

HTA-Report | Summary

Interventions for enhancing medication compliance/adherence with benefits in treatment outcomes

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Scientific background

Compliance is defined as the extent to which patients follow medical instructions. In contrast adherence is determined as the extent of the conformance between the actual and with the health care provider agreed patient's behavior.

Measurements of the compliance or adherence in drug therapy can be divided in various ways, for example into objective, biochemical, subjective and clinical methods. In general, direct and indirect methods are to be distinguished.

Several factors affect the compliance or adherence. In June 2003, the World Health Organization (WHO) stated five dimensions of adherence affecting factors: condition, therapy, patient, social/economic and health system.

The WHO estimates the degree of compliance or adherence in developed countries to be about 50 %. Good compliance or adherence is considered to be associated with improved effectiveness of medical interventions, poor compliance or adherence with increased morbidity and mortality.

Poor compliance or adherence can cause enormous costs in the healthcare system. In Germany, medical costs due to poor compliance in drug therapy are estimated to be up to 10 billion euros annually. They are supposed to be in the range of the expenditures for major diseases such as coronary heart disease. Due to demographic change, the burden of chronic diseases in Germany is expected to increase until 2020, therefore the Non-Compliance or Non-Adherence problem is also supposed to become more crucial.

Different methods are used for enhancing the compliance or adherence. These interventions can address each of the five dimensions:

- Condition affecting interventions: for example identification and treatment of compliance or adherence influencing co-morbidities (depression, gastritis).
- Therapy affecting interventions: for example selection of the appropriate pharmaceutical dosage form, drug packaging, simplifying of the dosage, and development of drugs with an improved side-effect profile.
- Patient affecting interventions: Interventions to improve the patient knowledge, motivation and skills to influence its illness positively (patient education, training, counseling etc.) as well as reminders (alarms, calendars, letters, prospects, phone calls, e-mails etc.).
- Social / economic aspects affecting interventions: for example social support (relatives, self-help groups), reducing the price or the co-payments for medicines, improvement of the health education, simplification of the access to medical care.
- Health system affecting interventions: for example improvement of the physician-patient-relationship, continuing education of the physicians, creation of financial incentives for healthcare providers to carry out compliance or adherence enhancing interventions as well as reduction of overwork.

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Within the scope of the



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Research questions

Medical evaluation

Which compliance or adherence enhancing strategies in drug therapy exist, that concomitantly improve treatment outcomes? How effective are these strategies with regard to the treatment outcomes?

Health economic evaluation

What are the cost-utility-relations of the compliance or adherence enhancing strategies which concomitantly improve treatment outcomes in drug therapy?

Ethical-social and juridical aspects

Which ethical-social and juridical implications are to be considered in the implementation of the compliance or adherence enhancing interventions with concomitant improvement of the treatment outcomes in drug therapy?

Medical evaluation

Methods

The systematic literature search was conducted in the medical electronic databases and was restricted to publications beginning from 2002 as well as to the languages German and English. Only published data were included in the medical evaluation.

The selection of the literature was performed in three steps: evaluation of the titles, abstracts and of the full text. Two independent reviewers were involved in the selection of the relevant publications.

Systematic reviews on the basis of randomised controlled trials (RCT), which compared compliance or adherence enhancing interventions to no intervention or different of these interventions among each other were included in the evaluation. Moreover these reviews should consider the effects of the compliance or adherence enhancing interventions on the treatment outcomes.

Results

The literature search was conducted in January 2007 and resulted in 1569 hits. 74 publications were selected to be examined in full text and one systematic review with data for 57 RCT was included in the evaluation.

A significant positive effect on the treatment outcome has been reported for 22 evaluated interventions.

The results for the following interventions were classified as reliable:

- counseling with providing of an information leaflet and compliance diary chart followed by phone consultation for helicobacter pylori positive patients,
- repeated counseling for over 18 years old patients with acute asthma symptoms,
- telephone calls to establish the level of compliance and to make recommendations based on that for the therapy of cardiovascular diseases, - calls of an automated telephone system with phone counseling in problem cases for under 75 years old diabetics,
- different family based interventions in patients with schizophrenia including repeated family counseling, education programs and "culturally modified family therapy"
- repeated "compliance therapy" sessions for stationary patients with acute psychosis

The results for effectiveness of the following interventions should be considered with more concern (because of the poor methodical quality of the underlying studies):

- specific counseling and providing of written instructions for parents of under 15 years old children with streptococcal pharyngitis,
- a brief training and providing of written instructions on how to use the spray (with or without additional slide presentation) for patients with pollen allergy,
- twice a day intake of controlled-released niacin (vs. four times a day intake of regular niacin) in men under 65 years with high risk for coronary heart disease,
- a program composed on providing of information pamphlets, personal counseling, visits of a support group and phone call for over 18 years old patients with expiratory wheezing,
- a pharmaceutical care program for patients with asthma or chronic obstructive pulmonary disease,
- a program composed of individualized counseling, adaptation of treatment to the patient's lifestyle, phone support (for questions) and monthly visits of the day clinic for HIV-patients (HIV = Human Immunodeficiency Virus),
- a program consisted of education, providing of video and written information, home visits, telephone monitoring, personalized mails according to personal relapse prevention plan for patients with depression or anxiety disease.

The most common thread of the most interventions was more frequent interaction of health care providers with patients in the course of therapy and attention paid to compliance or adherence.

The effect size of the compliance or adherence enhancing interventions on the treatment outcomes can not be estimated from the available data.

Discussion

Although the interventions carried out in the primary studies were briefly presented in the underlying systematic review the exact contents and the quality of the interventions can only be judged in a limited way. Moreover, it is not always clear from the studies description, which publications comprise compliance and which adherence enhancing interventions.

Many of the reported studies had a poor report quality concerning the considered interventions. Especially in studies published until 1998 the data concerning the patient allocation concealment into the study groups are missing.

Many studies use patient's self-reporting of the drug consumption for the estimation of the compliance or adherence. Sometimes also very inexact parameters are used for the measurement of the treatment outcomes. In many studies there is also a lack of information on patient's blinding. The reliability of the conclusions of the studies is restricted due to the mentioned methodical shortcomings.

Economic evaluation

Methods

A systematic literature search was conducted in the medical also health economic relevant databases (described in the medical evaluation). Similar to the medical evaluation, the analysis of the literature search was carried out in three steps.

Systematic reviews of health economic analyses which compared compliance or adherence enhancing interventions to no intervention or different of these interventions among each other were included in the evaluation.

Results

The literature search was conducted in January 2007 and resulted in 1448 hits. 51 publications were selected to be examined in full text and one systematic review with data for six studies into the health economic evaluation. From the available data, no reliable results could be provided concerning cost-benefit relation of strategies for enhancing compliance or adherence in drug therapy with concomitant improvement in treatment outcomes.

Discussion

The literature search which was conducted in the evaluated systematic review in 2000 is not complete and not up-to date. The description of the studies included in this review is extremely bad. The design, methodical quality of the evaluated studies as well as details of the provided interventions can only be appraised approximately from the presented description.

The evaluated studies showed many shortcomings. Clinical estimates were derived from obsolete information sources of low evidence and no study met the requirements of RCT. No study used cost estimates for the compliance or adherence enhancing interventions in euros or referred to interventions in the German health care system. Cost estimates were generally derived in the time before 2000. Therefore, the transferability of the efficacy and cost estimates determined in these studies to the current situation in Germany is limited.

Ethic, social and juridical aspects

Methods

In the course of the conducted systematic review it was also searched for publications which primarily considered ethical-social and juridical aspects of these interventions for the German context (data on information sources and search strategy are presented in medical evaluation).

Results

The literature search was performed in January 2007 and resulted in eleven hits. Two publications were selected to be examined in full text. No publication concerning ethical-social or juridical implications could be included in the evaluation. The hand search in the internet yielded no relevant hits.

Discussion

Although no relevant publication to ethical-social aspects could be identified from the conducted literature search, it has been discussed recently, that the compliance or adherence enhancing interventions can restrict the autonomy and the privacy of the patients. The access to effective compliance or adherence enhancing interventions for some social groups may be limited.

Summary discussion of all results

Previously published studies were predominantly focused on patient- or therapy-related factors of the compliance or adherence. The health care system has also an essential impact on compliance or adherence. Health care system directed interventions were not appropriately evaluated yet.

Conclusions

Some compliance or adherence enhancing interventions in drug therapy with improvement in treatment outcomes may be used. To implement any intervention by healthcare providers its description in the primary study should be considered.

No conclusions about the cost-utility-relation of the compliance or adherence enhancing interventions in drug therapy can be drawn from the existing data. The cost-utility relations should be estimated in high-value health economic evaluations (studies or models).

Using compliance or adherence enhancing interventions the patient's autonomy and privacy are to be restricted as few as possible. The access to these interventions should be guaranteed for all social groups.