

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



Researchers are becoming increasingly interested in data that have been gathered for purposes other than research. Information from electronic medical records, registries and wearable sensors can be processed using advanced statistical techniques to search for patterns, relationships and trends. But the opportunities opened by “real world data” are also offset by risks of hidden sources of error and overinterpretation of findings.

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Trash that glitters like gold?

COMPILING RESEARCH FINDINGS has become quite the craze. It's trending. Within the field of medicine, the number of systematic reviews has tripled in ten years. Results from such reviews are considered to provide reliable information and are frequently cited.

On the surface, all systematic reviews appear to be equally credible. But appearances can be deceiving. On closer scrutiny, some prove to be unreliable: incomplete, biased, or misleading for other reasons. Indeed, as is the case with other research methodology, reviews may be abused to benefit special interests.

A WELL-KNOWN SCIENTIST who is sharply critical in this context is John Ioannidis, Professor of Medicine and Statistics at Stanford University in California. In an article in the journal *Milbank Quarterly*, Ioannidis points to research on antidepressants as an example.

Between 2007 and 2014, which is to say after suspicions of a link to increased risk of suicide were already being voiced, no fewer than 185 metaanalyses were published about these medications. But hardly one in three analyses even suggested the possibility of problems with such treatment in their conclusions. And such suggestions were especially rare in cases where any of the review authors were employed by the pharmaceutical company.

Lisa Bero, a researcher at the University of Sydney and co-chair of the Cochrane Collaboration Steering Group, is another pioneer in the field of systematic reviews. In a recent article from the *American Journal of Public Health* she reminds readers of the link between investigative outcomes and industry-sponsored research that has also been exemplified in review articles about passive smoking, artificially sweetened beverages and blood pressure medications.

The problem is also that factors that may bias reviews are not always apparent. Among 682 systematic reviews registered in the Medline database during one month in 2014, one in three failed to account for how the literature had been searched, or how the quality of the study was judged (Page MJ et al., 2016).

MANY HIDDEN PROBLEMS in systematic reviews actually occur in all types of studies – not just in the medical field. For example, researchers may unilaterally focus on benefits while ignoring harmful effects. Or, they may only assess average results, without taking into account variations in outcome between different individuals or groups. Or they may underestimate the significance of practical experience among those who use the intervention and their relationship with users, clients or patients.

Despite the rising popularity of systematic reviews, the results should not be unequivocally accepted as true and indiscriminately used in clinical practice. Quality often falls short; many problems of methodology are hidden and the parameters that are measured may also be irrelevant to patients, users, practitioners and decision-makers.

The words of Swedish poet Gustaf Fröding still apply: "Dirt is dirt and trash is trash, though it in gold reposes". Systematic reviews may have become the gold standard in research synthesis but as we know, gold is not all that glitters.



Ragnar Levi Editor

▶ **THE INFORMATION SOCIETY**
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– habits and living conditions,
working life and leisure, consumer patterns and relationships, wellness and illness.

Medical researchers are now also becoming increasingly interested in what the literature refers to as *real world data* (RWD). The concept is used in different ways, and currently lacks an exact definition. It often refers to information concerning the health and treatment of individuals that can be found in registries and medical records, but also to health and lifestyle information in smartphones and wearable sensor devices. The common denominator is to take available information that has not primarily been gathered for scientific purposes and to use it for research purposes.

When large amounts of observational data are processed using advanced computer technology, an array of possibilities opens up to researchers. Some of the most dedicated advocates, mainly from industry, argue that RWD will soon be able to replace expensive and time-consuming randomised studies as the scientific cornerstone of health care. They hold that an abundance of natural observations that are analysed using multiple correlation analysis could be translated into "real world evidence".

Most independent researchers hold a more sceptical view: observational data are important as a complement, but cannot replace randomised clinical trials. It is difficult to ignore the effective protection that randomisation provides against certain important confounders that can skew the results. When chance determines what intervention a particular participant is offered, there is less risk of confounding – including by unknown factors. Moreover, in randomised studies where both researchers and study participants are purposefully kept unaware of which treatment each participant receives – known as double blinding – the risk also decreases that the comparison will be skewed by expectations or differences in patient care also decreases. This risk remains with observational data.

Nevertheless, randomised studies have well-known drawbacks. When researchers tighten their questions in strictly designed trials, the set-up also becomes less realistic. Treatment outcomes in the standard clinical setting sometimes

deviate considerably from those obtained in randomised studies. One reason is that registries encompass substantially more patients, and they are more “typical” than participants in most large clinical trials, who are intentionally selected to enable the study to yield clear results. In everyday clinical practice, patients are often older and have more comorbidity than those selected for formal studies. Moreover, they do not follow treatment advice as carefully.

Therefore, RWD can serve as an important complement to provide a more realistic, yet also more complex, view of treatment outcomes.

Three important areas of application for such data are: to describe actual health outcomes, to test treatment methods in practice and to study actual costs.

1. DESCRIBE ACTUAL HEALTH OUTCOMES:

Well-known examples of RWD can be found in quality and health data registries, as well as in case reports from clinicians concerning suspected adverse effects.

In the future, information from electronic medical records could also be used more, following patient consent. Wearable sensors for clinical monitoring could become an additional source of information, as could social media containing information concerning the habits and lifestyles of individuals.

Researchers can analyse such data to describe treatment outcomes in routine health care, including unexpected and rare side effects, while simultaneously considering lifestyle and other factors that may affect patient health.

Analyses of RWD can also be used to study variations in treatment efficacy and side effects in relation to routine use of treatment methods. The findings may result in new hypotheses and innovative treatments that can later be tested through experimental studies.

Large and well-maintained registries may clarify how treatment outcomes and side effects vary among different individuals who receive the same treatment for the same disease. Registry data may also give clues to the impact of characteristics among patients, care providers, the care environment and the organisation.

2. TEST TREATMENT METHODS IN PRACTICE:

Clinical trials of new treatments would more closely reflect reality if they could

be carried out directly in everyday clinical practice. One type of study that can test treatments in an everyday clinical setting is the so-called pragmatic randomised trial. In this venue, researchers leverage the advantages of randomisation, while also striving to recruit a larger, more varied and representative group of participants than can be achieved through traditional clinical trials. And instead of comparing with placebo, a particular treatment method can be compared with realistic treatment alternatives. Study participants are followed up as part of the routine health-care process, while treatment effects are measured using relevant RWD.

Many argue that pragmatic randomised trials contribute important knowledge, and this concept is hardly new. Nevertheless, few such studies have been funded or carried out.

A few years ago, Swedish researchers launched a type of pragmatic study that may be simpler and less expensive to conduct since it takes advantage of existing registries – an approach known as registry-based randomised clinical trials. Available quality registries are used to identify potential study participants, to randomise different treatments and to monitor treatment outcomes.



MODELIA / SHUTTERSTOCK

3. INVESTIGATE ACTUAL COSTS: Health economics calculations regarding cost-effectiveness should include correct information not only on the effects of various interventions in terms of health and quality of life but also about the actual costs of various treatments. These calculations serve as a basis for decision-making in health care.

However, in clinical trials it is often difficult to find useful information about costs. The actual figures may be completely different. The more closely the data reflect reality, the better. Indeed, here is yet another area where RWD can be used to advantage.

INFORMATION MUST BE accurate and relevant, regardless of scientific area of application. The risk of errors is considerable in chart notes, computer systems and registries that were not initially intended for research purposes. Registry data may be incomplete or inconsistent and may have been improperly handled and analysed. Yet another problem is that routinely gathered health data may not always reflect the most essential elements – how people feel and function.

Finally, there is a risk that processing large quantities of data may lead to data dredging: so many possible correlations are investigated that statistically significant correlations may arise by pure chance and then be accepted as true.

Information obtained from real life may provide valuable knowledge, but only if such information is gathered and analysed with true scientific rigour. ♦ **RL**

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Patients (Dis)connected?

Digital tools are becoming increasingly important in health care. Patients, users and personnel are expected to be connected, equipped and knowledgeable. However, new technology is a double-edged sword that can cut both ways, depending on the user. Careful assessment is needed to avoid harming those in greatest need of help.

SWEDEN IS ONE OF THE MOST digitalised countries in the world; the country ranked third in the EU in 2017.¹ For example, internet use is among the highest in the world, and digitalisation of health care will continue to grow.²

This development is described as a fundamental change in structure, a technological revolution.³ Large investments are required to meet the high

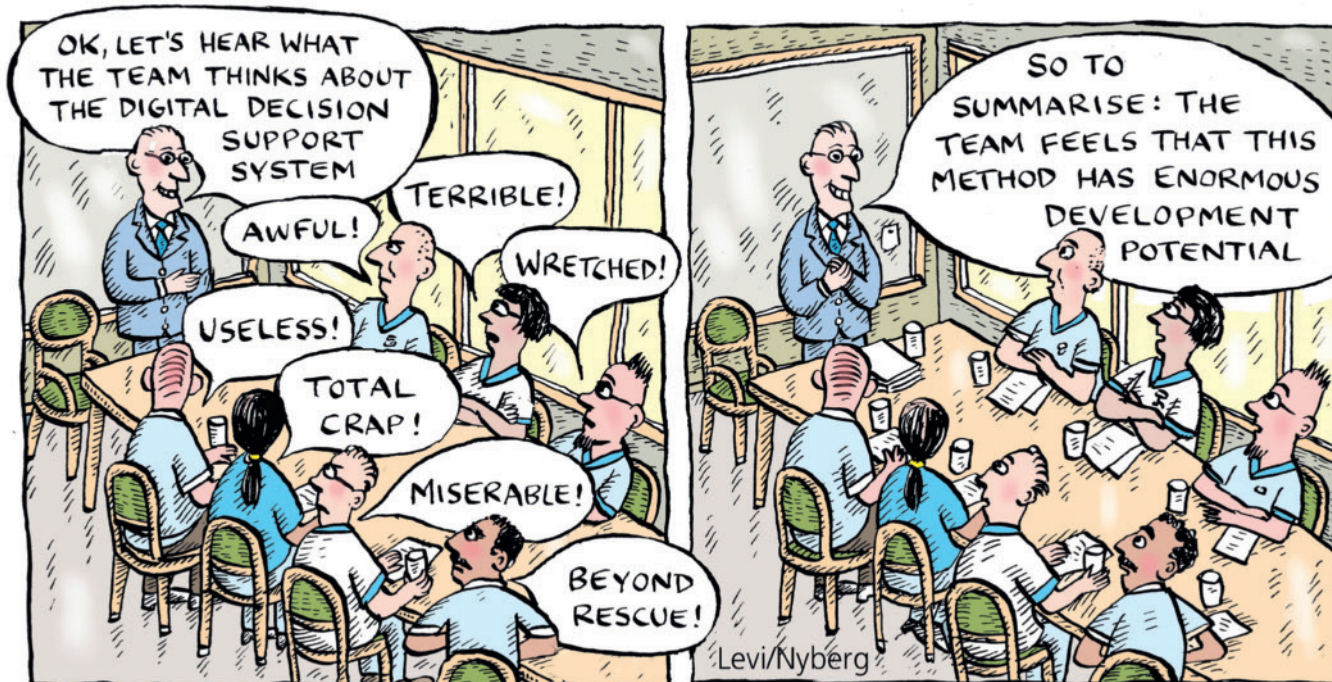
expectations of benefit to patients and users alike.

AS IS THE CASE with any initiative, digital technology may of course entail both good and harm. Since digitalisation of health care and social services entails major changes, the consequences may be far-reaching – positive or negative, expected or unexpected. For this reason, decisions must be based on evidence

rather than on hopes and assumptions.⁴

First, eHealth projects must investigate more frequently than in the past whether the tools are actually appropriate in practice for their intended use and effect. [4] Important technology choices should be based on an assessment of their documented effects on quality of care, health and wellbeing, as well as on their actual impact on cost.

Second, a more structured approach





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must be taken to investigate the effects using appropriate scientific methodology, in line with established international guidelines.^{5 6}

Third, the results must be published – regardless of whether or not they are favourable. The risk otherwise is that only positive experiences will come to light.⁴ All new and valuable knowledge must be shared with all other organisations that are considering the same tools.

PROFESSOR GÖRAN PETERSSON, who has years of experience concerning these issues, including as director of the eHealth Institute in Kalmar, states:

“The implementation of digital technology must be based on systematic testing, assessment and follow-up. Assessment is crucial to the success of eHealth projects. The tools must be tested under realistic conditions, by an independent party with the expertise to provide critical constructive scientific testing.”

He further comments “Many digital health project developers have difficulty seeing the forest for the trees. The question is not just how to hone the technology, but also how it affects the organisation, services and above all, human health.”

Göran Petersson is critical of the trend towards direct large-scale deployment of new digital solutions.

“Digital tools also need to be introduced step by step in a managed process – much like medicines or other purely

medical interventions,” he says and continues:

“New products must be tested on a small scale first, in a test bed. This is how to find out whether the technology has any negative effects, or if it needs to be adjusted. If it works well, it can be scaled up, but not otherwise.”

Even on an international scale, several groups have called for improved and more scientifically oriented assessments of eHealth projects.^{7–9}

Demands are being made for more systematic assessment of the effects of the interventions on human life and health, wellbeing and finances. Ethical issues must also be clarified. Assessments must present reliable facts and be carried out independently of manufacturers. Otherwise special interests may take the upper hand and people could be harmed.

ANOTHER IMPORTANT QUESTION is how to reach the appropriate target groups. New technology often spreads unevenly in the general population. According to US sociologist Everett Rogers¹⁰, there are five categories of adopters, ranging from early to late: innovators, early adopters, early majority, late majority and laggards. The latter groups include many people who have limited potential and few resources to test new technology – even when there are obviously good reasons to do so. Therefore, the “digital divide” may have the most adverse effect

on those whom health care and social services are expected to prioritise.

In a written Swedish questionnaire¹¹ provided to 1264 individuals between age 65 and 85, 20 per cent of respondents state that they completely lack access to digital devices such as laptops, computers, smartphones, tablets, e-readers or smart TVs. This figure may be an underestimate, according to the authors, since one in three failed to complete the questionnaire and non-responders are known to have less access to technology.

In another questionnaire¹², albeit one to which only one in five of the selected population responded, 44 per cent of people aged 76 and older state that they do not use the internet at all. In the same age groups, 12 per cent state that they do not use the internet at all, even though they have access at home.

When digital technology in health care and social services functions well – and is used as intended by those for whom it was developed – it can create a stronger safety net for people who need help. However, society must ensure that there is a reasonable balance between benefit, risk and cost.

Building a solid basis for decision-making in turn requires that the effects of the methods on health, wellbeing, finances and ethics be scientifically assessed – and reliably so. ♦ **RL**

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Faults and Fallacies When Findings are Quoted



When research results are referred to in the news feed, as in social media, far from everything claimed to be scientifically proven is actually correct. Here are twelve common problems that may be useful to keep in mind.

Exaggerations



The purpose of headlines and posts in news feeds is to attract clicks and readers. In many cases, simplification of research findings leads to exaggeration. In worst case scenarios, the communicated information may be completely erroneous. Always be alert for the actual evidence.

Misquotes



Research findings cited or referenced in the news feed are often distorted and misinterpreted – unintentionally or otherwise. Always refer to the source when something important is involved.

Half-truths



It is improper to present only those findings that are desirable, while ignoring those that may be inconvenient, or even contradictory. Cherry-picking findings to fit a particular agenda is equivalent to spreading half-truths.

Special interests



Companies often pay researchers to conduct and publish research. While this practice does not necessarily invalidate the findings, it may have undue influence. Therefore, find out who has funded the study. It may have been designed to suit special interests.

Association or causation?



Watch out for confusing association with causation. Just because two things occur at the same time, one does not necessarily cause the other.

Both mosquito bites and heat stroke are more common in the summer, but of course such bites do not cause heat stroke.

Loose assumptions



Hypotheses are needed to spur research. But research reports must clearly show what has actually been demonstrated, in contrast to assumptions that remain to be proven.

Too few participants



The rule of thumb is that small clinical trials (or rare incidents in large trials) yield unreliable results that may sometimes be completely wrong. The greater the number of observations, the more reliable the results.

Biased selection



When people are invited to participate in a scientific study, the selection should be representative of the group targeted by the study. Selection bias increases the risk of misleading conclusions.

No control group



Clinical trials should always include a control group for comparison with the test group. These groups should be as similar as possible, with the sole exception of the effect of the intervention under study. For this reason, subjects should be assigned to the test group or control group through a randomised process.

No blinding



To achieve a fair comparison between the test group and control group, participants should not know the group to which they belong – a process known as blinding. This approach avoids the influence of any expectations concerning the intervention. In a double-blind study, researchers are also kept in the dark until all measurements and analyses have been completed. This is especially important in regard to outcomes that are not objectively quantifiable.

Unconfirmed findings



To substantiate the veracity of research findings, new independent studies must be repeated to confirm them. Strong assertions require strong evidence. As a rule, new surprising findings must be confirmed before they can be accepted as true.

No fact-checking



Peer review is an important part of the research process. External researchers review and question studies before they can be published in a scientific journal. Findings that have not been reviewed in this manner are considered to be less reliable and may even be wrong. ♦ RL

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Endometriosis Patients want better-informed and faster help

Endometriosis may cause pain, create problems in daily living, and clearly lower quality of life. Still patients often feel that their concerns are not taken seriously and establishing the right diagnosis often takes a long time. The gaps in scientific knowledge are also large. The SBU assessment points to a need to hone the diagnostic process and to use a more consistent approach when studying treatment methods.

IN MANY CASES THE TIME TAKEN TO diagnose endometriosis is unnecessarily long, causing considerable suffering and attendant complications. When women present for abdominal pain it is important for healthcare providers to inquire early on about dysmenorrhea, difficulties becoming pregnant and dyspareunia.

In cases where well-founded suspicion of endometriosis exists, diagnostic imaging prior to surgery holds clinical importance, especially vaginal ultra-

sound, as shown by SBU's assessment of the accumulated scientific literature. Ultrasound examination is simple to carry out, though it requires an experienced clinician. When imaging is compatible with endometriosis, the findings provide sufficient confirmation. However, normal ultrasound findings do not necessarily rule out the diagnosis.

TREATMENT FOR ENDOMETRIOSIS has two purposes – to reduce pain and to increase the chances of becoming pregnant. Avail-

able treatment includes drugs, especially hormones, and surgery – either separately or in combination.

Unfortunately, it is difficult to estimate how effective these methods are, according to SBU. Despite the many published studies in this field, the effects can seldom be reviewed using a scientifically reliable approach. The reason is that the studies have been conducted in different ways, which prevents the results from being grouped together for comparison.

SBU'S CONCLUSIONS DIAGNOSIS, TREATMENT, AND PATIENT EXPERIENCES

Endometriosis is a chronic disease that may entail infertility and severe pain. The disease may have a large negative impact on quality of life and daily living.

► Treatment with GnRH agonists and progestogens seem to have similar pain-relieving effect, but GnRH agonists decrease bone density.

► Postoperative treatment with progestogens and monophasic contraceptives seem to have similar pain relieving effect in women with chronic pelvic pain and dyspareunia. Hormonal intrauterine contraceptive devices may reduce dysmenorrhea compared with no treatment.

► Vaginal ultrasound has clinical value in the diagnosis of ovarian endometrioma, and

prior to surgery for deep endometriosis. This applies to the elucidation of how widespread the disease is among women with well-established clinical suspicion of endometriosis. Vaginal ultrasound is inexpensive, readily available, has no contraindications and requires no preparation. Healthcare professionals conducting ultrasound examinations need to be experienced.

► During fertility treatment, prolonged pretreatment with GnRH agonists has a higher chance of resulting in pregnancy for women with endometriosis, compared with short-term pretreatment.

► Women with endometriosis symptoms feel they encounter ignorance about endometri-

sis in non-specialised care. They experience delays in both diagnosis and treatment, and feel that healthcare professionals do not take their problems seriously. Moreover, it would appear that increased expertise and improved attitudes among healthcare professionals could improve the living situation for women with endometriosis.

► Despite the large number of identified studies, there is a general lack of scientific evidence for most treatments. Future research should be more standardised regarding duration of treatment, follow up and evaluation of outcome/pain. More research is needed in the important areas of diagnostics and evaluation of surgical outcome.



MEDICAL IMAGES RM / STEVE OH, MS CM

However, regarding medications, the systematic review shows that progestogens probably do provide pain relief equivalent to GnRH-agonists, but without the risk of reducing bone density, and that hormonal intrauterine devices possibly reduce dysmenorrhea compared with no treatment at all.

Most independent studies that compare hormone therapy with placebo show decreased pain. Regarding other medications, such as analgesics, anti-inflammatories, and immunomodulators, the scientific basis is insufficient to draw any definite conclusion. The same applies to dietary treatment.

The effect of surgery on pain relief and improved fertility is uncertain due to a lack of well-conducted studies. In certain cases, surgery is necessary, such as when the ureters or intestines are involved.

But in many other situations, striking a balance between the potential treatment benefits and risks of surgical complications is difficult.

SOMETIMES PHARMACEUTICAL treatment is continued after surgery. According to aggregate research, women with pelvic pain and dyspareunia may experience equivalent pain relief from progestogens alone as from monophasic oral contraceptives containing equal amounts of oestrogen and progestogens.

Endometriosis may make it difficult for women to become pregnant. Ovulatory stimulants and artificial insemination may improve the chances, and research shows that this may be facilitated by pretreatment with GnRH agonists for several months instead of for just a couple of weeks.

CONCERNING THE PATIENT encounter, qualitative studies show that women with endometriosis feel that healthcare personnel who do not specialise in such problems have inadequate knowledge of the disease and do not take them seriously, which delays diagnosis and treatment. Encounters with healthcare personnel who are perceived as having expertise and engagement in such issues may instead bolster the woman's sense of being able to manage her problem. ♦ **RL**

About the report

Endometriosis – Diagnosis, treatment and patient experiences. A systematic review and assessment of medical, economic, social and ethical aspects (2018). Stockholm: SBU, 2018.
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English summary at www.sbu.se/277e



Epilepsy More patients may benefit from surgery

More people with epilepsy who fail to respond to pharmaceutical treatment could become seizure-free with surgery. Surgical removal of brain tissue is only suitable for certain patients with focal epilepsy, but in such cases this method is often effective and the cost is low to moderate in relation to its benefit. Yet this approach is seldom used.

TWO OF THREE PEOPLE who medicate for epilepsy become seizure-free. The remainder usually experience fewer and milder attacks. But some patients are not helped by medications.

In such cases surgery may be appropriate – provided that the investigation shows the seizures originate in a well-defined area of the brain, a condition known as focal epilepsy. The surgical procedure entails removal of some of the brain tissue from the area that triggers the seizure.

THE SBU ASSESSMENT SHOWS that such procedures, known as surgical resection, could be used more often than in current practice among carefully selected patients who fail to respond to pharmaceutical

treatment. In cases where surgery appears to be appropriate, the procedure is often effective. Considerably more operated patients are seizure-free after one to two years of follow-up than are those who continue with medications alone. The difference is 49 percentage points.

THE RESULTS ARE ALSO favourable from a health economics standpoint. In relation to the effect that surgery can provide on patient health and quality of life, the cost is likely to be low to moderate, according to SBU calculations. A thorough discussion of the potential risks and benefits must be undertaken with the patient, family members and treatment team before surgery can come into question.

Another treatment for which the SBU has conducted a scientific review is

the high-fat, low carbohydrate ketogenic diet. In some children who fail to improve on medications and who have undergone a thorough medical investigation, the ketogenic diet is effective. The cost is difficult to calculate and may potentially be high.

The SBU review of diagnostic and treatment methods serves as the basis for the Swedish National Board of Health and Welfare's new national guidelines. ♦ **RL**

About the report

Diagnosis and treatments for epilepsy. A systematic review and assessment of the medical, health economic, social and ethical aspects. Stockholm: SBU, 2018. Project Manager, SBU: Sten Anttila, registrator@sbu.se English summary at www.sbu.se/281e

SBU'S CONCLUSIONS EPILEPSY: DIAGNOSIS AND TREATMENT

- Most of the diagnostic and treatment methods used in Swedish health care for epilepsy are based on scientific evidence.
- There is strong scientific evidence that surgery is an effective treatment for a select group of people with epilepsy who are resistant to pharmaceutical treatment. Yet, surgery is infrequently used in Sweden.

The estimated cost of surgery per quality-adjusted life year is low to moderate.

- There is moderately strong scientific evidence that a ketogenic diet is an effective treatment for a select group of children with pharmacoresistant epilepsy. The estimated cost per quality-adjusted life year is high, but estimates of such costs remain uncertain.

- More research is needed in some areas, for instance, regarding the treatment of epilepsy in certain age groups, as well as for the treatment of comorbid conditions such as when epilepsy occurs concomitantly with depression, psychosis or ADHD.

Young Less criminal behaviour in treatment foster care than residential care

Adolescents with serious repeated criminal behaviour appear to respond better to treatment foster care than to residential care, according to the SBU systematic review and assessment of the available research in the field.

COMPARED WITH residential care, placement in foster care under the Treatment Foster Care Oregon (TFCO) program results in less future criminal behaviour and fewer placements in locked settings among adolescents with serious behavioural problems. Young people in treatment foster care also appear to suffer from fewer mental health problems and are less likely to use illicit drugs than youths in residential care. These effects have been observed in studies that monitored conditions for up to two years after initiation of care.

The young people in question require placement outside the home – but not in ordinary foster care homes, since their behavioural problems are too serious. In Sweden, most of them are placed in various types of institutions where each staff member cares for several adolescents at the same time. Examples include residential homes (so called HVB, “*homes for care or residence*”) and secure residential care facilities for young people who require extra supervision because of criminal behaviour, substance abuse or mental ill health.

THE STUDIES DO NOT indicate why treatment foster care is probably more successful than other types of residential care. One of several possible explanations could be that treatment foster care only receives one person at a time, which could lower the risk of coming under the negative influence of peers with similar problems under residential care. The

TFCO integrated approach involving family, school and individual needs could be another contributing factor, though there is no basis to determine this.

THE OUTCOMES OF the TFCO approach are likely superior to residential care. But what about the costs? The SBU analysis shows that TFCO costs less than placement in secure residential care facilities, but slightly more than residential homes. In addition, an SBU review of a Danish economic analysis found that the overall long-term outcome may entail lower costs for society than residential care.

Each year about 2,000 adolescents in Sweden are placed in residential care because of serious problems such as criminal behaviour and substance abuse. Residential care is often supplemented with various treatment interventions. A 2016 SBU report shows that knowledge concerning the risks and benefits of these interventions is inadequate with respect to anti-social behaviour among adolescents in residential care. A recent survey conducted by SBU also shows that one in four institutions state that their personnel do not have any training in these methods. Professional supervision is rarely available. ♦ **RL**

About the report

Treatment Foster Care Oregon for seriously delinquent adolescents. A systematic review and assessment including economic and ethical aspects. Stockholm: SBU, 2018. Project Manager, SBU: Knut Sundell, Knut. Sundell@sbu.se
English summary at <http://www.sbu.se/265e>



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Treatment foster care

Treatment Foster Care Oregon (TFCO) is a temporary intervention, which in part involves protection and general care in a home environment, as well as treatment. It was developed as an alternative to institutional care for adolescents with serious behavioural problems, such as repeated and serious criminal behaviour.

Just one adolescent at a time is placed into each treatment foster care home. Each individual has a customised treatment plan and a professional treatment coordinator, who is responsible for five to 15 youths. Foster care parents receive training before and during placement. They receive guidance and have access to relief as needed. Crisis support is available around the clock. The intervention clearly focuses on schooling. The child's health and medical care needs are monitored during the placement period. Youths who live with treatment foster care families that operate according to the TFCO model are supported by a specialised adolescent therapist, as well as a social skills trainer as needed. The family of origin also receives treatment.

MONKEY BUSINESS IMAGES / SHUTTERSTOCK



SBU'S CONCLUSIONS TFCO FOR SERIOUSLY DELINQUENT ADOLESCENTS

► There is evidence of moderate certainty that placing seriously delinquent adolescents in TFCO reduces the risk for future criminal behaviour and consequently lowers the number of days in locked settings compared with adolescents placed in residential care. TFCO may also reduce the risk of delinquent peer associations and drug use, while improving the individuals' psychological health compared with individuals receiving residential care.

► TFCO costs are lower when compared with fees set by secure residential care, but slightly higher than the rates of residential homes, assuming that the duration of care in the different settings is the same. Considering the long-term effects, TFCO is more cost-effective than both types of residential care mentioned above.

► Approximately 30–40 adolescents in Sweden annually receive TFCO. If more people are to receive this treatment, additional TFCO teams need to be established, which

would require an increase in funding that would allow for more effective training and certification.

► The alternative to TFCO is institutional care, normally supplemented with various interventions. The evidence of their benefits and harm is inadequate due to lack of effectiveness trials. From an ethical point of view, it is important to have reliable knowledge of the pros and cons of all supplementary treatments used.

Cholecystectomy Possibly fewer surgical injuries when bile ducts are routinely x-rayed

In Sweden, almost all patients who have gallbladder surgery undergo intraoperative x-ray examination of the bile ducts – a routine practice that has been called into question. In other countries such x-rays are carried out selectively, i.e., only when the surgeon considers it to be necessary. But according to the SBU's scientific assessment, routine cholangiograms during surgery may be beneficial.

WHEN THE GALLBLADDER is surgically removed, there is a risk of injury to the biliary tree. Among the 13,000 people who undergo this procedure in Sweden each year, such injuries occur in 30–40 patients (0.3 per cent). One third of them sustain serious, and in the worst of cases life-threatening, injuries that may require extensive additional surgery and cause chronic suffering with reduced quality of life.

The SBU assessment of the available research shows that there may be fewer injuries when the biliary tree is routinely x-rayed in conjunction with the procedure, rather than just in those cases when the surgeon considers this to be necessary. Without routine intraoperative cholangiography (IOC), the types of injuries that are most likely to occur may require extensive corrective surgery, cause chronic suffering with reduced quality of life and, in the worst of cases, result in death.

MEANWHILE, ROUTINE USE of IOC results in higher total radiation exposure to this patient group than does selective use. As-

suming that approximately 40 percent of all patients in Sweden could be eligible for selective investigation, the added radiation resulting from routine use of IOC is estimated to induce one new case of cancer among the 26,000 patients in Sweden who undergo this surgery over a two-year period.

The extra cost for routine rather than selective IOC is estimated at SEK 14.5 million per year (EUR 1.41 million). This is balanced by a reduction of cost of approximately SEK 6 million (EUR 580,000) per year because of the bile duct injuries that are avoided.

AVOIDING SURGICALLY INFLICTED injuries prevents undue suffering for patients. In a base case scenario of SBU's health economic analysis, the cost per saved quality adjusted life year (QALY) is approximately SEK 300,000 (EUR 29,100) if IOC is used routinely instead of selectively. However, since there are no data on outcomes and risks of using selective IOC in a Swedish setting, this analysis is based on several assumptions, some of which are highly uncertain. This is reflected in the sensitivity analysis. ♦ **RL**



INSPIRATION.GP / GETTY

Intraoperative cholangiogram

During surgical removal of the gallbladder (cholecystectomy), an intraoperative cholangiogram may detect gallstones in the common bile duct. It also allows the surgeon to view the bile duct system's anatomy, from the liver to the small intestine.

About the report

Intraoperative cholangiography in cholecystectomy. A systematic review and assessment of the medical, health economic, social and ethical aspects (2018). Project Manager, SBU: Jan Adolfsson, Jan.Adolfsson@sbu.se
English summary at www.sbu.se/292e



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