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Evidence based dentistry and ethics

Evidence based clinical practice is important in dentistry as in medicine. However, dental care can be more demanding than medicine because a natural recovery often helps the physician. A wound can heal, and an infection can disappear. A broken bone can repair while a decayed tooth cannot heal. It will always be a decision on what to do or not to do. This raises the interesting question of whether clinical guidelines and evidence-based practice can support us in being more attentive when treating patients. Are guidelines imperative? Is it morally contestable to ignore well established evidence when it comes to treatment? On the other hand one problem is the lack of high quality evidence in clinical dentistry as well as in medicine. In the real world diagnoses and tests are not 100 % valid, and no treatment is perfect. This paper presents some dilemmas resulting from uncertainty, it analyses various types of uncertainty, and discusses various approaches to evidence and guidelines. Uncertainty and limits of evidence has to be recognized and addressed by the clinician when treatment decisions are made. However, deviance from well accepted standards requires well founded arguments.

As professional health workers we are expected to offer our patients a tailored clinical service. One size does not fit all. How can we provide the optimal oral health service for each of our patients? How to choose among several alternatives when it comes to treatment decisions? The patients' opinion has come more to the fore in modern legislation.

Forfatter

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But most often, our advice is essential. How should we make decisions based on a critical reflection process? This also belongs to dental ethics. We all have some kind of professional moral so we know the difference between concepts of wrong and right in many clinical situations. Dental ethics deals with our ability to reflect on the morals of our actions and on the moral rules set by us as professionals. Can clinical guidelines and evidence-based practice support us in being more moral and conscious when we treat patients? Evidence-based practice has been developed to utilize the best available evidence from medical research and thus strengthen the normative moral base. Does this mean that it is not moral to follow clinical guidelines? This paper aims to discuss these matters through theoretical and clinical approaches.

The concept of Evidence Based Dentistry

The concept of evidence based health care has a long history starting from Hippocratic oath. Nobody can deny the importance to apply reliable, scientifically tested measures in health care. Experimental sciences, e.g. physics are understood as giving the ideal of a reliable method in gaining true knowledge. Therefore, also in health sciences, stronger evidence is based on several (at least two) independent high quality randomized and controlled trials (RCT) leading to similar, logically consistent conclusions. Weaker evidence stems from experience of individual cases. There are long check lists in textbooks for the evaluation of the quality of the studies (1).

While the idea of estimating the truth of observations on

Hovedbudskap

- Det er god etikk å være oppdatert på hva som er allment aksepterte retningslinjer for god klinisk praksis.
- Det er god moral å følge anerkjente retningslinjer og begrunne eventuelle avvik.
- Våre handlinger som helsepersonell skal i prinsippet alltid være til pasientens beste.

the quality of the research seems to be natural, several problems arise after a closer examination. Is it possible and morally acceptable to try to get experimental evidence for all kind of health problems? How to weight the probability of risks against the expected benefits? How to treat patients in cases where no reliable evidence so far exists? How about contradictory results and recommendations i.e., how to handle uncertain knowledge?

According to Popper, instead of trying to find confirming evidence, effective, critical research tries to find counter examples falsifying the opposite hypothesis. If the opposite hypothesis can be falsified by observations, we can temporarily rely on the hypothesis (2). In health sciences, this principle cannot always be followed because the safety of patients participating in clinical trials is first priority. When randomized clinical trials are designed there is quite often a question whether the different patient groups receive equal service or treatment (standard of care). The principle of equipoise deals with ethical dilemmas when assigning patients to different groups («arms») in a clinical trial and where there are reasons to believe that the patients in the one arm will receive better treatment than in the other. This has been addressed e.g. in periodontal research where the outcome measure entails irreversible loss of attachment and preliminary data might suggest the superiority of the active agent to be tested (3). However, our knowledge on contraindications is often based in clinical anecdotal cases and not on strictly planned studies.

Most general principles of evidence based medicine are relevant as such also in dentistry. However, in certain sense, dental care can be more demanding than medicine. In medicine, a natural recovery often helps the physician. A wound can heal, and an infection can disappear without leaving any marks in the body. A broken bone can heal when fixed, and the appliances can be permanently removed while a broken or decayed tooth cannot heal. At the best we can stop the disease e.g. caries or periodontitis, but we have to deal with the symptoms in terms of cavitated teeth or non-functional teeth due to attachment loss. We have then to use different materials and techniques. Ideally our treatment including the biomaterials that we use should have a lifelong longevity without causing any harm. Therefore, the quality of the biomaterials has to be good and they have to be carefully tested. This leads to difficulties, both in theory and practice. It is very demanding or impossible to carry out long-lasting, perhaps 5–10 year-long clinical studies as regards for instance the quality of filling or prosthetic materials. How to get the controls? How to blind the patient or the doctor? Our knowledge on these things is often based on our clinical experience, which can be quite subjective due to many factors such as missing controls or non-representative selection of the cases etc. In case we really had long lasting high quality RCT trials, this information would in practice lead to a situation where the tested products are no more in the market; the companies are already advertising «new», «better» products with too short follow up periods. We meet this kind of problems with the new filling materials in everyday practice.

Can guidelines be evidence based?

The presumption that clinical guidelines can be evidence based hosts a fallacy often (mistakenly) referred to as the naturalistic fallacy, i.e.,

inferring from is to ought. Hence, because most people with condition X benefit from examination Y and treatment Z (the description), my patient Amanda must be examined with Y and treated with Z (the prescription). Whether this actually is a fallacy, strongly depends on the conception of «guidelines». When guidelines (based on statistically controlled experience) are conceived of as prescriptions, we are reasoning from is to ought. That is, what is the case for most people, ought to be the case for this particular patient. However, this is obviously wrong, as no method is perfect, and there always are exceptions. Diagnostic tests do not have 100 % sensitivity and 100 % specificity, and no treatment is perfect, with full effect and without side effects or risks. We can call this first conception of guidelines, guidelines as law.

A second interpretation is «guidelines as a rule of thumb», i.e., the norms of a guideline are recommendations that should be considered for standard cases, but should be modified or ignored in other cases. In this interpretation of guidelines, the evidence (description) has less normative content (prescription), and there is less danger to «commit a natural fallacy».

What then about guidelines interpreted as indications of preferred action or as recommendation? This notion of guidelines uses evidence (what is for most patients) as an indication for what should be considered also for this particular patient. However, it does not make a rule that has to be obeyed (by all professionally good persons). This conception of guidelines may be called *prima facie*, as the guidelines are more than rules of thumb, but less than full-fledged rules or principles. We should be able to give good reasons when we deviate from guidelines, but when such reasons are present it is justified to depart from the guidelines. Even more: when the preconditions for the guidelines are not met, they should not be followed (without reflection). This conception of guidelines is placed between the previous interpretations, and is more normative than being a rule of thumb, but is less normative than being absolute laws or principles. Not giving patients what is the most efficient and safest alternative for most people requires a reason.

Guidelines translate from facts to values. Interpreting guidelines as facts (about how one should act) is as challenging as basing guidelines (regarding actions in fact-based situations) on values alone. In this translation between facts and values, guidelines can constitute professional identity, in the same manner as ethical codes, education, and professional ideals can. There are of course intermediate interpretations of guidelines in addition to the above presented, but the above interpretations may explain why guidelines may be considered as a straitjacket on the one hand or as bureaucratic junk on the other.

Moral challenges with not using existing evidence

Is it morally contestable to ignore well established evidence? The obvious answer is yes. If there is reasonable agreement amongst professionals about evidence for a particular treatment, and a professional does not provide this treatment without overriding arguments, this contradicts with the prevailing professional standard (neglect) and is morally reprehensible.

However, in most professional matters there are divergent opini-

ons and evidence may not be unanimous. Diverging from evidence or from generally accepted guidelines or standards may also be morally reprehensible in this case, e.g., if the professional is unaware of the professional controversy, and gives no arguments for the deviation from the professional standard.

The latter case may be less reprehensible than the former, but may also be more frequent. Lack of adherence to guidelines and standards is well known in other fields of medicine and appears to be a challenge in dentistry as well (4,5). According to a commentary by Matthews (6) «it is not impossible to teach an old dog new tricks», but the effects of implementing guidelines might be limited. However, lack of adherence may not be a moral challenge in itself, as the deviance from standards may be well founded and well argued for. The moral problem emerges when such arguments are wanting.

Moral challenges with lack of evidence

One pervasive challenge in modern dentistry is the lack of high quality evidence. For surprisingly many procedures high quality evidence is scarce. One reason for this is substantial enthusiasm with new methods and implementation without thorough assessment. After a method has been used for a while it becomes unethical to test its effectiveness and safety in a rigorous way, e.g. with RCTs, as it is unethical to use placebo or alternative methods in the control group, as most professionals believe that these are inferior. Hence, we face problems both with equipoise and standard of care in research ethics. In such cases, the curiosity and eagerness, which is so important to science, hamper our scientific knowledge if we hype new findings and implement new methods on the basis of poor evidence.

The lack of evidence, as well as the lack of rigor in scientific research, becomes a moral challenge. We offer patients services without a solid knowledge base with regard to effectiveness and safety. This is a basic challenge which can only partly be addressed by more high quality research. 100% certainty is yet not attainable in the biosciences. Therefore it is important to accept uncertainty and establish strategies on how to handle it.

The morality of various modes of uncertainty

Most knowledge in the life sciences is uncertain and clinical decisions are made under uncertainty. Evidence does not always stem from experiments or controlled trials, and decisions have to be based on intuition in addition to analysis (7). Evidence from «hard science» is not always available, and we have to supplement with «middle science» and «judgment» based on Bayes theorem.

Accordingly, it can be helpful to distinguish between four levels of uncertainty (8): risk, specific uncertainty, ignorance and indeterminacy. Risk is defined by the probability and consequences of known outcomes. Specific uncertainty is when we know potential outcomes of a condition or a treatment, but we do not know their respective probabilities. We may know some of the mechanisms behind a certain condition or intervention, but we do not know their probabilities. Genuine ignorance is when we do not know possible outcomes (and therefore not their probabilities). The challenge is that we do not know where to look for these unknown factors: we do not know what we do not know. Uncertainty may also origin from the

fact that phenomena can be classified and detected in many ways. This kind of uncertainty is called indeterminacy.

What are the moral challenges following from these kinds of uncertainty? Ignoring relevant risks may be morally reprehensible, e.g., ignoring the risk factors for having loss of dental implants due to peri-implantitis or ignoring the need for supportive treatment (9). However, handling risk requires an assessment, and a calculated risk never gives answers to how we should act (is does not imply ought). It is quite reasonable that the person who will experience the consequences of a condition or intervention would have a say on how to handle the risks.

Handling specific uncertainty is more challenging (both morally and epistemically), as we have to communicate and handle possible outcomes where we do not know the probabilities. It becomes even more challenging with ignorance, where we do not know about potential outcomes. However, this problem increases as we are not always eager to assess unexpected effects (either positive or negative). E.g., it took many years before the unexpected effect of thalidomide on the children of pregnant women was recognized. In hindsight this could have been discovered much earlier, if one had been more open minded and critical.

Indeterminacy strongly depends on social responsibility. Our systems of classification are based on preconceptions of how we can help people in the best possible way. However, these preconceptions may be poorly founded, or founded in strong professional interests. In this case indeterminacy is morally challenging.

A practicing dentist may not be informed about existing evidence. How to know who is competent? Am I competent to practice? How to follow the scientific literature? Which studies are reliable? What is the role of peer review-system? Who is responsible if the dentists do not have good education? Are the criteria of malpractice based on EBD? These are questions on the framing and formation of knowledge, and have strong ethical connotations. From a clinical perspective it is morally blameworthy not to be informed, i.e., not to know the current status of evidence, but also not to acknowledge professional controversies.

Example 1. Culture differences can create difficult medical ethics problems

In Scandinavia there is a common understanding among university teachers in paediatric dentistry that it is important to keep children caries free if possible or to treat caries when it occurs (10). Juris (five) and Aija (four) are two siblings who are born in one of the former Baltic States. They came to Norway 8 month ago with their mother and an older sister. After reunion with the father who worked as a carpenter, the family settled down in a small place. The children went to kindergarten and after some time, the nursery school teachers became aware of the children's eating problems and that they probably had toothache due to poor dental health. The staff took contact with the local Child Protection Services (CPS). This in turn involved a medical doctor and a dentist in the Public Dental Health Service. The children were examined by the dentist, and there was indication for extraction of most teeth due to severe caries.

The children had dental behaviour management problems and

they were referred to the nearest hospital for extractions in general anesthesia. They were given two appointments, but did not show up at any of those. The parents explained to the CPS that they were afraid the children would not survive the general anesthesia because a relative in their homeland once had a bad experience. The parents also claimed that the oldest daughter had decayed primary teeth. However, her permanent teeth were not affected by this, as they were quite nice. In their homeland bad teeth in preschool age would regularly not be treated. The parents did not think that their children suffered or experienced any pain due to poor dental health and they withdrew the children from the kindergarten.

The CPS wanted a second opinion and the parents accepted a new appointment. Juris and Aija were then examined with some efforts by two specialists in paediatric dentistry. In addition to clinical examination, radiographs and clinical photos were taken. The examinations revealed that both children had several dental abscesses and fistulas. Most teeth were destroyed by severe decay (figur. 1). Her brother Juris showed a similar clinical picture in all four quadrants. The paediatric dentists offered oral sedation dentistry, but this was refused by the parents. The patients' history has been changed to protect anonymity.

What should be the message to the local CPS? What are the consequences of untreated dental decay/infection on short and long term? What are the recommendations from a dentist's point of view? Can we prioritize the children's oral health and also showing respect to cultural differences?

Discussion example 1

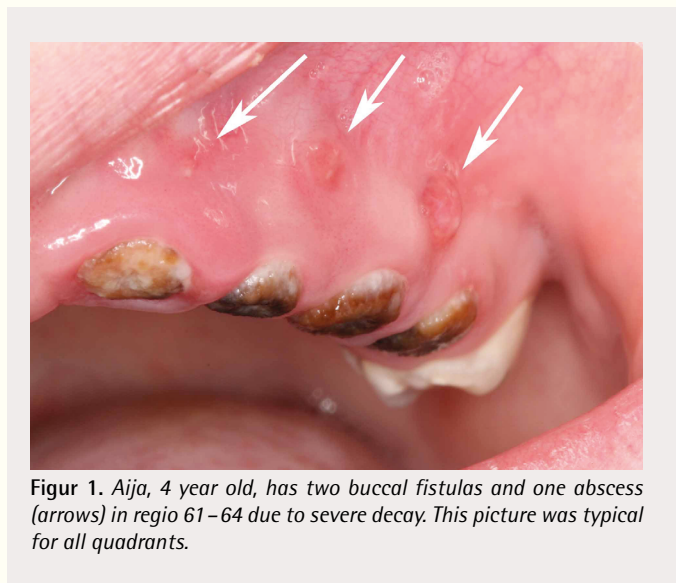
Bacteremia caused by oral bacteria as a potential danger to general health in susceptible cases has been considered for years. In modern dentistry it is a well accepted principle to eliminate or treat such foci such as teeth with infected or necrotic pulp. However, the direct link between odontogenic infections and related systemic, focal infections is difficult to show (11).

According to the «Convention on the Rights of the Child» (12) the children should have access to «the highest attainable standard of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.» Children have their own rights which are independent of their parents' opinions or priorities. It is the health workers or others who have to identify the child's needs when parents let the child down.

Although there is little social stigma related to the condition in the children's homeland, this is not so where they live now. One could therefore argue that treatment is in the best interest of the child also from a social point of view. However, as the tentative treatment (extraction) may not alter this stigma, this argument loses weight.

It is obvious that Juris and Aija have no responsibility for their own poor oral health; their oral conditions are caused by caregivers' choices. In this case the local CPS has been informed and is taking action to the neglected siblings. It is the CPS's responsibility how to act in this case and the dentist's evaluation and recommendations are important information when they make their decision.

The CPS decided to be in dialogue with the parents, but no attempts to convince the parents to make an appointment with a



Figur 1. Aija, 4 year old, has two buccal fistulas and one abscess (arrows) in regio 61–64 due to severe decay. This picture was typical for all quadrants.

dentist succeeded. The mother claimed that the family rather would return to their homeland than let the children undergo any kind of dental intervention. However, she could accept fluoride varnish applied by a dental hygienist.

The example illustrates challenges that may occur when evidence is applied in a cultural context. It shows how evidence based interventions have to be weighed against cultural conceptions and preferences. The case may also indicate that what is considered as professional evidence may differ from one culture to another. The requirements for professional evidence may be different in different countries.

Example 2. Differences in treatment decisions – is variation natural?

Research has proven that criteria for instigating therapy show great variation among dentists (13,14). Based on a figure with different radiological appearances of approximal carious lesions the dentists were asked (15): Which lesion or lesions should be restored immediately? Assume that the patient's caries activity is low and the oral hygiene is adequate. A total of 2375 dentists in Norway replied. A majority of the dentists (57 %) would wait until the lesion was visible in dentine, whereas 36 % would commence operative treatment when the radiolucency had reached the middle third of the dentine. On the other hand 7 % of the dentists would restore lesions confined to enamel. In a similar study undertaken in 1983 66 % of the respondents would place a filling when the lesion was confined to enamel.

The question under discussion is then; is there a fraction of dentists for some reason or another who are lagging behind with respect to criteria for placing restorations? Is it from an ethical point of view acceptable that if you visit dentist A you will receive one restoration while dentist B will place 10? The majority of dentists would perhaps do one or two restorations in a similar case.

When such variation is evident, who has the responsibility to act? The individual dentist? The Dental Association? Health authorities? Public Dental Health Service? Media? Patients? Politicians?

Lack of adherence to guidelines and evidence is well documented

in the literature for medicine and dentistry. This is a moral challenge when the guidelines are well founded and evidence is of high quality. However, the moral imperative (and judicial liability) is reduced if the evidence is poor. As pointed out earlier, lack of adherence to guidelines may be warranted if there is specific uncertainty, however it may be less warranted if it is due to professional or pecuniary interests.

Example 3

Does oral infection cause cardiovascular disease? This is a field of great controversy, where there are heated debates with regard to whether the existing evidence is sufficient for decision making or whether more high quality evidence is needed. There are both scientific challenges (16) and moral conundrums (17).

English summary

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