

MEDICAL SCIENCE & PRACTICE

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Key Questions Left Unasked

Biomedical researchers publish millions of articles annually. But only a small share add new, reliable, and important information that can be applied in medical practice. Meanwhile, essential questions – some decisive to life – are left unasked.

Worldwide expenditures for biomedical research exceed 100 billion US dollars (USD) per year. A large share of the total goes to basic research. Treatment studies, ie, research aimed directly at solving medical problems, account for only a small percent. Numerous analyses in Sweden and other countries indicate that the lack of clinical trials poses a serious problem.

Considerable time and money are committed to studies that yield little or no usable knowledge. Patients participate unnecessarily as research subjects.

Getty

Anecdotal Evidence Revisited

For as long as humans have lived on this earth we have told stories. Around campfires, from pulpits, in cafes, at sewing circles, and during hospital rounds – everywhere we go we are captivated by the life stories of our fellow humans.

Many have made a living from these anecdotes – not only writers and journalists, but clever PR professionals as well (although the latter prefer the term “storytelling”). As one contemporary consultant said: “If you market a story well it will be passed on, whether it’s true or not. Storytelling can make your company appear unique and exciting – even if it’s actually ordinary and dull.”

The personal story has become a smart method for product positioning, particularly via the Web where stories and testimonials are woven into websites, blogs, and microblogs: “Forget your migraine, mine disappeared immediately by resting on a bed of nails... Hey, I tried the new diet pill and lost loads of weight, like ten kilos in two weeks ... My friend used this anti-wrinkle cream for seven days and looked like ten years younger...”

In modern, science-based medicine with its emphasis on testing the benefits of different treatment methods, not surprisingly the anecdote has fallen into disrepute. Case descriptions are rare in the scientific literature. I guess they detract from the impact factor of scientific journals. The word anecdote itself can be traced back to the Greek *an* and *ekdotos*, literally meaning unpublished.

But without anecdotes, we risk losing something essential. Sure, case studies can be misleading, especially if you try to draw general conclusions from single observations. After all, a single case or one case series cannot reveal the probability of a treatment method doing more good than harm in patients with a particular disease. When selected cases are not the rule but the exception, then generalised conclusions are easily off base.

However, anecdotes work. They can be effective teaching tools in medical education, and they are crucial to the ongoing advancement of medical research. Case descriptions also generate hypotheses that can lead to new discoveries and treatments, and they constitute the most important source of new knowledge about rare events, for instance, previously unknown diseases or uncommon side effects.

In her book *Narrative-Based Medicine*, GP and researcher Trisha Greenhalgh observed that patients’ personal stories could provide important knowledge, not just in medical diagnostics, but also for understanding grief, pain, and hope. By telling stories and listening to others we can create meaning and context, even when something is difficult to fully comprehend. This is an important complement to evidence in health care.

The anecdote is not the disadvantaged cousin of evidence. It’s a full-fledged sibling – but one with completely different characteristics.



RAGNAR LEVI, EDITOR

Gary S Chapman/Getty



According to Professor Iain Chalmers, British scientist and one of the founders of the Cochrane Collaboration, resources are wasted when research is targeted at the wrong questions, when studies are inappropriately designed, when reporting of the results is biased, delayed, and incomplete, or when the results are not published at all.

One of the problems, according to Chalmers and his colleague Paul Glasziou at the Centre for Evidence Based Medicine in Oxford, is that researchers launch new studies without fully investigating what is already known. For instance, a survey from 2005 showed that not even half of those who had designed a new study were aware that a Cochrane review had covered the same area.

The Lancet takes this problem seriously and requires authors to discuss how their findings compare with exist-

ing systematic literature reviews and meta-analyses. For years, SBU has advocated that PhD work should begin with a systematic literature review that reports on what is known already. Representatives of SBU have suggested this to university deans, and at some Swedish universities the situation has started to improve, ie, systematic reviews will be approved as a part of the doctoral work.

KNOWLEDGE GAPS

Identifying knowledge gaps in treatment research is the first step in filling them – instead of investigating questions that other researchers have already answered. In 2009, the Swedish Government asked SBU to identify healthcare methods about which too little is known. This effort is fully underway. Using its systematic literature reviews as a starting point, SBU is constructing a database of methods that

have been insufficiently studied. A model in this context is DUETs (Database of Uncertainties about the Effects of Treatments) in the UK that lists 2000 knowledge gaps and uncertain effects concerning treatment methods.

But if research is to help improve health services, it is not enough for researchers to merely ask relevant questions. The studies must also be designed appropriately. Although clinical trials are expensive, deficiencies in their design are not uncommon.

SKEW RESULTS

In comparing different treatments with each other or with placebo, researchers might, eg, fail to conceal which individuals belong to the trial and control groups respectively – which could skew the results. A review of 234 studies that had been published in well-known scientific journals found blinding-related problems in 18% of the cases and uncertainties in 26% of the studies.

Shortcomings in publication of the results also represent a waste of research resources. Findings that do not come up to investigators' expectations are at a disadvantage, ie, publication is delayed, less comprehensive, and the work is less likely to appear in established medical journals. Studies suggest that this is often attributed to the researchers and their financiers, not the journals.

Even if a scientific journal publishes the results, a fair presentation of the study as a whole is far from certain. At times, publications report on endpoints other than those primarily targeted by the study, or findings are presented in a way that does not allow comparisons between similar studies.

INITIATIVES NEEDED

Chalmers and Glasziou show that current resources for treatment research should be better utilized. But new public initiatives are also needed, according to many. Studies

focusing on the questions of patients and caregivers are few in comparison to studies focusing on the self-interests of industry and academia. For instance, more trials need to compare surgical and medical methods, assess psychosocial interventions, and study lifestyle changes. Also, too few studies investigate the elderly and children. Therefore, proposals have been forwarded to create a European counterpart to the National Institutes of Health (NIH), which finances this type of research in the United States. In Sweden, a governmental study on clinical research identified the need for a special fund for treatment research.

Currently, this is no more than a proposal. While awaiting the implementation of these or other plans, it is important to invest existing research funding where it offers the greatest possible return to patients. [RL]

Further Reading

Chalmers I, et al. Avoidable waste in the production and reporting of research evidence. *Obstet Gynecol* 2009;114:1341-1345.

UK questionnaire on the use of research funding: www.mrc.ac.uk/Achievementsimpact/Outputsoutcomes/e-Val/index.htm

PUSH FOR MORE STUDIES OF CLINICAL VALUE | SOME DRIVING FORCES

Patients, professions, producers, and politicians demand scientific documentation on clinical effectiveness

Different therapies (eg, pharmaceuticals, medical devices, surgical methods, and other therapies) are compared in terms of benefits, risks, and costs. Drugs are compared head-to-head, not only with placebo. Medications are compared to nonmedications.

The questions that researchers aim to study have relevance for producers and patients

Researchers identify the questions of greatest concern to patients. New, primary studies are started only if needed, ie,

when existing research findings (reviews) cannot provide answers.

Healthcare producers/financers (eg, county councils) enable, support, and follow up research

It is advantageous for healthcare staff to pursue clinical research that benefits patients and the organization itself. Healthcare producers/financers realize that high-quality clinical research is costly and takes time. Patient records and quality registers are used to follow up the outcomes of care.

Studies are designed in an optimum manner within given parameters

Every study is designed so it can actually

answer the questions posed. Adequate samples of research participants from relevant patient groups are studied for a sufficient length of time. Sources of error are prevented. Clinical trials are registered before they are launched.

Study results are accessible to everyone involved and are reported fairly

All relevant aspects of the research results are published. Articles and research reports adhere to accepted international guidelines (eg, CONSORT, STARD) for reporting research findings.

Canceling Old Methods to Leave Room for New

When health services introduce new treatments proven to be superior, they do not necessarily discard the less favorable alternatives at equal pace. Proposals to invest in new treatment methods should be accompanied by discussion on disinvestment of ineffective, obsolete routines.

British physician and epidemiologist Archie Cochrane (1909–1988), a prominent figure in evidence based medicine (EBM), writes in his book *Effectiveness and Efficiency – Random Reflections on Health Services* how as an activist medical student he marched through the streets of London holding a homemade sign proclaiming: “All effective treatments must be free.”

– Perhaps the flipside of the sign should have held a complementary slogan, says Professor Måns Rosén, Executive Director of SBU. He might have added, “Ineffective or harmful methods should not be free”.

MUST BE DISCARDED

The motto on the flipside plausibly follows the one on the front, suggests Måns Rosén. Resources are limited. If everyone is to have access to effective treatment, then interventions that do not offer value for money must be discarded. Methods that do

not provide medical benefits sufficient to justify their costs should not be used in publicly financed health services.

– It is unethical to continue using ineffective methods in public health services when other options have proven superior. Public resources are wasted – citizens receive less health in return for the tax money spent. Inferior methods should be eliminated.

But even if the principle of disinvestment is clear, it may be difficult to apply.

EASY CHOICE

Certainly, the choice is easy when a method is shown to be both less expensive and more effective than current options that could be abandoned by the health service. But perhaps the more common situation is that a new technology might be less cost effective than current options, but nevertheless contributes something valuable, eg, a new treatment principle or another profile of side effects. Or it is cost effective in some patients, but not others. Hence, the method can defend its position in the treatment arsenal – but its use should be restricted to evidence based indications.

– Often what needs to be phased out are inappropriate indications rather than inappropriate technologies, says Måns Rosén. Then the challenge to health services would be to tighten up the indica-

tions for using various methods so the most cost-effective alternative can be selected – not to completely discard a method. This frees resources that health services can put to better use elsewhere.

MIGRAINE

An example comes from the Dental and Pharmaceutical Benefits Agency (TLV) and concerns triptan drugs used in treating migraine. In July 2010, TLV decided that a broad assortment of triptan drugs should be covered under the public health insurance plan since it is impossible to predict which triptan drug would be most appropriate in a given case. Hence, TLV decided that all triptans except sumatriptan should receive limited subsidization. However, they should be prescribed only when sumatriptan is not sufficiently effective. “Expensive drugs should not be subsidized as first-line treatment options when other drugs with similar effects are available at a lower price,” writes TLV.

UNCERTAINTIES

For nonpharmacological methods, it will be no less challenging to limit their areas of use. In 2009, the government assigned SBU to identify and disseminate information on healthcare methods that have not been adequately assessed. A database of scientific

Further Reading

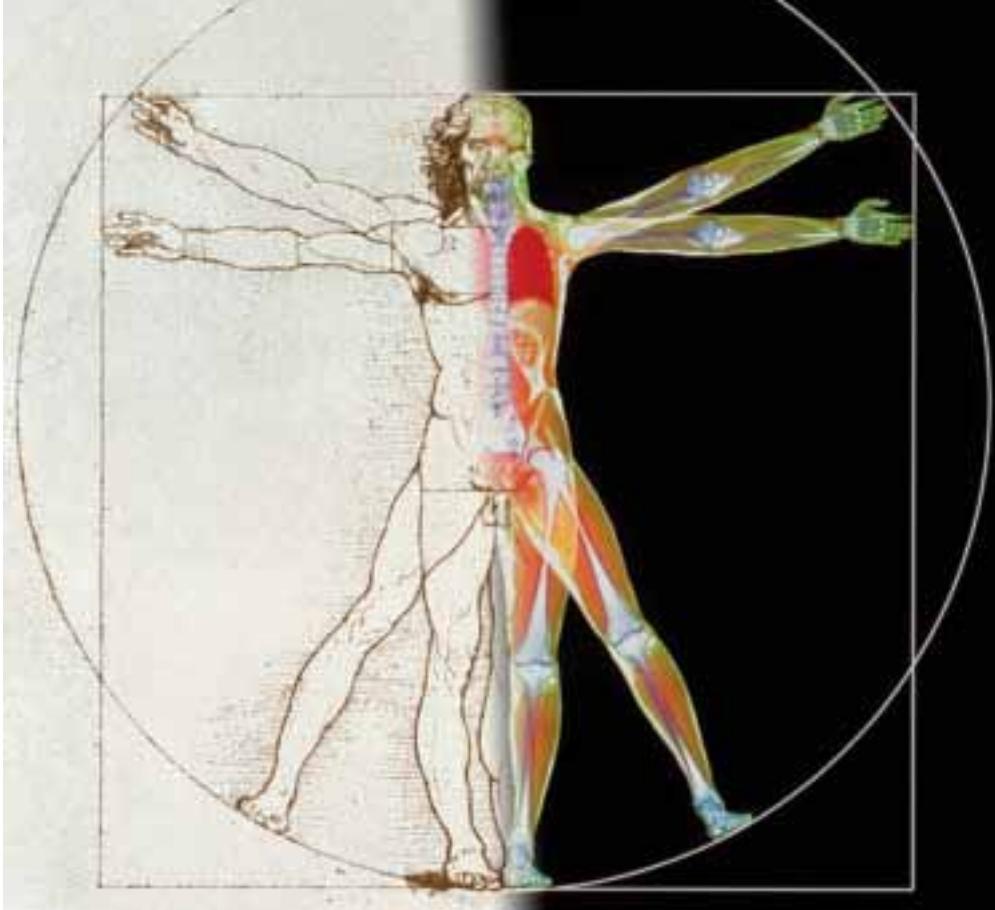
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Elshaug AG, et al. Identifying existing health care services that do not provide value for money. *Med J Aust* 2009;190:269-73.

SBU. *Self-Monitoring of Blood Glucose in Noninsulin-Treated Diabetes: A systematic review*. Stockholm: SBU;2009. Report no. 194.

SBU. *Patient Education in Managing Diabetes: A systematic review*. Stockholm: SBU;2009. Report no. 195.

TLV. *Triptanläkemedel mot migrän får förändrad subvention (Swedish)*. TLV. 6 Jul 2010.



Da Vinci/Science Photo Library (collage Westin Design)

uncertainties in the methods used by health services is currently under development. The aim is to subject more methods to clinical trials and in some cases limit their use, or phase them out. (see p. 2)

In a comprehensive context, discussions on efficient methods and economizing healthcare resources should not be limited to diagnostic and treatment methods.

An equally important

question is which of the models used in health services organization and administration are effective and which ones are not. It is conceivable that, even in this sector, assessing and eliminating interventions could contribute toward improving resource utilization.

LIVE LONGER

The costs for health services in Sweden and comparable countries are unlikely to

decrease in the future. The long-term trend points in the opposite direction. Increasingly, more citizens are living longer. A substantial share have several lifelong diseases and take multiple medications. New, expensive, high-tech methods of diagnosis and treatment, eg, for cancer, are constantly being added to existing methods.

Controlling escalating costs requires fully informed priori-

tization decisions that include ethical considerations. An important aspect in this effort involves eliminating certain methods, or at least limiting their use. [RL]

HAS A METHOD OUTLIVED ITS USEFULNESS? | SOME SIGNS

- New evidence has emerged that lowers the general rating of the method's benefits, risks, and cost effectiveness compared to alternative interventions. Examples: recent large and well-executed trials of the method, meta-analyses, postmarket surveillance of side effects, clinical audits, registry studies, escalating costs, evidence showing that the method's effectiveness in routine practice is inferior to what has been reported in studies.
- New methods (innovations) proven to be superior have emerged, or current methods have evolved to the extent that they fully or partially replace the method in question.

- The method has changed so that its benefits, risk profile, and cost effectiveness have deteriorated since it was last assessed. If used inappropriately, eg, by unqualified persons or outside of evidence based indications, it could be ineffective or harmful.
- Care needs have changed, eg, a particular health problem has decreased. Reduced utilization of a method is, however, not equivalent to a reduced need for care, but could be due to limited access or other barriers to utilization.
- Practice patterns have shifted. The method is already being displaced in some areas, eg, in other countries or in some

clinics as reported by practice studies, quality registries, etc.

- Controversy and debate where carers, patients, families, or decision makers report problems that could be attributed to current methods of diagnosis, treatment, or rehabilitation. To be substantiated by evidence.
- Advice and proposals about new methods from experts and researchers, patients and family groups, staff groups in health and social services, healthcare administrators, policy makers, agencies, and the medical industry. To be substantiated by evidence.

(Based on: Elshaug 2009)

Tracing the True Cause

Cause of illness is a key concept in health care. But a critical eye is needed to distinguish correlation from causation.

Healthcare staff and decision makers are primarily concerned with two types of causes – those that lead to illness and those that lead to health.

But determining which factors actually generate illness and health can be difficult. Many of the associations identified in observational studies are not causal.

For instance, a researcher studying the association between alcohol and cancer compares not only the number of cancer cases in high versus low consumers of alcohol, but also considers smoking habits. Tobacco smoking is a confounder, since there are probably more smokers among high consumers of alcohol and since smoking increases the risk of cancer.

A confirmed link between alcohol and cancer does not necessarily mean that alcohol causes cancer. Researchers must consider smoking and every other confounder before they can draw sustainable conclusions about a causal association.

NOT ALWAYS APPARENT

The problem is that confounders are not always apparent. The best way to reduce the influence of such underlying causes is to conduct a trial that randomizes partici-

pants to two groups – a trial group and a control group. In large randomized trials we assume that random selection means that all factors affecting the outcome, except the one being studied, are fairly equally distributed between the groups.

But randomized trials are not always feasible or appropriate. For instance, in the case of alcohol and cancer, such a trial would require changing the trial group's alcohol consumption and then, many decades later, studying whether cancer is less or more prevalent.

Clinical researchers have long wrestled with the question of how to establish a cause when it is not possible to conduct an experiment. Over a century ago, Robert Koch, a German microbiologist, described several criteria to use in determining whether a microorganism caused a disease. Koch's postulates were to play a major role in the fight against infectious diseases.

Today, the British epidemiologist Sir Austin Bradford Hill is probably as well recognized as Koch. In a famous lecture from 1965, Hill pointed out several aspects that should be considered in addressing whether or not a causal association exists.

CONSIDERATIONS

Hill's list of considerations, often referred to as criteria (even though Hill did not describe them as such), were

later expanded and criticized. Nevertheless, they point toward questions that can be worth asking when interpreting causal associations.

The most important aspect concerns the temporal relationship. Obviously, a cause will always precede its effect – but in many studies it is difficult to tell which actually came first. For instance, this applies to case-control studies, ie, studies that retrospectively investigate whether people with a certain disease were also exposed to a suspected risk factor, compared to a healthy control group.

Another aspect that Hill discussed was the strength of the association. The stronger the association, the greater the probability of a causal association.

NO GUARANTEES

However, there are no guarantees. He pointed out that even weak associations occur between cause and effect. But it is improbable that a strong association occurs simply as a result of missed confounders, measurement errors, or selection errors. Should this occur, the influence of the error must be at least as strong as the association itself, and this, according to Hill, is uncommon.

A closely related question concerns the level of exposure and degree of health, ie, the dose-response relationship. Hill used the term biological gradient. If such a relationship or gradient exists, the stronger one factor is, then the more

Further Reading

Hill AB. The environment and disease: association or causation? *Proc R Soc Med* 1965;58:295-300.

Doll R. Fisher and Bradford Hill: their personal impact. *Int J Epidemiol* 2003;32:929-931.



pronounced the other will be, and a causal relationship might exist between them.

Here, however, there is reason for caution. For instance, a confounder that affects both factors could result in a dose-response relationship. Also, the absence of a dose-response relationship is not proof that a causal association exists. The effect might appear only after the causal factor crosses a particular threshold value, eg, the association between alcohol consumption and cardiovascular disease.

Hill also asserted that biological feasibility must be considered when evaluating a suspected disease cause. Further, investigators need to consider if the new association concurs – or conflicts – with current knowledge about the disease.

If one factor disappears when the other is removed, this reversibility would further suggest a causal association.

The same applies if the association is specific to a particular disease, ie, the disease never appears in people lack-

ing the suspected causal factor. However, one can argue that a particular disease could have multiple causes, that a particular factor could lead to multiple diseases, and that several contributing causes might be necessary for a disease to appear.

CLINICALLY IMPORTANT Cause of illness is an important matter since it relates to the issues of effective prevention and treatment. But as Hill noted, there is a risk in always requiring total certainty prior to making important decisions affecting health. On the other hand, there are serious risks in disregarding the standards of scientific evidence – and this problem is substantially more common.

The higher the stakes in terms of health effects, risks, and costs, the higher our demands on the evidence must be. However, the most important evidence-based decisions will not always have the strongest backing. [RL]

CAUSES AND EFFECTS | SOME CLUES

The association is strong | A weak association does not, however, rule out the possibility of a cause and its effects.

The association persists | It has been reported on repeated occasions by different researchers, in different contexts, and at different points in time. Repeated findings could, however, be a result of systematic error in study design or execution.

The association is specific | A disease often appears in conjunction with a suspected cause, and the suspected cause seldom appears in healthy individuals.

Cause precedes effect | However, delays can be difficult to establish in retrospective studies.

Dose and response are connected | If the effects become greater as the cause

increases in strength, this could be due to a common confounder that increases both concurrently.

The association appears to be biologically feasible and does not conflict with known facts | Compare with existing, well-documented evidence. Many important biological associations remain unknown. Things that appear unreasonable today could become self-evident tomorrow.

Experimental data support a causal association | Studies where the suspected cause has been added or subtracted can strengthen the hypothesis.

The GRADE working group (www.gradeworkinggroup.org) considers similar aspects in their system for grading quality of evidence, eg, effect size, consistency, and dose-response relationship.

CORRELATIONS CAN BE ATTRIBUTED TO

Selection or measurement error | The data are inconsistent or result from errors in selection of study participants.

Chance | Some risk always exists for results being statistically significant by chance.

Confounders | Two phenomena co-vary because both are caused by a third, underlying factor.

Causal factors | Two phenomena are connected because one causes the other.

Quality Counts

Assessing a method often means measuring its effects. But an intervention's value is not limited to how well it solves a certain problem. Value is also measured by users' perception of the help offered and the changes that follow.

The extent to which a given intervention affects human longevity, health, and quality of life is often considered the most important outcome in health care. Clinical studies that measure the effects of different interventions must identify the benefits that patients gain in terms of increased survival, greater relief of symptoms, and improved quality of life as measured by a valid rating scale.

Other aspects of healthcare interventions are difficult to convert into figures and are too elusive to be captured by usual measurement methods. Different interventions with the same measurable effects on health might be perceived differently.

One example concerns following up patients with cancer, explains Sofia Tranæus,

Project Manager at SBU.

– A Danish assessment to follow up gynecological cancer included both quantitative and qualitative studies, says Sofia Tranæus.

DIFFERENT INFORMATION

– According to the quantitative investigations, follow-up exams had no effect on quality of life. But the patient interviews revealed that these exams could reassure patients and provide a sense of relief when medical findings were normal. Different studies yielded slightly different information.

– Of course, the results of qualitative methods can partially overlap the results of quantitative scales measuring quality-of-life, admits Sofia Tranæus. Instruments for measuring quality of life are often based on findings from patient interviews.

– But in many instances the qualitative studies provide completely new information.

COMPLEMENT

– The efforts often yield different types of knowledge that complement one another, she

says. Qualitative methods can provide insight on what the different interventions mean to patients and practitioners, but do not inform us about the magnitude of the intervention's effects.

One example of a question that qualitative research could help answer concerns how telemedicine is changing the relationship between the patient, the physician, and consulting specialists. Instead of studying, eg, how a patient's prognosis is affected, qualitative research methods can analyze how the parties interact and reveal what happens in communication.

– In contrast to quantitative studies, at times it is the researchers themselves that collect, analyze, and interpret the data.

– Even though researchers try to remain neutral, preconceptions can creep in and color their observation – which, of course, raises questions concerning reliability, says Sofia Tranæus.

– The risk of unintentionally tainting one's findings is naturally greater in studies where one's own interpreta-

WAYS TO COLLECT QUALITATIVE DATA | EXAMPLES

Interviews | Open-ended or structured; individuals or focus groups. Often used to study experiences (eg, events, opinions, feelings, needs, and desires).

Observations | Participation or nonparticipation, which is documented in various ways, eg, notes and audio/video recordings. Often

used to study behavior (eg, interaction among individuals, group processes).

Questionnaires | Often with open-ended questions.

Written documentation | Including diaries, minutes, case records, literature.



tion is an integral part of the results.

– But there are different ways to reduce that risk. For instance, researchers can allow the informants, those participating in the study, to review and evaluate the accuracy of the interpretations.

DIFFERENT PERSPECTIVES

Triangulation is another method. Here, different researchers analyze the data, possibly from different theoretical perspectives. Data can also be collected in several ways, eg, through questionnaires and interviews.

The samples in studies using qualitative methods do not necessarily need to be representative. But can we then draw general conclusions?

– When we aim to analyze a phenomenon rather than quantify it, large, randomized and statistically representative samples are not necessary. On the contrary, a strategic sample could be better.

Researchers might choose to describe only special cases that undermine established universal truths. Or, to achieve a multidimensional profile of a phenomenon, they could aim for the widest possible variation among informants.

Sample size is not always determined at the outset; researchers might choose to collect data until they believe that further material would offer no additional knowledge.

– Generalization of qualitative research findings is often based on documented similarities across different situations. Researchers make the assumption that these similarities render the findings transferable.

A particularly important matter for SBU concerns how to evaluate the reliability of studies.

– First, the report must be lucid and logically structured, explains Sofia Tranæus. The questions must be well defined, and the report should describe why the researcher chose qualitative methodology to investigate them.

FULLY DESCRIBED

– Like the context, the selection of trial participants should be relevant. If the study is based on a theory, this must be reported. The research method must be fully described so the reader can evaluate whether the data have been collected, verified, and analyzed appropriately.

– All interpretations must

be clearly supported by the data and placed in a context of previous studies in the area. Researchers should also report on problems that emerged during the study and how they were addressed. They should discuss conceivable weaknesses and present their arguments for and against transferring the results to other contexts.

Well-executed, qualitative studies can yield deep and detailed knowledge about patients' experiences and interpretations of their illness and the interventions offered. Such knowledge can be necessary to determine which interventions would be most appropriate in a given situation.

Studies with qualitative information can also help decision makers better understand problems where they might lack personal experience.

Often it is necessary to determine the effect size of healthcare methods. But this is not always sufficient. [RL]

WAYS TO SELECT PARTICIPANTS | EXAMPLES

Snowball method | Several people are asked to suggest others who should participate. Those who are recommended by several individuals are particularly important to include. The sample grows rapidly as more people are asked, like a rolling snowball.

Exceptional cases | The sample is targeted at unusual sources and outliers that might contribute unique and valuable information.

Maximum variation | Dissimilar sources are chosen to achieve a multifaceted view of valid principles and themes, despite substantial differences in the sources.

Homogeneous groups | Everyone in the sample meets certain criteria. Aims to provide deeper knowledge about this category of people in the study, eg, through focus group interviews.



Image-Source

Important to Replace Lost Teeth, but Methods Poorly Tested

Tooth loss lowers a person's quality of life and makes it more difficult to live and interact normally. It can affect everything from self-esteem to speech, facial expressions, and chewing. SBU's assessment shows that treatment helps people regain a normal, higher quality, life.

SBU has assessed the body of research on treating tooth loss and confirms that treatment has a major impact on people affected.

With tooth loss, individuals also experience deterioration in their quality of life, according to the report. For many patients, life becomes restricted and characterized by a loss in self-esteem, lower social status, and functional deterioration. Treatment for tooth loss helps patients return to a normal life and improves quality of life.

Methods currently available include removable dentures that patients can insert and remove on their own, bridgework of replacement teeth that is cemented to existing teeth, or implants anchored in the jawbone and support a removable denture or fixed tooth-replacements.

Research is too sparse to determine which of these methods offer the best function, are most attractive, and are most cost effective.

However, follow-up studies

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have reported on the longevity of implant methods – after 5 years, 90% of the single-tooth implants and 95% of the implant bridges remain in place.

COMMON AND COSTLY

Concurrently, SBU published a report on endodontics (root canal therapy). Although these procedures are both common and costly, the evidence in this area is limited. Research does not answer the question of whether a milder treatment could preserve dental pulp. Likewise, the evidence does not show which techniques and materials work best in filling root canals. A survey conducted by SBU clearly shows that Swedish dentists have different opinions, eg, regarding when it is appropriate to replace a root filling.

NATIONAL REGISTRY

The report calls for a national registry that would make it possible to monitor the quality of pulpal and root canal treatments, for example, how long different root fillings last without causing new problems.

To address uncertainties about the methods used in dentistry, further comparative studies are needed. SBU and the Swedish Research Council are taking the initiative to find ways to strengthen the research in this area. [RL]



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Reducing Preoperative Antibiotics Without Increasing Infection

Prophylactic treatment with antibiotics before surgery can reduce postoperative infection rates. Used correctly, antibiotic prophylaxis can cut total consumption of antibiotics.

In a recent report, SBU reviewed the scientific literature on preoperative antibiotic prophylaxis and surveyed its current use in Sweden.

Cutting the use of antibiotic prophylaxis would, in many instances, reduce the risk of developing multiresistant bacteria without increasing the risk of infection. For example, in some knee operations, several doses of preventive antibiotics are administered where a single dose would be sufficient, according to SBU's

assessment. In hernia operations that include insertion of mesh reinforcement there is no reason to use antibiotics.

CESAREAN SECTION

In specific situations, however, antibiotic prophylaxis could be used more frequently. A questionnaire survey by SBU indicated, eg, that some departments do not administer antibiotic prophylaxis before elective Cesarean sections even though scientific evidence shows that it protects against infection.

Simple routines to register all postoperative infections at all departments of surgery would be a way to monitor and further improve the use of antibiotic prophylaxis, asserts SBU.

Strong scientific evidence suggests that antibiotic prophylaxis protects against infections, eg, in surgery and endoscopy of the colon, rectum, and stomach (including appendectomy), cardiovascular surgery, breast cancer surgery, and joint replacement.

COST EFFECTIVENESS

Too little evidence is available to draw conclusions on the cost effectiveness of antibiotic prophylaxis. The cost of treatment is low compared to the price of the care episode. Evidence is insufficient concerning the risks and costs of antibiotic resistance from a societal perspective. [17]

BENEFITS VS RISKS

- The medical benefits of antibiotic prophylaxis (reduced number of infections) must be weighed against the risk for development of antibiotic-resistant strains of bacteria.
- Antibiotic resistance is progressing more slowly in Sweden than in many other countries, but resistant bacteria spread across national borders.



FAST Ultrasound Can Spot Lethal Bleeding

Severely injured patients with bleeding in the abdomen or pericardium can die unless hemorrhaging is detected and treated. A special ultrasound technique – in the hands of physicians with the right education and training – can provide quick information and save lives.

Early and rapid ultrasonography of the abdomen and pericardium – Focused Assessment with Sonography for Trauma (FAST) – can benefit patients suffering abdominal injuries and unstable blood circulation.

The examination can be performed in the emergency department. If the results show the presence of blood in the abdominal cavity or pericardium the patient can be transferred directly to surgery. No time is lost in transporting patients to the radiology department, and patients are not exposed to x-rays from computed tomography.

EQUALLY EFFECTIVE

But physicians must have sufficient education and training in the method to avoid the risk of overlooking a hemorrhage. In the studies reviewed by SBU, between 69% and 100% of hemorrhages were detected, and exams were conducted by emergency physicians and surgeons educated and trained in the method.

Too few scientific studies are available to determine the extent of knowledge and experience required to achieve the best results from the exam.

LACKING ROUTINES

Studies of sufficiently high quality are not available to determine if the method is cost effective. But since the added cost of ultrasonography is low compared to computed tomography, the method should be cost effective if practitioners have sufficient education and training to assure diagnostic accuracy. The cost per examination, including education, is estimated at 200 to 250 Swedish kronor (SEK).

FAST is used in the United States, Turkey, Australia, and other countries. The exam is noninvasive, ie, patients are not exposed to radiation, incisions, or injections. [17]



Marcelo Santos/Getty

EXAMINING SEVERE INJURIES

- When patients are evaluated and treated after acute physical trauma, eg, from a serious accident, clinicians must look beyond the visible bodily injuries. Internal bleeding is a common, life-threatening condition sustained from trauma. Patients presenting with trauma to the upper body may need to be examined for possible hemorrhaging in the abdominal cavity or pericardium.
- FAST examines four areas for free fluid: the pericardium, the perihepatic and hepatorenal space (area surrounding the liver and the space between liver and kidneys), the perisplenic area (around the spleen), and the pelvis (behind the bladder).

Evidence Needed To Prevent Child Sex Abuse



Sexual abuse of children is more common than many think. SBU's assessment calls for better studies showing which medical and psychological interventions can prevent perpetrators from subjecting children to sexual abuse.

The Swedish Government assigned SBU to review the body of research on medical and psychological methods to prevent sexual abuse of children. SBU's assessment reveals a substantial deficiency in evidence on effective methods to treat perpetrators. Better research is necessary; primarily controlled trials that are adequately large and include several countries.

JOINT PROJECT

– I hope that we in Sweden can promote the assessment of different methods, for instance, through a joint EU project, comments SBU's Executive Director, Professor Måns Rosén. This includes preventive interventions for adults and adolescents at risk of sexually abusing children.

– In the absence of better studies, interventions must draw on the scant evidence currently available, and the results must be followed up.

Research to date suggests, for example, that outpatient programs based on a combination of social ecology

theory* and social learning theory** can prevent recurrence in adolescents who have sexually abused children. A reasonable strategy could also involve the implementation and follow-up of methods to reduce the factors driving sexual offences, eg, sexual preoccupation, in perpetrators at the highest risk for recurrence.

PROTECTING CHILDREN

The Council of Europe has established a convention targeting the protection of children against sexual exploitation and sexual abuse.

Niklas Långström, Professor of Psychiatric Epidemiology, chairs the SBU Project Group.

– Better studies in the field are necessary if Sweden, in line with the convention, is to offer effective interventions against abuse, says Niklas Långström.

Some individuals in the risk zone for child sex abuse seek help on their own initiative. [RL]

* Social ecology theory is rooted in the interaction between humans and their environment; in this context, adolescents and their relationship and interaction with their environment and family.

** Social learning theory is based on the idea that one can learn behaviors, eg, through child rearing, learning from role models, and imitating the behavior of others.

HIDDEN STATISTICS

- Many cases go unreported. Only about 10% of all sex crimes in Sweden are reported to the authorities, and it is possible that the figure is even lower when the victims are children.

- Adult males account for more than 70% of sexual

abuse in children that leads to prosecution. Adolescents account for approximately a quarter of all reported cases of sexual abuse in children, but the behavior seldom continues when they reach adulthood. Women comprise less than 5% of all persons suspected or convicted.

Home Blood Pressure Monitoring Convenient for Motivated Patients

Measuring blood pressure at home means fewer office visits and greater convenience for patients. But routines for using and following up the method are lacking, and no one knows its usefulness in guiding medications beyond one year.

An estimated 1.8 million people in Sweden have high blood pressure. One third of this group receive treatment, eg, antihypertensive drugs and help with lifestyle change. Determining the appropriate drug dose usually requires patients to visit a physician's office regularly to have their blood pressure measured. As a complement to this method, patients can monitor their own blood pressure at home by using an automated blood pressure measurement device. To use this device, patients must learn how to operate it and be motivated to use it. The responsibility for treatment remains with the provider.

TRAINING

SBU's review of the literature shows that home blood pressure monitoring is equally as effective as office monitoring in guiding antihypertensive medications. Moderately strong scientific evidence shows that patients take prescribed medications to the same extent, and the reduc-

tions in blood pressure are similar. However, research does not answer the question of whether home blood pressure monitoring is better or worse in guiding treatment aimed at reducing the risk of cardiovascular disease.

Patients that use home blood pressure monitoring can save costs in health care since they make fewer clinical visits. Home monitoring also benefits patients since they can avoid the inconvenience of visiting a clinic or physician's office to check their blood pressure.

LOW ADDED COST

Lacking are established routines or programs on how to use and follow up home blood pressure monitoring, and how to design education for staff and patients. For instance, it may be necessary to educate patients about the risks of altering the drug dose on their own initiative and about purchasing drugs or measurement devices on the Internet. Also, since few studies report on follow-up studies exceeding one year, little is known about the long-term usefulness of home blood pressure monitoring in guiding treatment. [17]



Geir Pettersen/Getty

FACTS | HOME MONITORING

- It is not unusual for patients to have somewhat higher blood pressure when measured in a clinical setting compared to the home. Hence, the threshold for high blood pressure is 135/85 mmHg for home monitoring and 140/90 mmHg for office monitoring.
- Measurement devices can be purchased from retailers. The price varies from approximately 70 to 215 US dollars (USD).
- SBU's report does not compare the different types of blood pressure measuring devices, but emphasizes that the devices must be validated and calibrated.

MEDICAL SCIENCE & PRACTICE

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