improvement processes in five areas.

The first area is palliative care, a concept that has been expanded to encompass end-of-life care. This work is based on a national care protocol, a literature review, and a quality register that monitors care—for instance how many die alone, or have severe pressure sores at death.

## FOLLOW UP

—About 80% of us will need palliative care towards the end of life, says Eva Nilsson Bågenholm. One of my tasks has been to see that we measure and follow up the quality of care. When the care of an individual towards the end of life changes direction from curative to palliative care, a physician should speak with the patient and family, a so-called *turning point* conversation where the physician informs them of the new

focus on palliation.

—Other quality indicators include assessing the patient's pain level using a reliable and approved method, assuring there is a prescription for injecting drugs for anxiety as needed, and evaluating the patient's oral hygiene.

## DEMENTIA

The second area for improvement concerns dementia. Here too, quality registers and national care protocols should be used as tools for improvement. According to Eva Nilsson Bågenholm, one of the fundamental problems is that too many patients have not received a specific diagnosis.

—Primary care must evaluate more of those with impaired memory and establish a correct diagnosis earlier. Then we can have the opportunity to test drugs for dementia, for instance, and we can have access to day care resources or respite care so that the family can rest and patients can reside longer in their usual living environment. For persons with dementia it is also important to avoid antipsychotic drugs, which are still prescribed frequently.

## PREVENT

A third area for improvement concerns actions to prevent accidental falls, malnutrition,

pressure sores, oral hygiene problems, and urinary incontinence. Here SBU reports, for example, provide a basis for quality improvement activities.

—All of these interrelated actions could be improved. If patients are malnourished, the risk for accidental falls increases, while falls and malnutrition increase the risk for pressure sores. Poor oral hygiene increases the risk for malnutrition, and so forth. Urinary incontinence is a major problem that reduces the quality of life and in fact can be treated.

Regarding the fourth area of improvement for frail elderly—medications—the goals are to reduce certain inappropriate medicines, to stop prescribing antipsychotic drugs as general sedatives for people who are not psychotic, and to replace antiinflammatory agents of the NSAID type with other agents.

—Here, all health professions must be involved to achieve change. It's not enough for physicians to change prescriptions; nurses and assistant nurses must also receive education concerning drugs.

## CONSISTENCY

The fifth and final area in the initiative for the elderly is also the most difficult: to achieve full collaboration by care and



Richard Klötz / IBL

## Further Reading

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Urinary incontinence in the elderly. A systematic literature review. Stockholm: SBU, 2013. SBU report no. 219.

Comprehensive geriatric assessment and care of frail elderly. A systematic literature review. Stockholm: SBU, 2013. SBU report no. 221.

Chronic ulcers in the elderly—prevention and treatment. A systematic literature review. Stockholm: SBU, 2014. SBU report no. 226.

social services. Here, says Eva Nilsson Bågenholm, much remains to be done.

–The lack of coordination is well known by everyone working in health care and social services. It's still a major problem that no one has a handle on the entire chain of health and social services for this group.

An elderly person in frail health could have over a dozen different health and social service contacts—home services, home health care, primary care, hospitals, rehab personnel, and so forth.

#### **BETTER STRUCTURES**

–For years we have discussed collaboration between county councils and municipalities and between primary care and hospital services—but often to no avail. For instance, the law stipulates having a fixed contact in health care when needed, but this seldom works in practice.

–So one of my ambitions has been to create structures that cut across boundaries: joint steering committees for county councils and municipal health and social services for the elderly in poorest health, local or regional action plans, and quality improvement managers that serve as a kind of coordinator.

–In any case, this would be a beginning, she notes.

#### **ACUTE CARE**

But there's a long way to go. The problem of fragmented

interventions for the sickest elderly becomes more obvious every day, not least in acute care.

–Acute care is designed for people with a single disease requiring specialised care, she says.

–But many frail elderly visit acute care for other reasons: they can't breathe, they have a urinary tract infection, they are dizzy or generally weak, making it difficult to manage at home—often a combination of symptoms.

–Many don't really need acute care resources, but they haven't received help in time.

–The targets that we measure are to reduce avoidable hospitalisation and rehospitalisation within 30 days after the latest hospital discharge.

#### **UNIFIED PATIENT RECORD**

When asked if a unified patient record isn't key in this context, Eva Nilsson Bågenholm replies:

–Definitely. But there are both technical and legal obstacles.

–Different laws are in force, it's not possible to have a fully unified patient record

or documentation accessible to all staff in health and social services. Most county councils and municipalities are working towards documentation that can be read by all health-care staff.

The reality facing many frail elderly is that they are frequently bounced back and forth from short hospital stays while at the same time hospitals are struggling with over-occupancy and long waiting times. The length of stay at acute care hospitals is only a few days.

Health services must provide better help earlier, but Eva Nilsson Bågenholm does not have a nation-wide solution.

#### **SOLUTIONS DIFFER**

–Solutions must adapt to local conditions: expanded primary care—perhaps with general practitioners that make home visits—strengthening of home health services, or specialists in ambulatory care settings. In Lidköping, a geriatrician has been employed in ambulatory care and in Ljungby a mobile general practitioner takes care of home care patients.

Uddevalla has a special unit for care of the elderly where district physicians can admit patients directly and avoid the emergency room.

#### **POSITIVE INITIATIVES**

Other examples are the Multi7 system in Västerbotten, mobile community care teams in Skaraborg, and a municipal project in Blekinge where patients receive extra support during the first weeks after returning home from hospital.

–Many positive initiatives are under way in different parts of the country—initiatives that must be followed up systematically.

The Swedish population of elderly in poorest health is estimated at just over 300 000 individuals receiving extensive health and/or social services.

If these patients are to be cared for in a better way, then primary care, hospitals, and social services must contribute not only their own individual expertise, but also they must collaborate. And well-intentioned attempts at collaboration must be assessed. [RL]



# Reviewing Complex Interventions

Scientifically testing a single, well-defined, healthcare intervention can be fairly easy. Testing combined interventions, and determining if the outcomes apply in other environments, is considerably more difficult – but not impossible.

When a clinical department successfully introduces an intervention programme and scientifically shows that the patients benefit from the intervention then other departments naturally want to follow. But how do they know whether or not the programme will work equally well in their context? If some components of a complex intervention must be adapted to a new environment, how can we be assured that the outcomes will be as good in the new setting?

This question arose when Sweden introduced stroke units – organised acute care units engaging a multidisciplinary team. The team is specially trained in stroke care and basically manages all of a patient's care.

## WELL-FOUNDED

Professor Emeritus Kjell Asplund, Chair of SBU's Scientific Advisory Committee, worked intensively with others to organise stroke care in this manner.

–A stroke unit is an example of a unified intervention that is very well founded from a scientific standpoint, he says.

Sweden has been in the forefront of development in this area. The first stroke unit was introduced in the 1970s at Serafimer Hospital, and randomised studies were done quite early.

Later, new randomised studies were conducted in other countries, and in the late 1990s research collaboration began within the Cochrane network, relates Kjell Asplund.

–In the early phase, before we knew which parts of the model were necessary for it to be effective, it was natural to adapt the interventions to one's own hospital and follow the care outcomes in new studies.

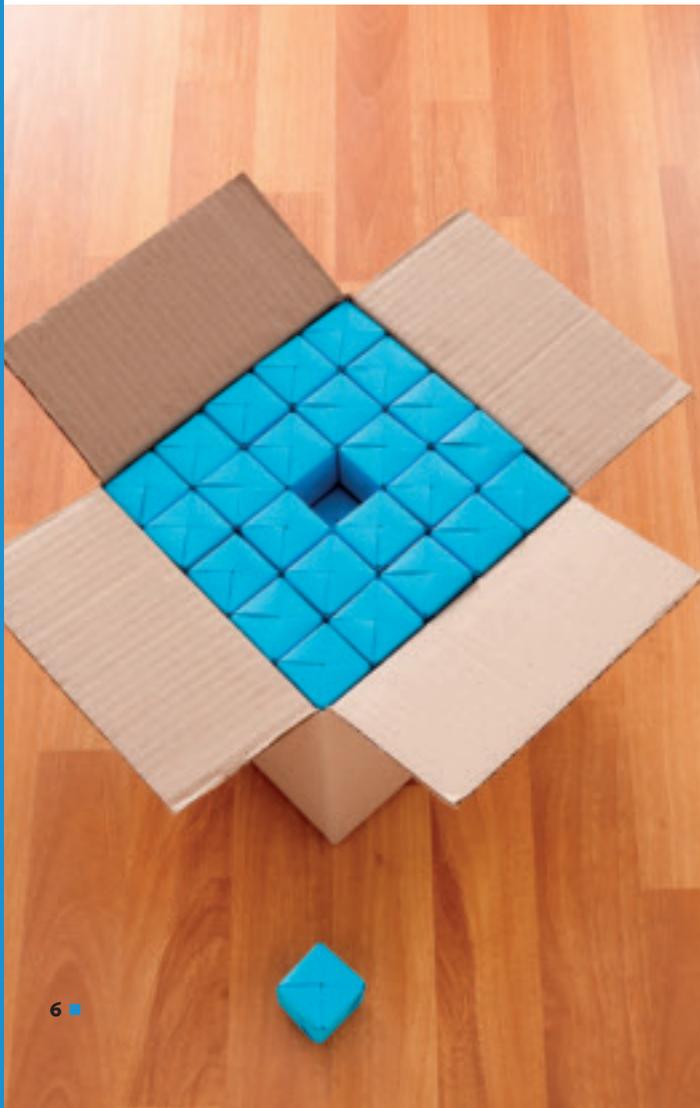
Eventually, enough data were collected to allow for a comprehensive analysis. Special statistical methods could then be used to detect patterns.

## SURPRISING

–When the data were analysed, it became clear that establishing a stroke team at the hospital was not enough. A special ward was also needed where all staff had specialised knowledge about stroke, otherwise no effects could be observed.

The results were surprising, recalls Kjell Asplund.

–We'd believed that the specialised skills of physicians and rehab staff were the most important, and that special facilities or broad education of staff were unnecessary. That would've been so much easier – and more practical. But that wasn't the case.



Fotografiska/ Getty



Today, most stroke patients in Sweden are treated at special units. The national average is 90%, and the figure is even higher at many hospitals.

–Unfortunately, a couple of hospitals in the country still average 75%, says Kjell Asplund. But internationally, Sweden generally holds a very high position.

When a new intervention programme is shown to be effective, and is introduced in different places without scientific follow-up, the risk is obvious. The programme can be watered down and changed—in the worst case so much so that its effects disappear and only its name remains. Often underlying such changes are legitimate attempts at simplification and savings, but the changes are not followed up by studies.

#### REPEATED STUDIES

–When it comes to combining interventions it is particularly important to conduct repeated studies.

The probability that the interventions must be modified is greater when dealing with complex interventions than dealing with single interventions. According to Kjell Asplund, this is probably what is happening with the home rehabilitation methods following early discharge—so-called *early supported discharge* (ESD).

–For patients who have

suffered moderately severe stroke there is good evidence that rehabilitation at home is at least equally effective in recovery as rehabilitation in hospital. But now neuro teams are starting to use the same approach for patients with other neurological disorders such as Parkinson and multiple sclerosis.

–This should be considered a new area of application, which should be assessed by new studies.

#### HYPOTHESES

Asplund offers yet another example of a complex intervention that he participated in reviewing in an SBU project—Dietary Treatment of Obesity.

–Even when it comes to diet there are examples of using large volumes of data in attempting to understand which components of the Mediterranean diet, for instance, benefit people with obesity. At least we have hypotheses that can be tested further. And perhaps it would keep us from calling every dish with a Spanish name a “Mediterranean diet”.

–At the same time, he adds, it’s probably less important to know exactly whether the nuts are better than the olive oil. Here, perhaps the take-home message is that we know the diet’s good—on the whole. [RL]

## ASSESSING COMPLEX INTERVENTIONS

Combined interventions, so-called *complex interventions* or *intervention programmes*, are interventions containing several components that can have effects and perhaps enhance each other.

Combined interventions to reduce the spread of multi-resistant bacteria in hospitals and programmes to promote physical activity in children and adolescents are two examples.

Assessing complex interventions is challenging. Even if the combined effect of a programme is evident, it is difficult to know which are the active components. Exceptionally large studies are needed to draw conclusions about the individual components in a programme. Each component in the programme must be described thoroughly.

It is often difficult to recreate the same complex intervention in new research environments and confirm the results

by new studies. Standardising the programme may even be undesirable—at times it is natural to adapt certain components to new contexts. This, however, increases the risk of changing the outcome. Hence, any modifications to the programme must be carefully documented—otherwise the results become difficult to interpret.

Change should be based on hypothesised modes of action so we know what could happen when modifying the programme.

When it is difficult to assign individuals to intervention programmes and control groups, cluster randomisation can be considered, i.e. where units (primary care centres, school classes, clinical departments, etc) with groups of individuals are randomly assigned. Then conclusions are drawn only at the cluster level, not at the individual level.

#### Further Reading

Craig P, et al. Developing and Evaluating Complex Interventions: New Guidance. London: Medical Research Council, 2008.

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# Cochrane Reviews Seldom Show Risks



Robert Nyberg

**Studies designed to show benefits are seldom large enough to investigate adverse effects. Systematic reviews of adverse effects are also rare.**

Although the benefits of an intervention must always be balanced against its risks, information about potential adverse effects is often lacking.

A key reason is that studies of treatment methods are often designed to show a method's

advantages, i.e. its primary purpose. The disadvantages, which hopefully appear much less frequently and therefore require larger studies, are not captured nearly as well.

Hence, even well executed studies can give an unbalanced view of the benefits and risks of an intervention. The same applies to systematic reviews of these studies.

A current review reveals that less than one tenth of systematic reviews specifi-

cally target adverse effects. Of 4644 systematic reviews in the Cochrane Library and the Database of Abstracts of Reviews of Effects (DARE), only 309 primarily address adverse effects.

To achieve better balance between benefits and risks in meta-analyses and systematic reviews, a Canadian research group is working on guidelines in this area. SBU's assessments must always encompass both benefits and risks. [RL]

## DO REVIEWS INFORM ABOUT ADVERSE EFFECTS?

### General

- Are adverse effects or similar concepts used in the title and abstract—or is the primary theme something else?
- Does the review address both benefits and adverse effects, or only one of these?
- Does the review address specific harms or adverse effects?
- What types of data have been searched, incorporated, and reviewed?

### Orientation

- What adverse effects are conceivable?
- Why does the review focus on certain adverse effects, conditions, and patient groups (e.g. to formulate or test a hypothesis)?
- Why is this specific type of study or source relevant for investigating this?
- What specific issues about risks/adverse effects should the review address?

### Methods

- Has the project plan (protocol) for the review been developed in collaboration with clinical experts in the area?
- What events or effects should be considered adverse effects?
- What types of studies and data should be included—and why?
- What other sources can be used to identify potential adverse effects (e.g. pharmaceutical agencies, industries)? Have these sources been searched, and if so, how and when?
- Have the studies been identified based on the presence, or absence, of the term *adverse effects* in the headings and abstracts of the studies?
- How has study quality been evaluated?
- How has information been harvested from the different studies/reports?

- What information have the reviews considered regarding treatment methods, patient risk profiles, education and qualification of caregivers, and risks?
- Has a causal association between treatment and suspected adverse effects been established and, if so, how?
- Has the review described the risks for skewing when studies have reported on adverse effects incompletely or selectively?
- How have rare side effects been registered in the studies or reports?
- How has the review handled the studies statistically when no cases of adverse effects have been reported?
- Have studies of lower quality, where the results can be skewed, been identified?

### Results

- Are the results of every included study described, and are reasons clearly explained why the results from each of the excluded studies were not presented?
- Has everything that could influence the risk for adverse effects, e.g. characteristics of study subjects or the length of time they are followed, been described for each study?
- Have the ways in which adverse effects were detected been presented for each study, e.g. via spontaneous reporting from patients and health services or actively asking about adverse effects?
- Have the research methods used to appraise and document adverse effects been presented for each study?

### Conclusions

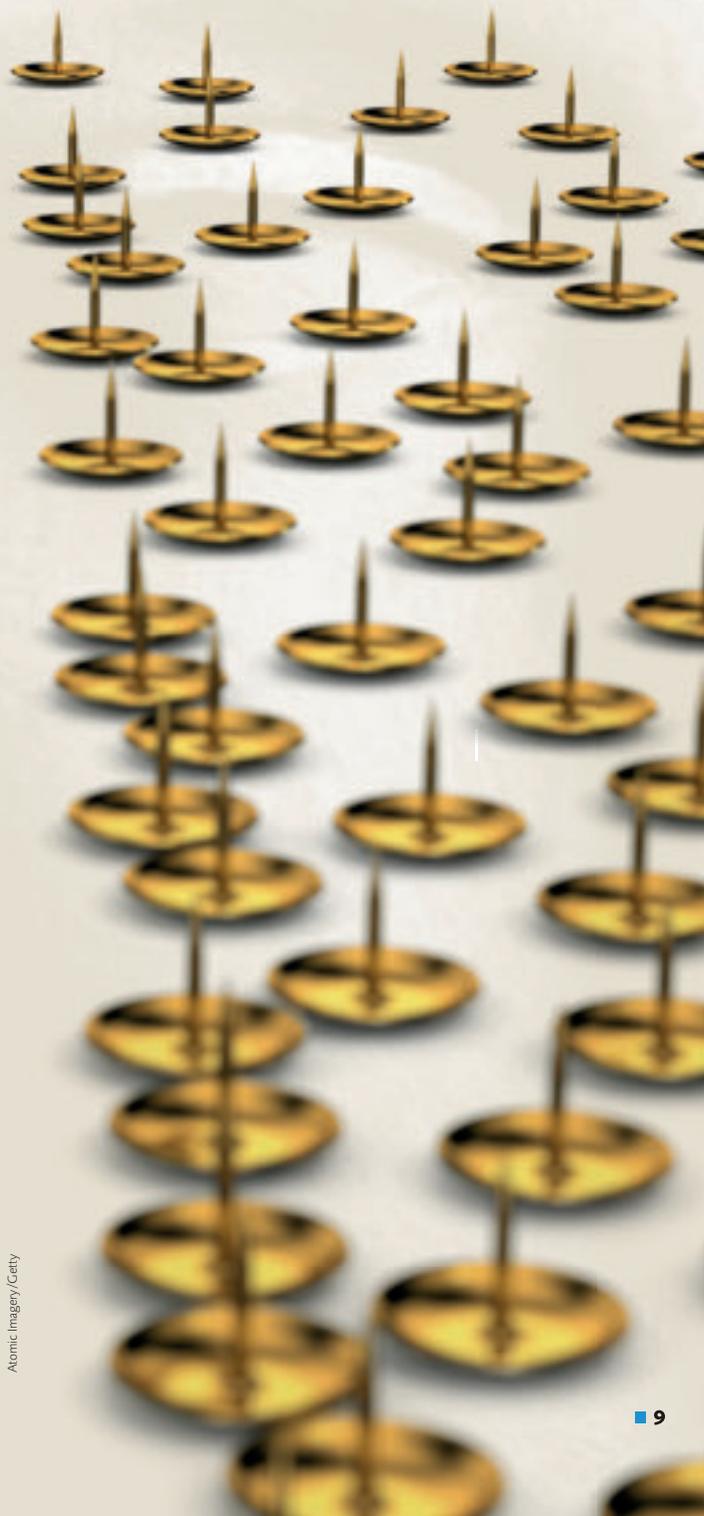
- As regards adverse effects, have the positive and negative effects of treatment been discussed in a balanced way, focusing particularly on the study's limitations, potential for generalisation, and other knowledge sources?

### Further Reading

Zorzela L, et al. Quality of reporting in systematic reviews of adverse events: systematic review. *BMJ* 2014;348:f7668

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Atomic Imagery/Getty

# Dyslexia – Structured Training Helps Children, but Evidence Is Weak

**Structured training that associates speech sounds and letters help children and adolescents with dyslexia improve their ability to read, spell, and comprehend text. But a unique literature review by SBU found too few studies to confirm the usefulness of other training, testing, and assistive technologies.**

In the first systematic literature review ever conducted in this area, SBU appraised research on tests and interventions for children and adolescents with dyslexia.

The assessment addresses three main issues. The first concerns whether methods are available to predict dyslex-

ia even before a child receives formal training in reading and writing—usually before 6 years of age.

The answer is affirmative; dyslexia can be predicted before a child starts school. Methods that measure awareness about speech sounds, rapid automatised naming, and letter knowledge in children appear to provide confirmation. However, the benefits and potential risks of such methods, or interventions in children before they are taught to read in school, have not been assessed.

## UNCERTAINTY ABOUT TESTS

The second issue concerns the reliability of the tests used to

identify and study dyslexia in children and young people aged 6 to 20 years.

SBU found that none of the 50 or more different tests available in Sweden have been subject to scientific appraisal. Hence, it is not possible to determine if they reliably measure that which they intend to measure. Here, more research is needed.

## READ BETTER

The third issue concerns the effects of various interventions in children and adolescents with dyslexia. The body of research shows that children with structured training in associating speech sounds with letters, i.e. phonics, develop better abilities to read and comprehend text, spell, and understand how different speech sounds are constructed. Training often begins at a very basic level and advances gradually.

## BENEFITS UNCLEAR

When it comes to most other interventions—such as other types of training, music therapy, assistive technologies, and alternative methods—the scientific evidence is insufficient to determine whether or not they offer any benefits.

The question concerning the benefit of various interventions is important. Dyslexia can also have an impact on life outside of school, e.g. recreational activities and relationships with friends, and

## 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](http://www.sbu.se).

## SBU'S CONCLUSIONS

If children with dyslexia are given structured training in associating speech sounds (phonemes) and letters (graphemes), their reading ability, spelling, reading comprehension, reading speed, and ability to pay attention to the phonetic structure of language (phonological awareness) increase.

Nothing can be said about the benefits of other forms of literacy training or assistive technologies (to support, compensate for, and develop reading skills such as mobile phone apps). These methods have not been sufficiently assessed.

Some tests may predict dyslexia even before a child

is taught to read and write at school. Deficits in phonologic awareness, rapid automatised naming, and letter knowledge are associated with dyslexia. This report has not assessed the benefits and potential risks of such early testing. Likewise, the report has not assessed interventions in children with such deficits before they are taught to read.

In Sweden, over 50 different tests are used to identify and study children with dyslexia. None of the tests have been scientifically assessed, i.e. studies have not investigated whether the tests are reliable and measure what they intend to measure.



in the long run on education, working life, and community life.

Studies are lacking regarding the effects of various interventions on quality of life, e.g. self-confidence, self-reliance, and self-image, and knowledge development.

#### **ETHICAL ISSUES**

The SBU report also addresses ethical issues related to studies and interventions.

Since a study creates expectations for receiving help, problems can arise if these expectations are not addressed

quickly, e.g. by schools lacking resources or expertise in the area. This is an equity issue.

Parents and teachers can also have different perceptions concerning the appropriate time for studies.

For many children, a dyslexia test can be stressful, and the value of extensive testing that could involve discomfort must be balanced against the child's right to privacy.

The right of self-determination means that the student and parents are the ones to determine whether the diagnosis should be private

or public, but naturally their perceptions can differ. Moreover, the student and parents may have different perceptions concerning the risk for stigmatisation. [RL]

## **BACKGROUND**

Dyslexia is a functional disability that is usually congenital.

Those with dyslexia have difficulty in decoding words and spelling, which in turn can lead to lower reading comprehension.

An estimated 5% to 8% of the population have dyslexia, but this can depend on how the threshold is established. Many studies have set the threshold at the 10% with the greatest reading and writing difficulties in the group of children and adolescents being studied.



Kevin Summers

## FROM SBU'S CONCLUSIONS

SBU has collected and reviewed research addressing methods for treating pressure ulcers, leg ulcers, and foot ulcers among the elderly. Preventive interventions for diabetic leg and foot ulcers were also reviewed.

The scientific evidence on treating hard-to-heal wounds in the elderly is limited. Most interventions require further research of high scientific quality.

The elderly/frail elderly population often has comorbidities and multiple medications, which can affect wound healing.

Data are lacking on current Swedish practices and the use of different interventions to prevent and treat hard-to-heal wounds. Quality registers contain representative data for some patient groups, but comprehensive national data are currently lacking. Limited

scientific evidence supports the following conclusions:

- Surgery for varicose veins can reduce recurrence of venous leg ulcers in the elderly.
- Dressings containing calcium alginate may lead to shorter healing time for pressure ulcers in the elderly. Healing effects of other dressings in this specific age group are insufficiently studied.

Substantial gaps in knowledge exist concerning how the organisation of health services affects patients with hard-to-heal wounds, including, e.g. the significance of specialised clinics, education, communication, coordination, and continuity.

Surgery for varicose veins in treating venous leg ulcers is probably cost effective. The cost effectiveness of other interventions is difficult to determine.

# Wound Treatment – Only Two Methods Show Effects on Hard-to-Heal Wounds in the Elderly

**Surgery for varicose veins offers better protection against recurrence of hard-to-heal venous leg ulcers than compression alone. And dressings with calcium alginate can heal pressure sores more quickly – as shown by research on hard-to-heal wounds in the elderly.**

Wounds that do not heal within 6 weeks are defined as hard to heal. No one knows how many elderly people are affected, but the number is high and will grow. In 2030 every fourth person in Sweden will be 65 years of age or older. Moreover, diabetes, one of the underlying causes, will become increasingly common.

The price is high. For the individual, such wounds are painful, reduce the quality of life, and involve high costs for health services. In industrialised countries, approximately 2% to 4% of the healthcare budget relates to problems associated with wounds.

## REVIEWED

Current research offers little information on the interventions that are most effective for prevention and treatment in elderly. SBU has collected and reviewed the studies available. Only two methods are shown to be effective, and the supporting evidence is limited:

- Pressure sores can heal better when dressings contain calcium alginate.
- Venous leg ulcers are prevented more effectively when compression therapy is combined with surgery of varicose veins.

The general conclusion is that more studies of high quality are needed, and the SBU report provides examples of areas that must improve.

## MUST CONSIDER

Researchers testing interventions for leg ulcers have seldom addressed the causes. Many of the elderly and frail have multiple disorders and take several drugs concurrently, which may impair wound healing. This may involve vascular disease, diabetes, rheumatoid arthritis, cancer, or other chronic diseases that reduce the individual's general health status, function, and nutrition. Studies must consider these factors.

The report also encompasses studies that investigate not only wound healing, but concurrently examine the risk for recurrence.

## ORGANISATION

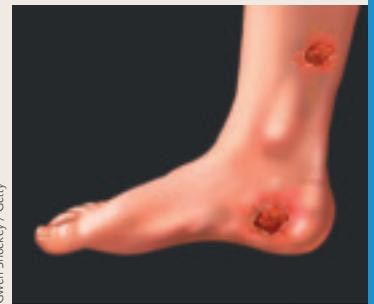
An important question for the SBU project concerns how the organisation of health services influences the potential for preventing and treating wounds. Here there are too few studies to draw conclusions supported by scientific evidence. Researchers need to investigate the importance of specialised clinics, education,

communication, coordination, and continuity.

Hard-to-heal leg ulcers may occur for different reasons, and it is important for physicians to identify the causes since they provide guidance for treatment. SBU's experts emphasise the importance of using ultrasound to study leg ulcers, providing compression for such wounds, and offering not only local treatment but also treating the underlying diseases.

Routines for treating leg ulcers vary widely – care is not equal across the country. The levels of education and expertise vary, but so do local traditions. Moreover, regional purchasing procedures influence the choice of dressing materials and consumable products.

Financial management resources and regulations concerning assistive technologies also vary across regions. [RL]



Owen Stockley / Getty

## BACKGROUND

Hard-to-heal wounds are categorised by cause as venous leg ulcers, arterial ulcers, ulcers with multiple concurrent causes, diabetic foot ulcers, and pressure ulcers.

Most common cause is poor blood circulation in the veins, but leg ulcers can also be due to problems with arterial circulation, inflammatory disorders (vasculitis), or diabetes.

Hard-to-heal wounds can be risky. In people with diabetes, mortality is twice as high amongst those who also have foot ulcers. Mortality is four times higher amongst those who have had some part of the leg or foot amputated.

# Anticoagulants Benefit Old and Young Equally

**Age alone is no reason to avoid anticoagulants, shows an SBU review. The balance between benefits and risks is at least as good in older as in younger patients. However, attending physicians must weigh benefits against risks with drugs for each condition and each individual patient.**

Anticoagulants may be needed following atrial fibrillation, stroke, and myocardial infarction – conditions that are more common during the later years of life. At times, the risk of haemorrhaging is considered a general argument against using blood thinners in the elderly.

But treatment with anticoagulants and antiplatelet drugs is at least as beneficial in older as in younger patients, shows SBU's assessment of the collective body of research. Although risks are greater in the elderly, the benefits are also greater, hence improving the balance.

When considering these drugs, it is important for the attending physician to assess each individual patient's risk factors for haemorrhaging.

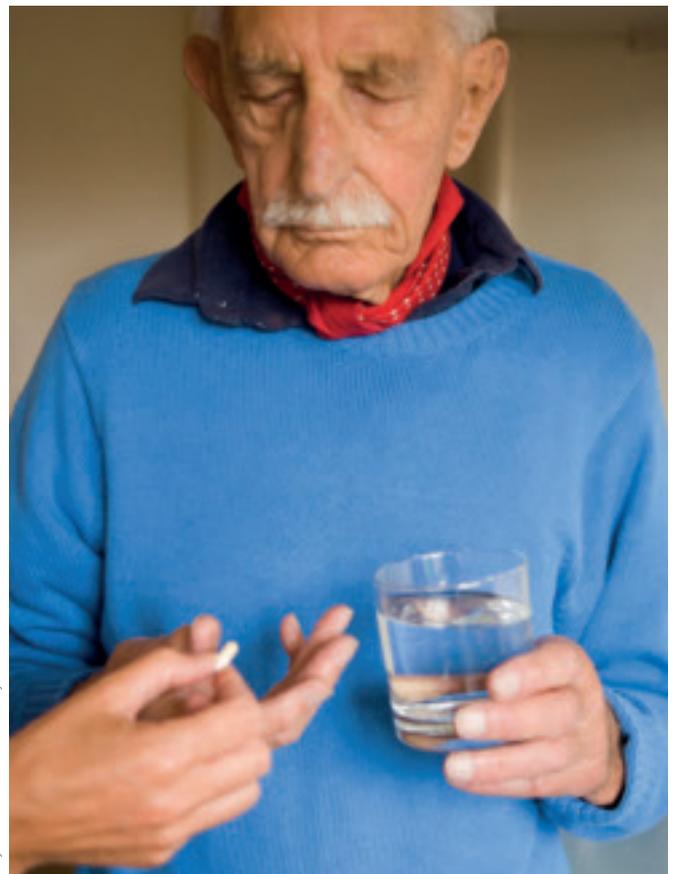
For instance, the risk for haemorrhaging is greater in people with untreated hypertension, impaired renal function, and previous severe bleeding. Treatment with warfarin and new anticoagulants can also be affected by other, concurrent pharmacotherapy.

## FOLLOW PLAN

Physicians should also take into account the organisation managing the patient's care and the probability that the patient can follow the treatment plan.

Previously SBU found that anticoagulants appeared to be underused in elderly with diagnosed atrial fibrillation, particularly in women and people over 80 years of age. Concurrently, it appears that some low-risk patients are overtreated with warfarin.

Professor Sigurd Vitols, who led the new project at



Mary Dunkin / Science Photo Library

SBU, comments:

–The report shows that anticoagulant treatment should be considered for certain medical disorders, even among the most elderly and

even for those suffering from cognitive impairment.

–It's important to prevent new problems that would further impair an individual's quality of life. [RL]

## CONCLUSIONS | BENEFITS & RISKS

The scientific evidence offers no reason to deny anticoagulant treatment (oral anticoagulants or antiplatelet drugs) solely on the basis of high age in patients. The balance between benefits and risks is at least equally favourable in elderly persons as in younger

persons. This applies to most of the indications studied, e.g. atrial fibrillation, stroke, and myocardial infarction.

Studies in this area seldom include profoundly sick elderly individuals on many concurrent pharmacotherapies. Hence, the attending phy-

sician must always appraise the individual's risk for haemorrhaging and take into account other pharmacotherapy that can exacerbate or affect risks, in particular treatment with warfarin or other new anticoagulant agents.

# Prostate Cancer – Role of MRI in Diagnostics Must Be Clarified

Suspected prostate cancer can be studied by ultrasound-guided biopsy. The added value to patient health from new imaging methods such as MRI has yet to be clarified. Basic facts about the number of false alarms and missed cases are needed to know how to benefit most from the new imaging technology.

Elevated PSA values in blood, suspect symptoms, or findings from clinical examination are used to investigate the possibility of prostate cancer. For instance, tissue samples are taken from the prostate with the help of ultrasound. The method can provide important information, but has limitations since one cannot be certain that the specimens come from exactly the right location. The biopsy may have missed a tumour.

## NEW IMAGING TECHNOLOGY

Hence, high expectations are placed on new imaging

technologies such as magnetic resonance imaging (MRI) and advanced applications of ultrasound. But it is not possible to appraise the sensitivity and accuracy of such technologies, and hence not their reliability. After assessing the body of research in this area, SBU found the scientific evidence to be insufficient.

From a purely statistical standpoint, analysts need information on how many false alarms and missed tumours are associated with the methods to be able to study the benefits in a clinical context. Potential benefits, for instance, might be that biopsies could be more accurately targeted or avoided – collecting specimens involves pain, discomfort, and certain risks.

## LIMITED ACCESS

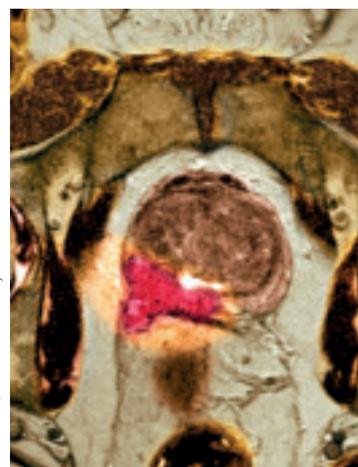
The current conclusion is that the reliability of diagnostic imaging methods for suspected prostate cancer remains uncertain. Present knowledge does not motivate using more advanced methods of

diagnostic imaging than ultrasound to routinely investigate suspected prostate cancer.

SBU's report also discusses costs. If the new technology is used in a large population, e.g. men with suspected prostate cancer, there is a risk that resources for advanced diagnostic imaging will be insufficient to cover other disorders. The studies are expensive, and access to equipment and expertise is limited.

To understand how the methods are used today, SBU administered a questionnaire to those in charge at county and university hospitals. The results show that practice varies, and guidelines are often lacking.

In the autumn of 2014, SBU published a further assessment of diagnostics for prostate cancer. It addressed the extent to which diagnostic imaging methods contribute towards identifying different stages of prostate cancer, which is decisive in choosing treatment. [RL]



Simon Fraser / Science Photo Library

## FROM SBU'S CONCLUSIONS | DIAGNOSTIC IMAGING

- Current evidence does not support using more advanced methods of diagnostic imaging beyond ultrasound-guided biopsies to investigate suspected prostate cancer.
- Higher quality studies are needed to investigate the reliability of various diagnostic imaging techniques.

This technical information is necessary for further studies to evaluate benefits in a clinical context. Potential benefits, for instance, could include more accurate targeting of biopsies, or possibly avoiding biopsies.

- To be able to assess patient survival, quality of life, and cost effectiveness relative to

diagnostic imaging methods, long-term studies need to address both diagnostics and treatment.

## CANCER

Prostate cancer is the most common cancer-related cause of death in Swedish men. Swedish men run a 16% risk

of receiving a diagnosis at some point in life, and 6% die from the disease. The causes of prostate cancer are largely unknown, but heredity and lifestyle both play a role.

# MEDICAL SCIENCE & PRACTICE

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Contact: [nilsson@sbu.se](mailto:nilsson@sbu.se)  
Expected publ: Summer 2015

### **DIAGNOSING SHAKEN BABY SYNDROME**

Contact: [arnlind@sbu.se](mailto:arnlind@sbu.se)  
Expected publ: Winter 2016/17

### **NEW FETAL DIAGNOSTIC PROCEDURES**

Contact: [hellberg@sbu.se](mailto:hellberg@sbu.se)  
Expected publ: Autumn 2016

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

Contact: [arnlind@sbu.se](mailto:arnlind@sbu.se)  
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