



INTENSIVE POLYPHARMACOLOGICAL TREATMENT OF TYPE 2-DIABETES IN DAILY CLINICAL PRACTICE

– a Health Technology Assessment – summary

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**Intensive Polypharmacological Treatment of Type 2-diabetes in Daily Clinical Practice
– a Health Technology Assessment**

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Summary

Background

Type 2-diabetes is a disease in growth associated with both personal and societal costs. App. 2 % of the population has diagnosed type 2-diabetes, and for the 60 year olds the prevalence of the diagnosis is app. 10 %. The incidence of the disease is climbing and newly diagnosed patients are younger. The quality of life of the patients deteriorates significantly due to sequelae, and the disease-growth increases the morbidity and the mortality rate in the population (1; 2). 15-30 % of the type 2-diabetics experience complications at the time of the clinical diagnosis (3). The majority of patients with type 2-diabetes is treated by general practitioners (GPs), but on a periodical basis treatment also takes place in out-patient clinics, e.g. in connection with treatment of complications (4; 5).

A Danish randomised controlled study shows that a specific multifactorial intervention directed at type 2-diabetics with enhanced risk of developing micro- and macro-vascular complications can reduce the risk of sequelae. This multifactorial intervention consists of pharmacological treatment of hyperglycemia, hypertension, dyslipidemia, and microalbuminuria in combination with behavioural modification (6) (ff. Steno-2-studiet). Another Danish randomised controlled study shows that individually oriented treatment by GPs, supported by teaching of the GPs can equalize the level of risk concerning the development of complications and the level of risk shown by the results in the Steno-2-study (7). A registry based study done in Århus County, based on 2005 numbers, shows that 21 % of all with proven type 2-diabetes are in poly-pharmacological treatment – defined as simultaneous treatment with blood glucoses-, blood pressure-, and lipid-lowering medicaments. Taken together the studies mentioned above indicates an unutilized potential to prevent sequelae among type 2-diabetics.

In 2003 a Health Technology Assessment (HTA) was conducted, which accumulates the existing knowledge on the effectiveness of different parts of the diabetes treatment, including the medical and thereby the poly-pharmacological treatment. On the basis of the HTA health economical consequences have been calculated (4). However, there is still a lack of knowledge concerning the existing organisational barriers and potentials in relation to intensive use of medicaments in diabetes treatment. Likewise there is a lack of knowledge concerning attitudes, quality of life, and experiences in relation to intensive poly-pharmacological treatment of diabetic patients. It is important to study these relations in order to progress from efficacy documentation to efficiency documentation, i.e. the progression from evidence measured in controlled randomised studies towards the knowledge of how intensive poly-pharmacological treatment can function under general clinical circumstances. The above serves as the background for this HTA, which is supplementary to the HTA of type 2-diabetes. Focus is placed on organisational and patient related circumstances that influence intensive poly-pharmacological treatment in daily clinical practise.

Aim

The overall aim of the project is to identify possible ways of improving intensive poly-pharmacological treatment of type 2-diabetics in Denmark. This aim will be reached through the study of investigate how intensive poly-pharmacological treatment of type 2-diabetics forms part of general clinical practice. The following question forms the basis of this research:

Which barriers and promoting factors exist among patients, practitioners, and in daily clinical practise, concerning intensive poly-pharmacological treatment of type 2-diabetics?

Furthermore, by considering the existing HTA on type 2-diabetics, this project aims to adjust the health economic calculations relating to poly-pharmacological treatment, thus updating the knowledge concerning the extent to which intensive poly-pharmacological treatment is used today, and to what extent the present costs have changed according to the expected.

Methodology

The report is comprised of four parts. Firstly, a *literature review* with focus on barriers and promoting factors concerning intensive poly-pharmacological treatment. Secondly, a *survey* based on questionnaires has been conducted among GPs in three chosen counties (North Jutland, Funen and West Sealand), focusing on the overall barriers and promoting factors concerning intensive poly-pharmacological treatment, as the GPs perceive them. The survey supplements a larger *qualitative study* in the three case-counties. In relation to the use of intensive poly-pharmacological treatment of type 2-diabetics this qualitative study sheds light on the strengthening and weakening circumstances in the daily clinical practise, and in the cooperation between out-patient clinics and general practice. This part, which is central to the HTA, rests upon observations from consultations in the general practise, and diabetes out-patient clinics in the three counties, as well as interviews with physicians and patients. The study is grounded in an actor-network theoretical perspective. In accordance with this approach, the analysis illuminates the network of human and non-human actors in which treatment takes place. Complementary, a focal-point analysis zooms in on the cross sectorial cooperation and communication between actors within the diabetic treatment environment. The last part of this HTA can be considered as a supplement comprised by an update on the existing *health economic calculations*. It is an estimation of costs, limited to the direct costs of monitoring and medical treatment of patients with type 2-diabetes. Finally, an update on the economic literature review, which is found in the HTA from 2003, concerning poly-pharmacological treatment has been made.

Results

The Literature review about the barriers and promoting factors concerning poly-pharmacological treatment of type 2-diabetics presents a picture of a treatment with effect, but also with a number of different barriers attached. Some of these are of clinical nature, and therefore they are described in the HTA on type 2-diabetes. Others are of social or organisational nature, and they are referred to here. According to the literature the treatment is still met with certain scepticism among both practitioners and patients. Limited access to specialists, and delayed transfer of the latest knowledge on treatments from diabetes specialists to GPs, can constitute a barrier for complex medical treatment. Likewise, the literature shows that poly-pharmacological treatment is subject to the same compliance problems as other diabetes treatment. Still, there are specific problems affiliated to the complex treatment with many medicaments, including the problem of taking the pills, especially if they are to be taken several times a day, and the problem of side effects. Similarly the attitude towards the treatment and its beneficial effects (of patients and physicians) seems to affect compliance. A few articles suggest that these problems should be met with technical solutions like electronic pill-boxes and combinatory medicaments. However, the literature does not present solutions of either technical or communicative kind which can be proven to redress compliance problems effectively.

Regarding more general barriers in connection with diabetes treatment in general practice, the literature review emphasises that GPs have difficulties convincing patients about the seriousness of the disease, as they only notice the short term and visible consequences of the treatment. The GPs prepositional attitude towards the patients' non-compliance, and a general underestimation of the seriousness of the illness by both GPs and patients are emphasised as barriers. Finally, the literature shows that the GPs view the diabetes treatment as an extensive project. The general

demand for fast consultations, and the pressure of a heavy work load, often makes it difficult for the GPs to digest and act according to new clinical guidelines.

In *the survey* conducted among the GPs in the three case-counties, the response rate reached 45 %, of which a mere 4 % did not practice intensive poly-pharmacological treatment. The analysis of the survey data builds solely upon answers from the GPs who practice the treatment.

A number of attitude based questions indicates what makes it difficult to practice the treatment, but also what seems promoting. The GPs do not lack information or knowledge. 94 % of the doctors inform that they, to a small degree or not at all, lack information or knowledge about the treatment. The survey, however, shows that the GPs experience other barriers in their daily practice. The following is noted as the most prominent barriers:

- That the diabetics do not have any symptoms and therefore do not feel sick (66,5 %)²
- That it is difficult for patients to oversee the large consumption of medicaments (62,9 %)
- That there is not enough time per consultation (59,7 %).

It is characteristic that the GPs emphasise both barriers and promoting factors attached to the patients. Taken together the GPs notice the following promoting factors:

- That the diabetics change their attitude towards intensive poly-pharmacological treatment (83,7 %)
- That the diabetics, to a larger extent, focus on the long term benefits of the treatment rather than the immediate problems and side effects (88,4 %)
- That combinatory medicaments are introduced (70,6 %)
- That a specific fee is introduced for consultations with type 2-diabetics in intensive poly-pharmacological treatment (69,9 %)
- That diabetes patients are systematically resummoned for monitoring (65,8 %)
- That tools for identifying type 2-diabetics, who is in need of intensive poly-pharmacological treatment, are developed (65,1 %).

The survey finally points to a relative high level of satisfaction concerning the cooperation between the out-patient clinics and general practice in Funen County. In contrast, a significant number of GPs in the other case-counties experience limitations when referring patients to and receiving advice and guidance from the out-patient clinics. Likewise, in contrast to Funen County, a significant number of the GPs in Westsealand and North Jutland comment that a better exchange of information with the out-patient clinics would promote the practice of intensive poly-pharmacological treatment.

The *qualitative study* shows that doctors (both GPs and specialists), even those who are committed, conduct the poly-pharmacological treatment in spite of several restraints, and that they often fail to reach their objectives. The study explores the background for these restraints and expands the understanding of how the organisation and practice of the diabetes treatment influence the success of the poly-pharmacological treatment.

It is emphasised that the artefacts of the diabetes treatment, comprised by evidence-based research results that are communicated through courses, literature, and clinical guidelines, give the medicinal part of the diabetes treatment stability and strength. Equipment for clinical measurement, as well as accounting systems, also strengthens and stabilizes the medicinal part of the diabetes treatment. Hereby the doctors have become motivated towards a commitment to intensive poly-pharmacological treatment. At the same time these artefacts support the doctors' role as an expert instead of adviser, giving the doctor the power to act. The patient, on the other hand, becomes a

2 The percentages in parenthesis include those doctors that have answered 'highly' or 'to some extent'.

more or less compliant supervised subject.

The study also points out that not all of the guidelines concerning the diabetes treatment are followed. The doctors choose to exert their efforts in areas where they have the power to act, meaning the pharmacological part of the treatment. The areas in which the doctors feels more insecure, meaning the areas that are dependent on the resolve of the patient, in particular the area of lifestyle interventions, slide out of the consultations. As a result the two areas of the diabetes treatment, pharmacological treatment and lifestyle interventions, tend to be conducted within two different networks: A network comprised by doctor, patient, monitoring, and medicine, and a network comprised by nurse, patient, and the social life of the patient. Accordingly it becomes difficult to establish a dialogue between patient and doctor, in which both parties jointly decide upon a treatment strategy that incorporates both areas of intervention.

In the survey the GPs emphasise patients' perception of illness and treatment as the biggest barrier for poly-pharmacological treatment. The patient interviews in the qualitative study do not confirm this assumption. The interviews show the importance of remembering that illness and treatment is understood and managed within different contexts relating to both practitioner and patient. An increased understanding of this can establish a better dialogue concerning the treatment. Furthermore, the study notes that the patients experience great ambivalence regarding the state of being neither ill nor healthy. Their treatment involves a risk, which they sense when they are treated at home, and when they show up for an examination at the general practice or the out-patient clinic. They manage the risk by taking it rather serious, and at the same time denying that it matters.

Furthermore, the study shows that the communication of evidence and clinical guidelines has helped to motivate the doctors towards a given type of treatment. The study also shows that the doctors are motivated by other circumstances. Two such circumstances have been identified. Firstly, an interest in working with patients, getting to know them as persons, and over time getting to follow their lives. Secondly, an active exchange of experience with specialists about general relations as well as specific patients. In this regard the study illustrates the problem that there is a limited flow of patients from the out-patient clinics to the general practice. This is an attractive situation for the personel of the out-patient clinics, but at the same time GPs are being cut off from following complicated patients over time. In this way the GPs lose the opportunity to acquire practical knowledge concerning the specialist treatment of their patients in the out-patient clinics, which again potentially could inspire the GP to acquire other type 2-diabetics in intensive poly-pharmacological treatment.

In the survey the GPs emphasise that lack of time is a barrier for intensive poly-pharmacological treatment. The qualitative study shows that the time is spend inappropriately. An incredibly large amount of the time allocated for consultation is spend updating medical lists. Often the patient becomes a sort of messenger, carrying information about change of medication, between practitioners in the health care system, because none of the practitioners have a clear overview of the patient's medication.

The results of the *economic part* of this HTA can be summed up by the following points:

- Data from Århus County show that the percentage of type 2-diabetes in intensive poly-pharmacological treatment has increased from 8 % to 21 %, in the time period between year 2001-2005. At the same time a larger percentage, 19 %, is exclusively in non-pharmacological treatment. In addition, the use of lipid-lowering medications has increased notably by 31 percentage points in the same time period.

- As a consequence of the increased number of type 2-diabetics, the accumulated cost per year regarding the continuous monitoring and medical treatment of patients with type 2-diabetes has increased and is currently estimated to be 0.9 billion DKK.
- Compared to the results of the HTA from 2001, concerning type 2-diabetes, the costs related to the treatment of type 2-diabetics with microalbuminuria and/or arteriosclerotic heart disease, in 2005, has approximated the expected maximum costs of implementing systematic and realistic poly-pharmacological treatment.
- Implementation of intensive poly-pharmacological treatment of all type 2-diabetics with microalbuminuria and/or arteriosclerotic heart disease can be expected to raise the costs per year by 340-920 million DKK.

Recommendations from the project group

This HTA emphasises the importance of assessing a medical technology in the context of the network, comprised by human as well as non-human actors, by which it is included and empowered. This perspective also elucidate that recommendations, which in a specific way relate to single-factors in the treatment, always have to be related to the consequence a change of the single-factor would have concerning the entire network surrounding the treatment. With this in mind the study is ended by a number of recommendations.

The recommendations are targeted towards two groups of actors. The first group is comprised by the stakeholders and decision-makers that seek to improve the exchange of information regarding pharmacological and unintended medication. The other group is comprised by clinicians that, on a daily basis, work with diabetes patients as well as the decision-makers who are involved with the efforts to improve the diabetes treatment in general practice.

In brief the study notes down recommendations regarding:

- Information exchange concerning medicine. There is a need for access to updated information about the present status of the medicaments used by the patient. This ought to happen through a database rather than the patient, and it ought to happen in a way so that it does not take up the valuable time of the consultation.
- Cooperation between general practice and out-patients clinics. This should be strengthened through the creation of an increased flow of patients between the sectors, and through an increased exchange of general as well as specific patient related information. Hereby the expertise of the general practice and the motivation towards the intensive poly-pharmacological treatment can be supported.
- The relation between pharmacological treatment and lifestyle intervention. There is a need to develop clinical conduct in a way that unites lifestyle and medicinal intervention. In this regard it ought to be considered how the balance between pharmacological treatment and lifestyle intervention can be adapted into the division of labour among doctors and nurses, and how to establish a common role of the practitioner that unites both sides of the treatment. Moreover, the patients can, to a greater extent, be involved in making decisions concerning ways of regulating the illness through medication and lifestyle changes.
- Concordance and self-care. There is a need to supplement the promotion of clinical guidelines by an experience-based exchange of good clinical conduct that promotes the treatment. For instance, how is it possible to set aside parts of the consultation for talking about the circumstances that make the patient accept or reject the medicaments? How, to a greater extent, can poly-pharmacological treatment be included as a treatment that takes place at home, and how can it be adapted into the daily routines of the patient? There is also a need to establish a dialogue concerning the attitudes of the patients, which are often ambivalent, towards their illness and treatment.

- The use of technology in chronic care. It is recommended to reconsider if the monitoring measurements, which the treatment is presently tied to, are carried out in the best way. Could patients do several of these at home (e.g. regular blood sugar rather than HbA_{1c}, blood pressure, weight)? And could the patient report these into the same information system as the one used by the practitioner? This would free resources, in the consultation, to be used in other matters of relevance to the treatment. At the same time an increased sharing of data supports the efforts to make the treatment a partnership between the doctor and patient. This would support the treatment, as its success ultimately rests upon a joint effort that both perceive per se and engage in.

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