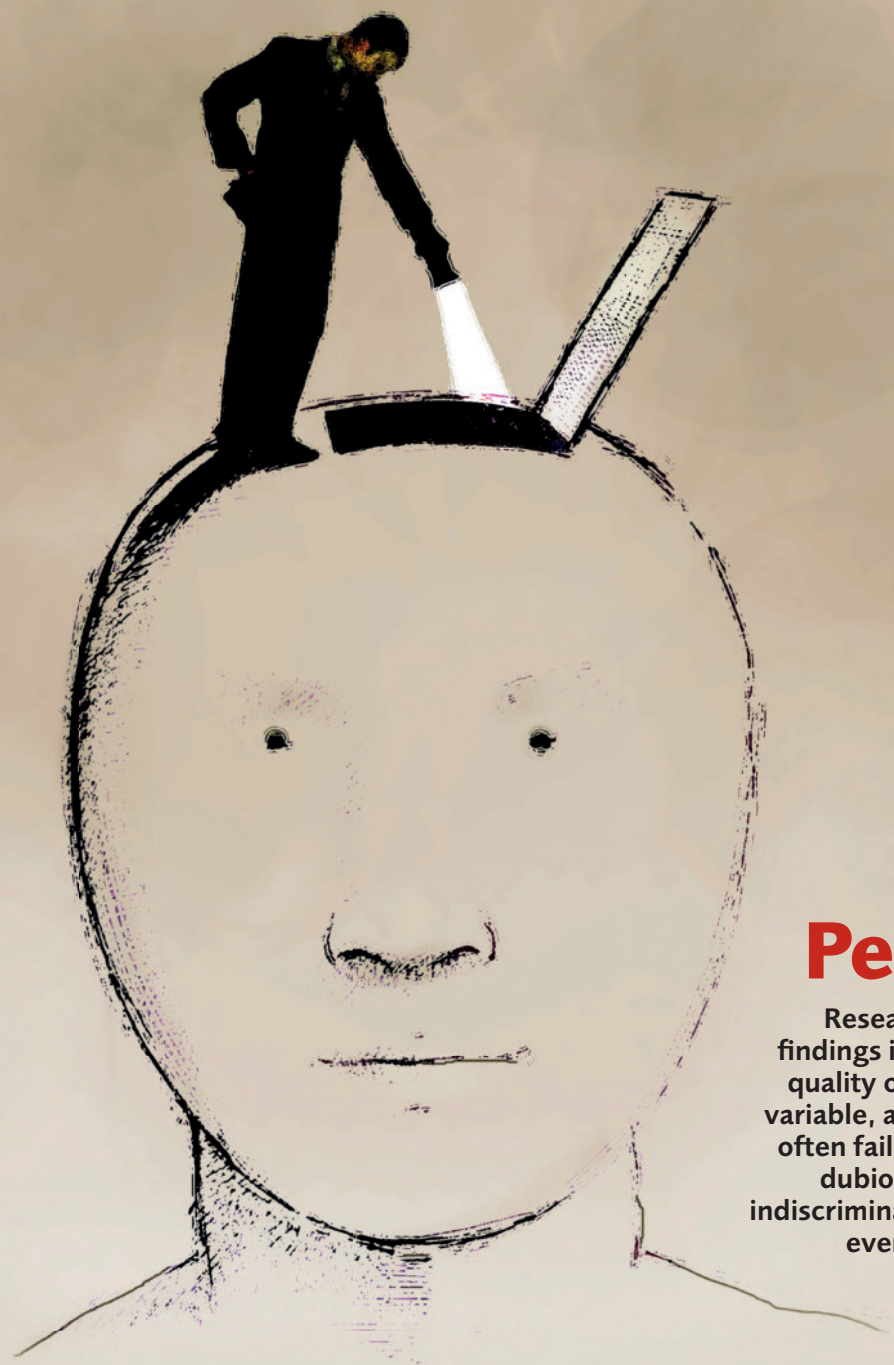
MEDICAL AND SOCIAL

ENGLISH SPECIAL 2018

Science & Practice

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



Wanted: Peer Review

Researchers need to publish their findings in scientific journals. But the quality of their submissions is highly variable, and professional peer review often fails. Editors are warning about dubious new journals that publish indiscriminately and make the situation even worse. **Cont'd, page 2 ▸**

GARY WATERS / GETTY

SBU – ASSESSING HEALTH TECHNOLOGY AND SOCIAL SERVICES

EU to Boost Joint Assessments

THIS PAST 31 JANUARY, the European Commission presented a proposal to boost cooperation among EU Member States in assessing health technologies, including medications and certain medical devices. After decades of voluntary cooperation, the new legislative proposal (https://ec.europa.eu/health) suggests a common regulatory framework within the EU. Hopefully, this will prove to be a leap forward for evidence-based health care.

The foundation is already there. The international HTA community has had a long-standing goal of sharing robust evidence, and there have been three consecutive Joint Actions on HTA at the EU level. Collaboration within the union was further spurred by the Cross-border Healthcare Directive (2011/24/EU).

The new proposal is that the EU Member States work together in four main areas:

1. Joint clinical assessments of the most innovative and potentially impactful health technologies – alongside the central marketing authorisation procedure (for medicinal products) or some time after the conformity assessment (for medical devices)
2. Joint scientific consultations at which developers of a health technology can seek advice from HTA authorities concerning the type of data and evidence that are likely to be required
3. Identification of emerging health technologies to help ensure that important innovations are identified early
4. Voluntary cooperation in non-pharmacological and non-device HTA areas, such as assessment of surgical procedures or the financial aspects of health technologies

ACCORDING TO THE PROPOSAL, the joint effort should be coordinated by a team of representatives from national HTA authorities and bodies in EU Member States. In order to avoid duplication and discrepancies, joint clinical assessments should not be repeated at the national level. However, Member States would be responsible for supplementing joint assessments with non-clinical evaluations of the financial, social, and ethical aspects of health technology. Each State will also evaluate the overall added value of such technologies and make decisions, such as pricing and reimbursement policies, for their healthcare systems.

The role of the European Commission would be twofold:
1. to provide scientific and logistic support for meetings and to facilitate cooperation with other EU organisations, such as the European Medicines Agency, for joint scientific consultations, etc, and 2. to make sure that the coordinating team works independently and transparently.

The proposal will be discussed by the European Parliament and the Council of Ministers with the aim of adoption by 2019. It can become applicable three years later, followed by an additional three-year phase-in period.

As evident in assessments, any theoretically promising health intervention may help or harm in practice. The same thing holds true for regulatory frameworks once they are put to the test. We would be wise to ensure that this one will work as intended.

Ragnar Levi Editor

SCIENTIFIC JOURNALS ARE expected to check the quality of the articles they publish. A peer review process has long been a fundamental criterion for classification as a scientific journal. According to Jonas Ranstam, medical statistician and former adjunct professor at Lund University, it goes without saying that manuscripts must be closely scrutinized. After having reviewed thousands of articles, he is no stranger to major problems. Certain types are common even in randomised studies, which occasionally are regarded as beyond reproach. He has more than one story to tell.

"ONE TYPICAL MISTAKE is failure to specify the primary endpoint under consideration. Researchers who are unable to verify the effect they were looking for may be tempted to focus on another endpoint instead. That is simply dishonest, misleading and totally unacceptable."

Another drawback he frequently runs into is that a study will have too few subjects.

"One reason may be that the researchers have overblown expectations for the efficacy of the intervention. Certain results may nevertheless be statistically significant due to pure coincidence."

Sometimes the article fails to specify the minimum size that an effect must attain to be clinically relevant.

"Failure to define a minimal important difference can create difficulties in large register studies as well. Small, inconsequential differences may show up as statistically significant."

A SIMILAR PROBLEM is the quest for statistically significant differences, often without an underlying hypothesis.

"That can turn into a scientific wild goose chase," Dr Ranstam says. "You end up in a multiplicity trap. The more effects you measure, the greater the risk that statistically significant differences will arise by happenstance."

Randomised trials must also be double-blind to better avoid some common biases.

"Otherwise the results may be skewed because the measurements and interventions have been affected. Occasionally there is no way of preventing the practitioners and subjects

TOTALLYPIC / ALAMY

from finding out. In such cases, at least the experts who assess the results must remain blinded."

EVEN WHEN JOURNALS engage experienced reviewers, the system is anything but fool-proof. Evaluations by SBU and others show that peer reviewers accept many studies that appear to be accurate at first glance but turn out to be unreliable upon closer reading.

While a significant percentage of submissions are rejected, particularly by reputable and oft-cited journals, many flawed articles still see the light of day. Major time and financial resources are devoted to studies that are so small, short-term and improperly designed that they do not even address the questions posed by the researchers themselves. Meanwhile, studies that could shed light on key clinical issues are conspicuous by their absence.

ADDITIONAL CHALLENGES have emerged over the past few years. Special online scientific journals have spread like wildfire. Their names are similar to those of well-known journals and they invariably claim to be peer-reviewed. Many maintain high standards, but some unscrupulous ones will publish virtually anything as long as they get paid. The number of online predatory journals was estimated at 8,000 in 2015. The World Association of Editors of Peer-Reviewed Medical Journals recently highlighted the problem.

The ability of predatory journals to attract researchers is no doubt related to the "publish or perish" syndrome. The opportunity to disseminate findings quickly and evade the stern eye of an editor may be particularly appealing to inexperienced scientists. The dilemma deepens if universities and funding sources attach more significance to the number of articles published than the quality of the journal.

IN SPRING 2017, *Nature* sent an application by an imaginary researcher for an editorial position to 300 scientific periodicals. One-third (120) of them were taken from a list of suspected predatory journals. The CV had been designed such that the research was clearly unqualified. The letters of acceptance started pouring in within a few hours, ultimately 40 of the journals presumed to be predatory. Eight online publications that charged fees but had been regarded as reputable fell into the trap, whereas all the established journals steered clear of it.

EVEN THOUGH PREDATORY journals are at the far end of the spectrum, inadequate review processes are not at all unusual. Three years ago, *Science* sent a feigned biomedical research article with unmistakable flaws to 304 online scientific journals. More than half, all of which claimed to have peer review procedures, accepted the article.

Journals began using peer reviews in the eighteenth century, but it wasn't until 200 years later that they became the rule rather than the exception. Due to its undeniable defects, the system has been highly controversial.

It has become increasingly evident that readers must be able to think critically to assess the reliability and relevance of research findings. ◆ **RL**

Suggested reading

- Munafò MR, et al. A manifesto for reproducible science. Nature Human Behaviour 2017;1, artikelnr 0021.
- Laine C, et al. Identifying Predatory or Pseudo-Journals. World Association of Editors of Peer-Reviewed Medical Journals. Publ 18 feb 2017, www.wame.org
- Shen C, et al. 'Predatory' open access: a longitudinal study ... BMC Med 2015;13:230.
- Sorokowski P, et al. Predatory journals recruit fake editor. Nature 2017;543:481-483.
- Clark J, et al. Firm action needed on predatory journals. Brit Med J 2015;350:h210.
- Bohannon J. Who's afraid of peer review? Science 2013;342:60–65.

Some fundamental questions about studies of efficacy

• Representativeness
Have the subjects been correctly selected? Do they typify the group to which they belong? Are the subjects essentially similar to the larger population for whom the findings will be used?

• Research methodology
Have the subjects been assigned to either a group that receives the intervention or one that does not? Have they been randomised to the two groups? Were the two groups essentially the same at baseline? If not, have the researchers tried to compensate for the differences in a correct manner?

• Findings
How intensive and long was the intervention? How large was its effect? Compared with what (a realistic alternative)? How precise was the estimate of the effect?

• Protection against biased results
Did the study follow up on all subjects included at baseline? Did all subjects remain in the same study group? Were subjects, investigators and researchers blinded from knowing who received the intervention? Apart from the intervention, were the two groups handled the same in all respects? Is a systematic review of the results of similar studies available? Have other studies and research teams demonstrated similar results?

• Relevance
Are the findings applicable to this context? Does the study present effects that are useful for patients and clients or are they only surrogate measures? What has been shown by systematic reviews of adverse effects? Is the probable benefit of the intervention greater than the potential harm? Do the results justify all the sacrifices that the intervention requires?

At Least Do No Harm

Many interventions by healthcare and social service professionals may generate both benefits and harmful effects. However, benefits are typically of greater interest to researchers. As a result, risk-benefit assessments may be misleading.

DANIEL GRILL / GETTY

FAIR AND COMPREHENSIVE evaluation of various interventions in health care and social services requires assessment of the potential benefits and harms.

In theory, research should provide an accurate overview of both. In practice, however, most research projects focus exclusively on benefits. They are structured and designed to demonstrate favourable effects. Patients, clients, practitioners, and policy-makers need additional information.

Studies that assign interventions to subjects on a random basis provide the most reliable conclusions about common harmful effects. But such studies are often too small and their scope too narrow to generate accurate findings about less frequent problems.

The assertion by a randomised study of benefits that "no adverse effects were observed" is insufficient to identify the possible risks of an intervention. More sophisticated follow-up is required.

UNCOMMON ADVERSE EFFECTS of drugs are illustrative. Clinical trials of new medications typically include 500–5,000 patients. Statistically speaking, adverse effects that occur in less than 1 in 100 or 1 in 1,000 patients will not show up in such randomised studies – only later, once the drug has been widely distributed. That is true even of dramatic harmful effects.

Moreover, drug trials rarely last for more than a few months. Adverse effects that take longer to develop are below the radar. In other words, both doctors and patients involved in the administration and consumption of new medications must report suspected problems to public medicines agencies. Such reports need to be analysed and followed up on by cohort or case control studies based on many subjects from population-based registries already available.

HASTY CONCLUSIONS THAT "the intervention is safe since we haven't noted any problems" cannot be blamed solely on our failure to use existing data. Research traditions also contribute. British researchers have pointed out that the potential negative impact of psychological treatment methods is not routinely investigated. A survey of 14,600 British patients found that 5% of them reported persistent adverse effects of therapy. Inappropriate methods may be only one of several possible causes, but the issue is clearly here to stay.

AN ACCOMPANYING editorial in the *British Journal of Psychiatry* proposed follow-up procedures for psychological treatment similar to those for medication in order to improve the situation. The first step should be to establish a consensus for describing, classifying and assessing suspected harmful effects of therapy. In the view of the authors, a framework for proceeding from follow-up and research to raise the level of knowledge and awareness would evolve.

Harmful effects of interventions in health care or social services are sometimes due to inappropriate use. Adverse effects may also arise when patients and clients do not have access to interventions that may have benefited them and for which resources could have been made available.

A recent article in *The Lancet* argues that healthcare systems in both high and low-income countries are guilty of underutilising effective interventions. Decision-makers may not have assigned these interventions sufficient priority. The system for administering could be inefficiently structured. Practitioners may lack the requisite knowledge and skills. Patients and clients may fail to request the interventions.

THE ISSUE OF OVERLOOKING harm also haunts systematic reviews. Numerous analyses have shown that fewer than 10% of reviews address harmful effects as a primary issue. Not even reviews designed specifically to summarise findings about adverse effects are always reliable. The difficulty may be as basic as the absence of a clear definition of the harm involved. Review authors might have failed to specify which types of studies they looked for and what minimum follow-up period was required. They might have overlooked the possibility that some subjects fared poorer at baseline or were more vulnerable.

An international research team directed by Dr Liliane Zorzela, an intensive paediatric care specialist at the University of Alberta in Edmonton, Canada, recently compiled checklists for better identification and reporting of harms in systematic reviews. Such tools are invaluable when shedding light on the dark side of interventions in health care and social services. ◆ **RL**

Harms: Some Critical Issues

- **Have potential adverse effects been investigated in a systematic way?**
- **If yes, were these effects a primary focus of the studies or were they only noted as incidental findings?**
- **What types of adverse effects were sought for in which patient/user categories, and why?**
- **How was harm defined in this context?**
- **Was the information based on published data only? If not, what sources and how was the data collected?**
- **Does the data show how frequently the same individuals suffered different harms?**
- **Is there any indication that the risk is greater among some patients, users or practitioners?**
- **Has the risk of bias been assessed specifically for adverse effects or only generally for all outcomes?**
- **What information on adverse effects is missing, for what reasons and may this affect the overall assessment of the intervention?**

Suggested reading

- Zorzela L, et al. BMJ 2016;352:i157 (and errata BMJ 2016;353:i2229).
- Zorzela L, et al. BMJ 2014;348:f7668.
- Saini P, et al. BMJ 2014;348:f7668.
- Scott J, et al. [editorial]. Br J Psychiatry 2016;208:2089.
- Jonsson U, et al. Contemp Clin Trials 2014;38:18.
- Glasziou P, et al. Lancet 2017. doi: 10.1016/S01406736(16)309461.

Upflifting Assistive Technology

Smart technology can help people with illnesses and disabilities lead ordinary lives. The performance and cost-effectiveness of assistive devices are not generally known. Access to such devices varies considerably within Sweden. Additional research would provide more people with the opportunity to lead productive lives and promote efficient use of scarce resources.

REGARDLESS OF AGE or level of functioning, people may need assistive devices to lead a satisfying life and remain involved in the community. A number of technologies offer assistance when it comes to hearing, speaking, transferring, eating, dressing, washing, toileting and other activities of daily living. Assistive devices can also compensate for other disabilities in a way that facilitates autonomy and an active social life. Which is not to say that there is a shortage of challenges. Assistive technology is a vast field, technological advances are breathtakingly fast, and many organisations are involved. Not to mention that devices are subject to complex regulations. The Swedish Assistive Device Commission appointed in 2015 had a broad task. Efforts to improve the situation are just now getting started.

IN SWEDEN, ONE OF the most controversial issues concerns fee and regulatory discrepancies from one part of the country to another. Disability advocacy groups, authorities, occupational and physical therapist organisation, etc., have long pointed to inequalities.

The National Board of Health and Welfare has determined that the fees for various devices, as well as the assortment of products offered, differ substantially both within and among counties, regions and municipalities. Orthopaedic devices, hearing aids, etc., are more likely to involve a fee. The devices that users must pay for themselves also vary.

One calculation shows that various user fees range from SEK 100 to SEK 1,700 depending on the county. The fee for double hearing aids ranges from SEK 80 to SEK 1,550. However, children with permanent disabilities are always entitled to assistive devices free of charge, regardless of where in Sweden they reside.

ANOTHER THORNY ISSUE has been public procurement. The challenge is to take advantage of technology without committing to expensive, uncertain and questionable solutions, including maintenance and support agreements.

The Swedish National Agency for Public Procurement, which has called for skills development among procurement officers, put together guidelines in 2017. Further, many have suggested that users should be more involved and be offered additional options if devices are to satisfy individual needs. Up to one-third of all prescribed assistive devices are reportedly unused.

According to a 2015 survey by the National Board of Health and Welfare, the main reason is that individuals may not have participated in either the assessment of their needs or the entire prescription process. Overall, people who report poor health participate less than others.

GIVEN THAT EFFECTIVE devices may be essential for activities of daily living and that public costs are substantial, a lot is at stake when patients do not obtain that which suits their particular purpose. In 2015, Statistics Sweden found that the net cost for disability and assistive device services was SEK 5.6 billion at the county level alone. Municipal expenses were not included.

Most devices currently prescribed are for people age 65 or older. Considering that the proportion of Swedes in that age group is expected to increase by 30% from 2010 to 2050, many observers anticipate that the need will rise.

Meanwhile, new technologies will make it easier to offset a number of disabilities. Everyday objects are increasingly equipped with sensors, computers and Internet connections. These can network and share data, opening new possibilities.

EXPECTATIONS ARE GROWING that future high-tech devices will provide and facilitate many healthcare and social services. Hope abounds that smart new devices will solve the growing problems associated with financing and staffing the healthcare and social service systems as the general population ages. The idea is to utilise digital technology to ensure that people can be more secure, active, involved and independent regardless of any disability they may have. Devices that can serve as reminders, warnings and guidance in the home might be particularly valuable.

Some smartphone and tablet apps contain functions that replace older products. For instance, personal digital assistants may offer cognitive support. The range of applications is always expanding.

MACROVECTOR / SHUTTERSTOCK

ONE FACTOR THAT contributes to the complexity of assistive device services is that responsibility is shared. The age of a potential user determines who should provide the device. Swedish municipalities, counties and regions are required to offer devices for care, treatment and activities of daily living as needed. Devices that enable people to work fall under the auspices of the Public Employment Office and Social Insurance Agency. Those associated with training and education are the joint purview of schools, universities and the healthcare system.

MANY DIFFERENT TYPES of practitioners are involved. Occupational, physical, speech, hearing and vision therapists, as well as nurses, can prescribe and assess the need for assistive devices. A referral from a physician may be required. The assessment is based on the impact of the disability on activities of daily living, along with the needs and wishes of the user and family. A team effort may be called for in order to distinguish between needs and wishes. Practitioners use various methods to assess need. The instruments vary depending on the disability, device and specialty of the practitioner. A distinction is sometimes made between life-sustaining, basic, daily and recreational needs. Professionals often lack knowledge about the reliability of the instruments and their role in ensuring that patients remain involved, perceive devices as appropriate and actually use them.

PATIENTS, FAMILY MEMBERS, practitioners and procurement officers may all have difficulty keeping track of the new devices that hit the market as technology roars ahead. Just one single category may include many versions and brands which may have a very short lifecycle. Finding the time to test and compare the various devices to make sure they are safe, effective and optimally beneficial can be a daunting task. Many manufacturers are small or medium-sized businesses without resources to conduct extensive clinical trials. Products, services and methods are often left to sink or swim on their own without reliable comparisons.

The field of assistive technology is vast. SBU contributes by reviewing trials and compiling evidence. Over the years, the agency has assessed a host of assistive technologies and devices. In 2017, SBU mapped current evidence on digital tools as a social stimulus for the elderly and their potential effects on psychological problems. This is a topic that begs the question of how to determine if and when people want technology to replace personal contact.

Evidence on the effects should be key when assessing need and prescribing devices. Increasing demand in ageing populations and rapid technological progress reinforce the need for unbiased information. Practitioners need to know which products are cost-effective. Further, assistive technology must be examined from an ethical point of view.

Inadequate knowledge could afflict the quality of life and level of functioning of large groups of people. The price may be high at both the individual and public level. ◆ **RL**

Categories of assistive devices

Among the purposes of assistive devices are to:

- compensate for the reduction or loss of physical and mental abilities
- retain or improve the level of functioning
- minimise disabling effects

Devices supplement other rehabilitation measures and may be broken down by capacity:

Hearing – hearing aids, telephone devices, signalling systems, etc.
Vision – DAISY players, Braille software, range lights, etc.
Hygiene – catheters, incontinence pads, etc.
Cognition, planning and memory – whiteboards, clocks, etc.
Communication – speech synthesizers, electrolarynxes, etc.
Transferring – walkers, canes, wheelchairs, etc.
Activities of daily living – toilet seat elevators, shower chairs, hospital beds, etc.
Moving – wrist bandages, shoe inserts, artificial limbs, etc.
Care and treatment – inhalers, ventilators, etc.

Habilitation and Rehabilitation

Article 26 of the UN Convention on the Rights of Persons with Disabilities states that:

States Parties shall take effective and appropriate measures, including through peer support, to enable persons with disabilities to attain and maintain maximum independence, full physical, mental, social and vocational ability, and full inclusion and participation in all aspects of life. To that end, States Parties shall organize, strengthen and extend comprehensive habilitation and rehabilitation services and programmes, particularly in the areas of health, employment, education and social services, in such a way that these services and programmes:

- Begin at the earliest possible stage, and are based on the multidisciplinary assessment of individual needs and strengths;
- Support participation and inclusion in the community and all aspects of society, are voluntary, and are available to persons with disabilities as close as possible to their own communities, including in rural areas.
- States Parties shall promote the development of initial and continuing training for professionals and staff working in habilitation and rehabilitation service.
- States Parties shall promote the availability, knowledge and use of assistive devices and technologies, designed for persons with disabilities, as they relate to habilitation and rehabilitation.

Well-founded decisions concerning healthcare and social service interventions require a fair, comprehensive assessment of the benefits and potential harms. But the perceptions of professionals, patients and clients concerning various effects may be based on wishful thinking rather than solid evidence.

Getting Real About Both Benefits and Risks

Risk assessment is not always a rational process, and factors other than actual probabilities may come into play.

Human nature makes it difficult to leave wishful thinking, creed, ideology and other subjective attitudes aside.

ACCORDING TO A RECENT systematic review[1] published in *JAMA Internal Medicine*, doctors rarely estimate benefits and risks correctly. The review was based on 48 studies that included 13,011 doctors and examined treatments, radiology results, screening and other diagnostic methods. A mere 11% of benefits and 13% of harmful effects were estimated accurately. Overestimating benefits and underestimating risks was more common than the other way around.

The same research team published a similar review[2] of 35 studies and 27,323 patients in 2015. Once again, incorrect estimates, and a tendency to overestimate benefits and underestimate harms, were frequent.

UNDOUBTEDLY, THE INCLUDED studies have their weaknesses. Many of them are small, and subjects' estimates of risk were compared to "true" magnitudes which the authors did not validate. However, the risk estimates of both doctors and patients clearly differed from those of scientists, who were generally less optimistic.

Researcher Lennat Sjöberg discusses ways that people perceive and assess risk in a chapter of a monograph[3] published by the Research Institute of the Stockholm School of Economics.

ONE OF HIS POINTS is that people have a proclivity for underestimating the risks to which they personally are exposed. They tend to be more objective about what other people face.

Smoking, drinking, diet and other lifestyle issues are typical in this respect. Smokers are clearer about the hazards when they look at other people. People see themselves as less vulnerable than their peers who find themselves in the same situation.

The sense of being in control is a contributing factor. If you believe that you can manage a risk, you may perceive it as smaller. Voluntary exposures may seem less dangerous than hazards that you think have been imposed on you.

GENDER, PREVIOUS EXPERIENCE and certain personality traits also affect risk perceptions to one extent or another. If one of your relatives died of a particular disease, you may overestimate your own chances of meeting the same fate. A doctor with a patient who experiences a serious adverse effect is likely to be more observant of similar medications going forward.

The scope for personal interpretation is greater in the case of uncommon and poorly researched risks. If a situation is complex and ambiguous such that the facts are elusive, the frequency of events which are easy to recall tends to be overestimated. Readily accessible memories assume exaggerated proportions at the expense of statistical probability.

A SYSTEMATIC REVIEW in the Cochrane Library[4] suggests that well-documented decision aids can help patients develop a more realistic view of the benefits and risks associated with various interventions.

The review is based on 105 randomised studies and 31,000 subjects. Decision aids included brochures, videos and online tools, as opposed to the general or minimal information provided by customary care services. All the approaches described the patient's options and helped them evaluate the conceivable impact on their life. Among the various choices that patients faced were surgical procedures, medical treatment, screening and genetic testing.

THE AUTHORS OF the review concluded that decision support educates patients about the various options they face. They feel as though they are better informed and have a clearer sense of their

ALEXANDER RATHS / SHUTTERSTOCK

own personal priorities. The authors also found moderate scientific evidence that patients become more realistic about the benefits and risks associated with various options.

Studies that deal with the way potential risks and probabilities are communicated indicate that various modes of presenting facts may influence how patients respond. While numerical figures are generally considered to be accurately understood, adding a verbal description can facilitate comprehension.

For example, when telling patients that an adverse effect arises 20% of the time, you might add that such a frequency is officially classified by public agencies as "very common". Saying that "20 patients out of 100" experience the problem may be easier to understand than "20% of patients" experience it.

A doctor who says that the risk of headache is 10% generally means that one out of every ten people experience it. But the patient might think that anyone will have a headache every ten times they take the medication or throughout 10% of the treatment period.

SIMILARLY, A DOCTOR may be more inclined to recommend treatment that is said to reduce risk by 50% than from 2% to 1%.

The opportunity of obtaining benefit is often viewed more favourably than avoiding a risk. Surveys have shown that both doctors and patients look at a 68% survival rate as more desirable than a 32% fatality rate. ◆ **RL**

References

1. Hoffmann TC, et al. Clinicians' expectations of the benefits and harms of treatments, screening, and tests: a systematic review. JAMA Intern Med 2017;177:407-419.
2. Hoffmann TC, et al. Patients' expectations of the benefits and harms of treatments, screening, and tests: a systematic review. JAMA Intern Med 2015;175:274-86
3. Wahlund R [ed]. Risker och riskhantering i näringsliv och samhälle [Risks and Their Management in the Public and Private Sectors]. Stockholm: Stockholm School of Economics Institute for Research, 2016.
4. Stacey D, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database of Systematic Reviews 2017, Issue 4.

ARM FRACTURE RECOVERY OFTEN SIMILAR WITHOUT COSTLY INVASIVE SURGERY

Fractures of the wrist and shoulder are increasingly operated on with metal plates, which are more expensive than other methods. But moderate dislocations may respond just as well to the alternatives. The SBU assessment points the way to an approach that would reverse the trend and ensure equal quality of care at lower costs.

INDIVIDUALS WHO SUFFER a fracture of the arm in late middle age or older do not appear to obtain significant extra benefit from surgery. Moderate dislocations may respond just as well to non-invasive options. Scarce resources can be used more efficiently.

SBU systematically reviewed all available trials concerning the treatment of fractures in populations where the average age was 60 or more, an age where brittleness of the bones is common.

FOR INSTANCE, PEOPLE who have a shoulder fracture without major dislocation can enjoy the same mobility and quality of life after conservative treatment with a simple sling. By the same token, a cast for a moderately dislocated wrist appears to ensure the same mobility as surgery with a metal plate, or percutaneous fixation. Pins and metal rods (percutaneous fixation) are equally or more effective than casts when it comes to quality of life, whereas grip strength is about the same either way.

SBU also reviewed current practice and resource utilisation in the Swedish healthcare system. According to the analysis, less frequent surgery would free up resources for potentially better use.

The latest available statistics indicate that 27% of wrist fractures and 14% of shoulder fractures are operated on

SBU'S CONCLUSIONS ARM FRACTURE TREATMENT IN THE ELDERLY

SBU has evaluated the effects, complications, health economic aspects and ethical considerations of arm fractures treatment in the elderly with a mean age above 60 years. The project originates from a proposal from the Swedish Orthopaedic Association. The systematic review also includes studies on how patients with osteoporosis experience participation in their care and their encounters with health care professionals.

- Using plaster casts to non-surgically immobilise less complex wrist (distal radius) fractures appears to result in the same functional outcome as surgical techniques, involving open reduction and internal fixation (ORIF) of a metal plate to the bone (plate fixation) or fixing external supports to the bone through small incisions in the skin (external fixation or pinning), at one-year follow-up. Treatment with plaster casting appears to result in grip strength equivalent to that achieved with external fixation/pinning methods. Quality of life outcomes appear to be as good or better with external fixation/pinning. It is increasingly common for patients with wrist fractures to be surgically treated, at a higher treatment cost.
- Treating less complex wrist (distal radius) fractures with surgery using either plate fixation or external fixation methods appears to result in equivalent function, grip strength and quality of life, at one-year follow-up. Plate fixation has become more common, even though more patients treated this way require reoperation and this treatment method costs more than external fixation or pinning.
- Using a sling to support the arm of patients with less complex shoulder (proximal humerus) fractures appears to result in the same levels of function and quality of life as the surgical treatment ORIF, at one-year follow-up. Non-surgical treatment results in the same functional outcome as a partial shoulder replacement (hemiarthroplasty) at one-year follow-up. However, the trend in Sweden is that patients with shoulder fractures are being treated surgically more often, at a higher treatment cost.
- Surgical treatment of less complex fractures of the wrist and shoulder may lead to unnecessary surgery. This could lead to fewer resources being available for other health care interventions.
- In their encounters with the health care system, patients with osteoporosis perceive that they often receive insufficient, incorrect or contradictory information, which complicates their health care decision making process. Patients with osteoporosis perceive that they are often left to themselves with insufficient information on how to manage their health. They want to be taken seriously as individuals.
- Several evidence gaps were identified. More randomised controlled studies comparing common treatment methods for arm fractures in the elderly are needed. The studies must have sufficient power, accurately describe the severity of the fractures, use validated instruments to measure outcomes and follow patients up for at least one year. Aspects of health economics also need to be highlighted in future studies. Studies that describe how elderly patients who specifically had arm fractures perceive their health care experience are needed. Future studies should also report the results from the perspective of both men and women.

within one month. Some of these resources could be allocated differently, according to the assessment.

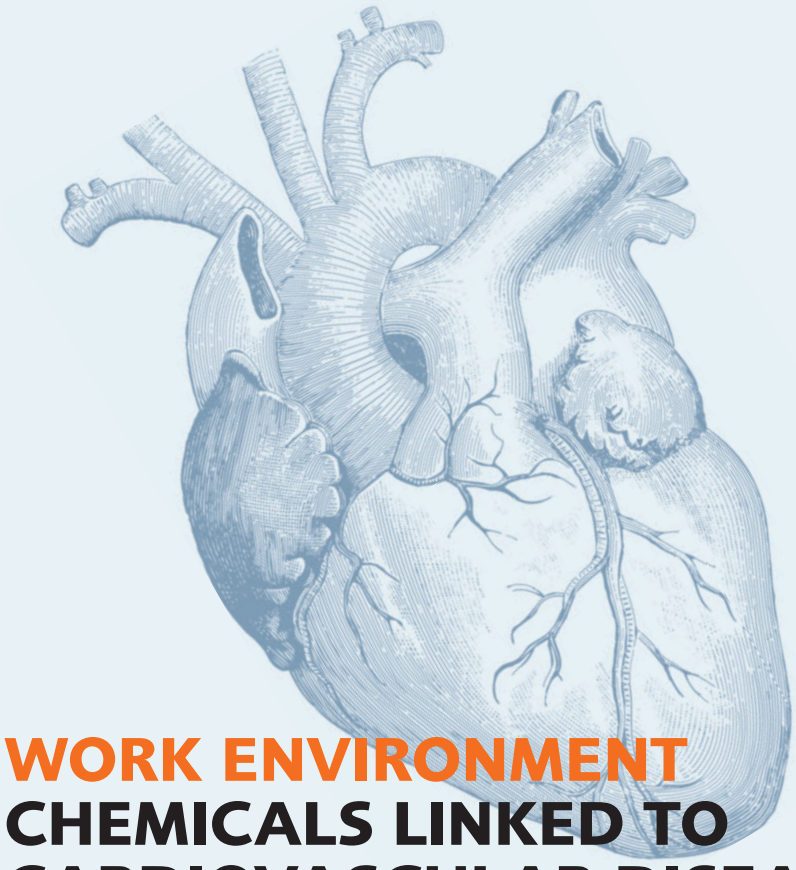
THE SBU REPORT presents a calculation: A three-quarter reduction of surgical procedures for various types of arm fractures in favour of casts or slings could save a total of SEK 66 million annually without compromising quality. The magnitude of the amount is due to a substantial variation for different kinds of fractures. Wrist fractures can cost as little as SEK 1,200 for a cast and as much as SEK 15,000 for surgery with a plate. Shoulder fractures can cost as little as SEK 345 for a sling and as much as SEK 68,000 for reverse prosthesis, which replaces and switches the position of the ball and socket.

ANOTHER SCIENTIFICALLY documented area for improvement concerns the information and solicitude given to people who have osteoporosis. Qualitative studies indicate that these patients report getting insufficient, erroneous and contradictory information such that they don't know what treatment or preventive measures they need.

The post-fracture repercussions may be extensive. Patients may be so worried about the risk for more fractures that they stay home all the time and become isolated. Lack of knowledge and information can delay intervention and cause unnecessary suffering. ◆ **RL**

About the report

Treatment options of arm fractures in the elderly. A systematic review and assessment of the medical, economic, social and ethical aspects (2017). Project Manager SBU: Karin Stenström, karin.stenstrom@sbu.se
English summary at http://www.sbu.se/262e



HEIN NOUWENS/SHUTTESTOCK

WORK ENVIRONMENT
CHEMICALS LINKED TO CARDIOVASCULAR DISEASE

Heart disease is more common among people who work around silica dust, engine exhaust, and welding fumes. SBU reviewed work environment studies of the correlation between various chemical compounds and cardiovascular disease.

In collaboration with leading researchers, the agency reviewed studies of exposure to various chemicals on the job and the prevalence of heart disease, stroke, hypertension, and pulmonary heart disease (cor pulmonale) which causes failure of the right ventricle and blood pressure in the lungs to rise. See the table on page 12 for a summary of the results. The information can inform work environment management efforts: exposure to certain risks at Swedish workplaces may need to be monitored and addressed by testing various measures.

THE SBU REPORT ANALYSES epidemiological studies that have linked a variety of chemicals to cardiovascular diseases. The review also examines the certainty of the correlations identified by the studies and pinpoints the areas that still lack reliable evidence. But the report does not quantify the strength of the correlations, i.e., how much more frequently a disease occurs when the work environment is exposed to a particular compound.

SBU emphasises that the impact of exposure on an individual must be assessed on a case-by-case basis. People differ when it comes to the propensity to develop various diseases. And the epidemiological studies analysed overall exposure to chemicals at the workplace level, not how individuals were exposed. SBU concludes that the research that has been evaluated cannot be expected to identify all compounds associated with cardiovascular disease. In the first place, only a limited number of compounds have been researched so far. In the second place, epidemiological studies do not typically consider compounds, which are uncommon at workplaces, that cause acute cardiovascular death. But hydrofluoric acid, as documented elsewhere, can fatally disturb the heart rhythm on skin contact alone.

The "healthy worker survivor" effect is ▶

▸ *Cont'd*

one of many challenges faced by researchers. The idea is that certain workplaces require employees to possess unusual physical capacity. The selection may be skewed towards uncommonly healthy individuals. Compounding the dynamic is the fact that people can stay at the workplace over the long run only if they remain in good health. In other words, a snapshot of the workplace at any point in time would show that employees are just as healthy as the general population, regardless of their exposure to hazardous substances. Researchers have methodologies in their toolbox to compensate for such systematic errors.

THE SBU PROJECT reviewed and eliminated more than 8,000 abstracts on the basis of study relevance and quality. That left 164 scientific articles about various chemicals and cardiovascular conditions. The conclusions are based on those particular studies, which concerned exposure to chemical compounds in the work environment, not at home or in public spaces. The new review supplements a 2015 assessment of other work environment factors that may be associated with cardiovascular disease. Previous SBU reports have also focused on symptoms of depression and exhaustion, back problems and arthrosis. ◆ **RL**

About the report

Occupational health and safety – chemical exposure and cardiovascular disease. A systematic review and assessment of the social, medical and ethical aspects (2017). Chair: Prof em Töres Theorell. Project Manager SBU: Charlotte Hall, Charlotte.Hall@sbu.se
English summary at http://www.sbu.se/261e

Chemical exposure	Cardiovascular disease			
	Heart disease	Pulmonary heart disease	Stroke	High blood pressure
Arsenic	■		□	
Asbestos	■	■	□	■
Benzopyrene	■		□	
Lead	■		■	■
Electrolytic aluminium production	■		■	
Phenoxy acids with TCDD	■		■	□
Production of paper using the sulphate method	■		□	
Carbon disulphide	■		■	□
Carbon monoxide	■			□
Quarts and other crystalline silicon dioxides	■	■	□	
Engine exhaust	■		□	□
Nitro-glycerine/dynamite	■		□	
Metalworking fluids	■			
Fumes from welding	■		□	
Tobacco smoke	■		□	
Other chemical exposures	*	*	*	*

GRAFIK: BJÖRN LUNDKVIST

* The scientific evidence was considered insufficient to draw any conclusions about the association between cardiovascular disease and several additional chemicals. For example, we found that there is insufficient evidence to establish whether there is an association between occupational exposure to mercury and the incidence of heart disease, stroke or high blood pressure.

■ Indicates an association between exposure and condition.

□ Indicates that there is insufficient evidence to draw any conclusions about the association between exposure and condition. Note that insufficient evidence does not indicate that the exposure is not harmful, rather that there is not enough information available to draw any conclusion.

□ Indicates that no studies meeting our inclusion criteria were identified between exposure and cardiovascular disease. There was insufficient evidence to determine if any of the chemical exposures assessed were associated with changes in blood pressure during pregnancy.

SBU'S CONCLUSIONS CHEMICAL EXPOSURE & CARDIOVASCULAR DISEASE

SBU has systematically reviewed the epidemiological evidence exploring how exposure to chemical compounds in the workplace correlates with heart disease, pulmonary heart disease, stroke and high blood pressure.

▸ **Heart disease:** There is evidence that workplace exposure to silica dust, engine exhaust or welding fumes, all of which are common workplace exposures in Sweden today, is associated with heart disease. An association was also seen for workplace exposure to arsenic, benzopyrenes, lead, dynamite, carbon disulphide, carbon monoxide, metalworking fluids, and occupational exposure to tobacco smoke. Working with the electrolytic production of aluminium or the production of paper when the sulphate pulping process is used is associated with heart disease. An association was also found between heart disease and exposure to compounds which are no longer permitted in Swedish work environments, such as phenoxy acids containing TCDD (dioxin) or asbestos.

▸ **Pulmonary heart disease (cor pulmonale):** There is evidence that workplace exposure to silica dust or asbestos is associated with pulmonary heart disease.

▸ **Stroke:** There is evidence that workplace exposure to lead, carbon disulphide, phenoxy acids containing TCDD, as well as working in an environment where aluminium is being electrolytically produced, is associated with stroke

▸ **High blood pressure:** There is evidence that workplace exposure to asbestos or lead is associated with high blood pressure.

▸ There is insufficient evidence to establish if there is any difference between how vulnerable men and women are to chemical exposure in the workplace.

CHOLECYSTITIS SURGERY WORKS BEST AT AN EARLY STAGE AND WITH LAPAROSCOPIC TECHNIQUE

Surgery for cholecystitis (inflammation of the gallbladder) works best within a few days of diagnosis. The period of convalescence could be reduced by three days per patient and save SEK 26 million a year. Acute cholecystitis could be operated on even more often with laparoscopic (keyhole) technique.

The main issue in cases of acute gallstone disease is whether to operate or wait. After having reviewed available studies, SBU concluded that researchers have not found any conclusive evidence one way or the other.

"As opposed to our expectations, the scientific basis is insufficient to make a determination," says Dr Johanna Österberg, Senior Consultant for the Surgical Department of Mora Hospital, Sweden – one of SBU's experts in the project.

THE ASSESSMENT showed that many patients never experienced a relapse over a period of 14 years when they choose to wait on surgery following acute gallstone disease.

"We need randomised studies of acute gallstone pain," Dr Österberg says.

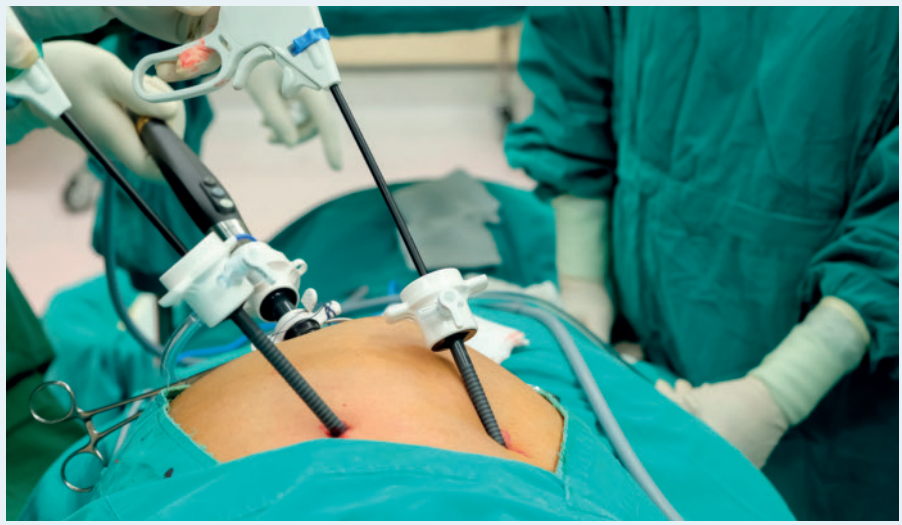
She adds that no evidence seems to discord the principle that many Swedish practitioners follow: wait after a single uncomplicated gallbladder attack, but consider operating without delay in the case of acute cholecystitis.

The SBU review still identified potential for improvement. Surgery for acute cholecystitis works best within a few days. Patients don't have to endure waiting, risking relapse. Acute phase surgery does not increase the risk of complications, and resources are freed up.

APPROXIMATELY 60% of Swedish patients currently undergo surgery during the acute phase. SBU found that some 3,300 days of convalescence and SEK 26 million would be freed up every year if the figure increased to 90%.

Laparoscopic technique instead of open surgery for acute cholecystitis substantially reduces the risk of complications, particularly wound infections and pneumonia. The majority of operations already use laproscopic technique, but there is latitude for more.

Finally, SBU points out that the Swedish national quality register enables monitoring of surgical practice for gallstone disease. ◆ **RL**



SAMRITH NA LUMPOON / SHUTTERSTOCK

About the report

Surgery to treat gallstones and acute inflammation of the gallbladder. A systematic review and assessment of the social, medical, economic and ethical aspects (2017). Chair: Associate Prof Claes Jönsson. Project Manager: Jan Adolfsson, jan.adolfsson@sbu.se
English summary at http://www.sbu.se/259e

SBU'S CONCLUSIONS GALLSTONES & CHOLECYSTITIS

- It is unclear whether patients experiencing a gallstone attack should receive surgical treatment or not. The scientific basis to assess this is insufficient and better studies are needed.
- The body of evidence is currently insufficient to determine whether it is better to always surgically treat acute inflammation of the gallbladder. More well-conducted studies are needed.
- Patients with acute inflammation of the gallbladder can be surgically treated in the acute phase, within a few days of symptom debut, without increasing the risk for complications (compared to when the surgery is done later in an asymptomatic stage). Increasing the number of surgeries performed during the acute phase could free resources for the health care system. Just over 60% of surgeries for acute inflammation of the gallbladder are currently performed during the acute phase. SBU estimates that increasing acute phase surgeries to 90% could free three in-hospital days per patient, or about 3,300 days per year (corresponding to nearly 26 million Swedish crowns yearly). What is more, patients who receive acute phase surgery are spared experiencing additional pain and suffering while they wait for their operation.
- The risk for complications is reduced when patients with acute inflammation of the gallbladder are treated using laparoscopic surgical techniques compared to open surgery techniques.

CHILD WELFARE SUPPORTIVE INTERVENTIONS MAY PROVIDE ASSISTANCE AT FOSTER HOMES

Children placed at foster homes may benefit from supportive interventions – they fare better and face a lower risk of changes or discontinuation of the arrangement. Few Swedish children or foster parents are offered that kind of support. The SBU review also found a lack of research concerning various methods to train and assess the suitability of foster families.

A total of 3–4% of Swedish children are placed at a foster home or institution at some point. Across their lifespan, they run an elevated risk for suicide, psychological problems, substance abuse, criminal behaviour and the need for long-term public assistance.

The systematic review and assessment by SBU examined whether supportive interventions for children and parents in foster homes can minimise the risk.

THE RESULTS GIVE cause for hope. The studies that were reviewed indicate overall that interventions can improve physical and mental health, as well as social circumstances and quality of life. Placement may need to be changed or discontinued less often as well.

The average, overall effect of the various programmes and supportive interventions that SBU evaluated point in that direction.

But both the interventions and studies differ substantially, and none of the interventions have been analysed by more than a few studies. Thus, current evidence is insufficient to determine what specific interventions or components that are able to help foster children.

NEVERTHELESS, THREE OF the interventions have been studied enough to demonstrate that they are effective in at least one specific respect. The Attachment and Biobehavioural Catch-up programme has proven capable of improving psychological health and reducing stress, etc. The Take Charge special education programme can strengthen autonomy and social circumstances such that children complete training, etc. Incredible Years can bolster the ability of foster parents to perform their tasks and reduce acting-out on the part of children. None of the other 15 interventions were examined for foster children by more than one study.

Potentially harmful or unwanted effects have not been examined in any study.

THE SBU PROJECT conducted a survey to identify the interventions currently used in Sweden. Questionnaires were sent to a random selection of 106 municipalities, as well as all 38 businesses that provide services on their behalf.

The responses mentioned 30 interventions which concern assessment of the suitability of foster homes and training of foster parents. The effects of these interventions have not been assessed by SBU. Few foster children or families receive support once the arrangement is under way.

SBU also interviewed four organisations that advocate for current or former

SBU'S CONCLUSIONS INTERVENTIONS TO HELP CHILDREN IN FOSTER CARE

- Interventions to children in foster care and their foster parents can improve the children's psychological and physical health, social situation, quality of life, and also the stability of placements. Due to the differences between the interventions and variation in the scientific design of the studies, it is not possible to determine which interventions or parts of these activities are better than others.
- There is evidence that three specific interventions are effective:
  - Attachment and Biobehavioural Catch-up targeting foster parents can improve children's attachment behaviours
  - Incredible Years can improve parenting abilities of foster parents, as well as decrease children's externalizing behaviours
  - Take Charge for young people can improve children's self-determination skills, high school completion and increase their likelihood of future employment.
- For the other 15 interventions that were identified in the systematic review, there were not sufficient studies to assess their effects, when applying the GRADE model of assessing evidence from evaluations. The absence of robust evidence for these interventions does not necessarily imply that they are ineffective, rather that the empirical evidence is not up to GRADE standards.
- None of the interventions currently used in Sweden have been evaluated in controlled trials. In Swedish foster care service, the emphasis is on investigating foster parent's suitability and preservice training. Providing structured interventions for children and foster parents in a systematic way when the child is in foster care is far less common. People who have grown up in foster care, their birth and foster parents – all express desires for interventions that support both children and foster parents during placement.
- Far more research is needed to assess the impact of foster care interventions. All 18 interventions that the systematic review identified can presumably be successfully implemented in the Swedish context, but their effects should be evaluated in Sweden. The interventions already in use in Sweden need to be evaluated. Studies that highlight cost-effectiveness of interventions for foster children are generally few and far between, and totally absent in a Swedish context.

foster children, their biological parents and foster parents. All four call for additional support. Foster parents want to know more about children's needs, while biological parents want help so that they can be more involved in their children's lives.

SBU's ethical analysis stresses that the public sector has a special duty to promote a child's best interests once it has assumed custodial responsibility. The lack of scientific evidence for the advantages and disadvantages of various interventions jeopardizes a child's rights. Another problem is inadequate documentation and follow-up of the interventions that are administered.

SBU CONCLUDES that the results of the studies reviewed can be applied to Swedish foster home care. Small Swedish municipalities that adopt new interventions should be aware that maintaining proper skills when only a few children are placed at foster homes may be difficult.

Implementation of a number of the interventions requires systematic approaches. Even if there is scientific evidence for the effects, procedures are needed to methodically adopt, uphold and discontinue foster home interventions. Systematic local monitoring and documentation of both benefits and harmful effects might be the right way to go. Quality registers could ultimately emerge as a result.

SBU further stresses that future research should examine the value of the interventions currently in use, as well as those that may be adopted down the road. ◆ **RL**

About the report

Interventions to improve foster children's mental and physical health. A systematic review and assessment of the economic, social and ethical aspects (2017). Project leader SBU: Knut Sundell, Knut.Sundell@sbu.se
English summary at http://www.sbu.se/265e

NACIVET / GETTY

ONGOING

Some Current SBU Projects

CHILD ABUSE/NEGLECT: PARENTING INTERVENTIONS
Lina.Leander@sbu.se
Expected: Spring 2018

DRUG THERAPY OF COMMON PAIN CONDITIONS IN THE ELDERLY
Jonatan.Alvan@sbu.se
Expected: Spring 2020

ENDOMETRIOSIS: DIAGNOSIS AND TREATMENT
Jenny.Odeberg@sbu.se
Expected: Spring 2018

EPILEPSY: DIAGNOSIS AND TREATMENT
Sten.Anttila@sbu.se
Expected: Spring 2018

FORENSIC PSYCHIATRY: PHARMACOLOGICAL INTERVENTIONS
Monica.Hultcrantz@sbu.se
Expected: Summer 2018

FORENSIC PSYCHIATRY: PSYCHOL/PSYCHOSOCIAL INTERVETIONS
Alexandra.Snellman@sbu.se
Expected: Summer 2018

INTERVENTIONS FOR UNACCOMPANIED MINORS
Pernilla.Ostlund@sbu.se
Expected: Summer 2018

YOUTH PLACED OUT-OF-HOME: ACCESS TO HEALTH & DENTAL CARE
Sofia.Tranaeus@sbu.se
Expected: Summer 2018

PSORIASIS: TREATMENT
Anna.Christensson@sbu.se
Expected: Summer 2018

TRAUMATIC BRAIN INJURY: REHABILITATION
Karin.Wilbe.Ramsay@sbu.se
Expected: Autumn 2019

TREATMENT FOSTER CARE OREGON
Knut.Sundell@sbu.se
Expected: Spring 2018

MEDICAL AND SOCIAL
Science & Practice

EXECUTIVE EDITOR Ragnar Levi, ragnar.levi@sbu.se • PUBLISHER Susanna Axelsson • TEXT Ragnar Levi [RL]
MAILING ADDRESS PO Box 6183, SE-102 33 Stockholm, Sweden • PHONE +46-8-412 32 00 • www.sbu.se
EMAIL registrator@sbu.se • TWITTER @SBU_en • DESIGN Alenäs Grafisk Form • PRINT Elanders, 2018
TRANSLATION Ken Schubert • CIRCULATION (SWE/ENG) 145 000/2000 • ISSN 1104-1250

VICTORIA SHAPIRO / SHUTTERSTOCK