Priority setting in Denmark

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1. Background and overview

To understand the Danish debate on priority setting it is necessary to have a rough picture of the structure of the Danish health care system, the most important parties, and the interactions between those parties. Priority setting is very much conditioned on this. For this simple reason the debate surrounding priority setting will vary from country to country as will the various approaches and solutions.

The Danish health care system is **decentralized** politically, financially, and operationally. Fourteen **counties** and the Copenhagen Hospital Corporation are responsible for health care (somatic and psychiatric hospital care, services from GPs, specialists etc, and the administration of reimbursement of medicines), and finance it out of county income and property taxes. The average county tax rate is 11-12% of taxable income. It is a proportional tax. The mean number of inhabitants per county is 341,000. The total population of Denmark is 5.3 millions. There is a four year term for the directly elected county councils.

Overall, much priority setting takes place in the counties, usually in connection with the decision on the annual budget. This priority setting can be termed *micro priority setting* because it takes place within nationally agreed economic limits. Due to the decentralised nature of the Danish health service, the counties have considerable autonomy in developing the county health service, and hence also priority setting. This means that no coherent national approach to priority setting has emerged with the exception of drugs and public health. However, obviously priority setting does take place, but in the individual counties.

The **national parliament**, Folketinget, provides the general legislative framework, e.g. patient rights, the hospital law, legislation on the limits of in vitro fertilisation etc.. The **national government** every year negotiates with **the Association of Counties** about the expenditure level/tax level for the upcoming fiscal year. Increasingly theses annual negotiations have turned into a health political forum where short and medium terms plans are decided (and funded), for instance increased resources for cancer or heart treatment, waiting list/time initiatives and the like. Thus, much *macro priority setting* takes place in this way. In the Danish context this kind of macro priority setting is the most important priority setting mechanism in that it provides the limits within which the counties are allowed to develop their health service.

The effectiveness of the various priority setting mechanisms, in particular the macro priority setting, is seen in several ways: First of all, the percentage of GDP (gross domestic product) going to health care at present is around 8.8%, see figure 1. Secondly, as figure 2 shows the per capita growth in health expenditures – in real terms – has increased by almost 100% from 1971 to 2002, but with large fluctuations: from a growth rate of 7.3% in 1974-75 and a negative growth rate of 1.7% in 1989-90.

Hospitals are publicly owned (by the counties) while **general practitioners and practising specialists** are private entrepreneurs working on contract with the counties. About 97% of their revenues come from the counties. Hospital services and services from general practitioners, GPs, and specialists are free, while there are co-payments for drugs, adult dental care, physiotherapy and the like. Co-payments make up close to 19% of total health expenditures.

The Danish hospitals have 'one source funding', i.e. they receive all their funding from one payer, namely the home county – not like for instance in Germany where hospitals get their revenues from a number of Krankenkassen. 'One source funding' enables the funding authority (the counties) to establish priorities for the hospitals more or less unilaterally.

The National Board of Health has an important regulatory and supervisory role for the whole health service. The head of the The National Board of Health refers to the Ministry of Health. In relation to priority setting the Board makes decisions about what constitute common hospital treatments, e.g. for instance in the late 80ies that in vitro fertilisation was to be considered a regular hospital treatment and hence to be provided free of charge. However, the National Board of Health does not make decisions concerning the extent to which such treatments should be made available. This is decided by the counties – usually as part of their budget process.

The Danish Centre for Evaluation and Health Technology Assessment was formed in 2001, but was preceded by the Institute for Health Technology Assessment. The Centre is a separate entity within the National Board of Health, [1].

The key aims of the centre include carrying out health technology assessments (HTAs) and evaluations of new and existing treatment with the aim of providing decision makers with material on which to base their decisions. A typical Danish HTA has four components: the effectiveness of the treatment ('technology'), economics, organization and patient related aspects, including ethical issues.

The Danish Medicines Agency is an agency under the Ministry of the Interior and Health.

The Danish Medicines Agency administers the legislation on medicinal products, reimbursement on medicinal products, pharmacies, and medical devices. The main objective of The Danish Medicines Agency is to ensure that medicinal products that are used in Denmark are of satisfactory quality, are safe to use and have the desired effect. In relation to priority setting the Medicines Agency has pivotal role in deciding on reimbursement on prescription drugs. If a drug is not granted reimbursement status, in reality it will rarely be used. This is the only substantial example of centralized priority setting in Denmark, and a very important one in that pharmaceuticals make up about 13% of the total health expenditure budget. This is described in detail below.

The Danish Council of Ethics (www.etiskraad.dk) was established in 1988 to provide the Danish Parliament, official authorities and the public with ongoing advice and information about ethical problems raised by developments within the national health service and the field of biomedicine, in particular as it relates to reproductive issues.

This is accomplished by submitting reports and statements etc. in specified areas and by mounting debate generating activities in the form of e.g. public enquiries and debate days, publishing of debate books, anthologies, videos and teaching material, and extensive lecturing activities. In addition the Council gives a rundown of its activities every year in an annual report

The Council on Ethics has published several reports on the principles of priority setting [2,3,4,5,6].

Figure 3 pulls together the various parties to priority setting and the role they play in the priority setting process. Due to the tax financing and public ownership of hospital – making up about 65-70% of all public expenditures for health – priority setting to a considerable degree is an integrated part of the annual budget process: First of all, at *the macro level* when the total fiscal frame for the coming year is negotiated between the central government and the Association of Counties and, secondly, at *the micro level* when the counties negotiate budgets with the hospitals. Once the hospital budget has been establisher, there may during the year be *rationing*, i.e. allocation of limited treatment resources because demand exceeds supply, resulting in, for instance, the build up of waiting lists.

Whereas both macro and micro rationing very much is a political (bargaining) process, rationing essentially is left to clinicians, e.g. to determine who is to be put on a waiting list and priority assigned to the patients on the waiting list. No politically approved criteria for waiting lists have been developed. However, it is usually assumed that clinicians follow simple rules like: people will be treated in the order in which they joined the queue unless an acute worsening of their disease occurs.

To the extent that *macro level* priorities are 'hard', i.e. do not cave in (very much) to pressure, and consistent they automatically induce a considerable degree of micro level priority setting – and if effective at this level - which more or less is the case in Denmark – rationing will be the result because (public) hospitals cannot turn to other sources of revenues. During the late 1980ies and the first half of the 90ies waiting lists grew and other areas fell behind the international development, for instance for cancer and heart surgery. However, as the Danish economy improved in the 90ies the health sector budget grew accordingly and the waiting lists started to fall – in particular after 2001. (for an international comparison see figure 4)

At the *macro-level* there is no doubt that the general economic climate in Denmark, for instance an acceptable economic growth rate, also leads to more generous funding of the health service. In other words: an important priority setting criteria at the macro level is the overall economic climate in Denmark. This of course, must also be seen in the light of the general priority setting across tax financed sector, e.g. education, social services or roads.

2. The political and professional debate

The Danish debate about priority setting dates back to the early 1980ies. It stemmed from the economic situation in Denmark at the time. A new centre-right government had taken over, and had as a major goal to bring the Danish economy back to a healthy state. Fiscal austerity was the battle cry. Over a ten year period public expenditures grew only very slowly. The growth in health expenditures was extremely slow and toward the end of the 80ies and early 90ies was negative for hospital expenditures, see figure 2.

This economic situation initiated a debate about the need not only for priority setting in health care but also about the relevance of explicit choices, i.e. for instance that certain treatments should not be offered (for a historical account in Danish see [7]).

Initially dissatisfied hospital doctors took the lead in the debate, but gradually it developed into a dialogue between physicians, politicians and administrators. For instance, a scientific society was established in 1988. The Danish Society for Medical Priority Setting where the mentioned three groups debated principles for priority setting.

The Danish debate can be divided into three stages.

The *first stage* – till early 90ies – was, as Holm [8] notes, characterised by a search for priority setting systems which through a complete and non-contradictory set of rational decision rules and decision aids like economic evaluation, could tell the decision maker precisely how a given service should be prioritised in relation to other services. For instance the Oregon approach attracted considerable attention. It became clear however that for instance economic evaluation (cost-effectiveness analysis) and health technology assessment are only decision aids, are only an input into a complex decision process.

The *second stage* took place in the mid nineties. If priorities cannot be directly be legitimised as the rational result of following rational rules like cost-effectiveness thinking, what should be done then? Increasingly attention focused on creating legitimacy by focusing on a set of meta-rules that govern the process of priority setting. The report on priority setting by the Danish Council of Ethcis is an example of this line of thinking, [9].

The report from 1996 looked at the current allocation process and found that no long term plans existed. Instead decisions were made in a piecemeal way that also lacked transparency so that the general public had difficulties understanding what was going on. Without documentation – but not unlikely – the Council of Ethics claimed that this led a situation where active interest groups could get more than their fair share. The Council

- Rejected rule-based systems
- Wanted better processes for priority-setting
 - Processes that took into account all relevant interests
- More transparency and accountability

However, due favourable economic conditions the priority debate in the last half of the nine ties more or less disappeared. So most of the ideas put forward by the Council of Ethics never were put to a test.

The *third stage* is taking place in the new millennium where the debate is rekindled, in part due to worries about the sustainability of the Danish welfare state (tax financing, an ageing population etc.). Focus in on a mix of value issues (for instance which types of reproductive techniques to allow), process (who to involve in the decision making process) and tools (for instance an increased use of technology assessment).

3. The stages of analysis of priority setting

It is useful to distinguish between priority setting for

- hospital treatment (somatic and psychiatric) section 3.1
- services from GPs, specialists, physiotherapist etc. section 3.2
- public health (prevention (in particular primary prevention) and health promotion section 3.3
- drugs section 3.4

Practice and procedures vary across these four areas of the Danish health service.

As a summary statement, it may be said that in Denmark there is *no general national policy on which health services or medical and care services must be provided as a priority*, i.e. for instance there is no 'basic basket of health care services' or the like. Prescription drugs with (partial) reimbursement may be the exception, see section 3.4.

However, some 'exceptions' have emerged over the past few years and start to form a pattern. Priority explicitly is given to patient groups with certain diseases – either acute (cancer), semi-acute (coronary surgery) or chronic (diabetes). It is usually embodied in an action plan, e.g. the first action plan for the heart area dating back to 1993 or the most recent one for diabetes, [10], from 2003. Psychiatry has also been developed this way by means of targeted agreements, concerning both treatment and (in particular) physical facilities, for instance only one patient to a room. The psychiatry strategy dates back to 1997 and continues today, [11]. This priority setting is part of the macro level priority process. In essence these priority establishing plans mean that a) targets are established, for instance for capacity and/or waiting time, b) additional resources, often explicitly earmarked, are channelled into the area. The development is monitored regularly to establish goal fulfilment. The action plans are usually negotiated between central government and the Association of Counties – although lately there has been a tendency for central government to establish the plans unilaterally.

It is also important to note that the plans rarely concern priorities for specific treatments – which is often what is associated with priority setting – but rather a subsector or sub-subsector, e.g. heart surgery where the question is not whether or not to have CABG, but instead how much, i.e. surgical capacity. Much priority setting may actually be too narrow if the focus is only on treatments ('yes – or no' to specific proposals).

From a planning and priority setting point of view it appears somewhat difficult to establish the line/rationale behind the action plans. If anything, the line of reasoning is as follows: 1. 'there is a problem' – perceived or real. For instance, that the rate of heart surgery, e.g. CABG, is (far) below international standards, or that waiting time for common elective surgical procedures, e.g. hip and knee replacement, appears to be excessive, or the physical facilities for psychiatric patients are not up to modern standards. The 'problem' is put on the agenda by (national) politicians, i.e. for psychiatry by the previous prime minister, by physicians, interest groups, combinations of the three groups

- 2. Something must be done.
- 3. An action plan is developed or there is agreement on goals, and
- 4. either additional resources are found or a reprioritization takes place.

This process may be termed 'priority setting by fire fighting'. However, with the danger of post rationalization in mind one may also claim however, that two of the action plans – heart and cancer ' - are about life threatening conditions and thus follows the thinking behind the Norwegian 1987-priority setting model, [12] where life threatening conditions have first priority. In addition one may also see a tendency towards establishing 'material rights', i.e. that citizens have a legal claim to certain treatments within a stipulated time limit, otherwise they obtain the right to obtain treatment at private hospitals or abroad but paid by the public coffers.

3.1.1 Example 1: Cancer

- from 2001 and onwards: waiting time guarantee for cancer diagnostics and treatment
 - maximum of two weeks from GP referral to first hospital examination/diagnostic investigation
 - maximum of two weeks waiting before surgery/treatment
 - maximum four weeks for radiation therapy
 - maximum four weeks for rehabilitation

If a hospital is not able to stay within these limits they have to find treatment possibilities at other domestic or foreign hospitals. In 2002 94 patients were sent abroad, [13].

3.1.2 Example 2: the heart plan

• since 1993 there has been a 'heart plan' – that has been updated several times over the years. Important parts of the plan concerned expanding the capacity for coronary-by-pass surgery (CABG), PTCA ('balloon dilatering') and coronary angiography (CAG) in order to bring down waiting time.

3.1.3 Example 3: two months waiting time guarantee

The latest waiting time/list initiative dates back to mid 2002. In view of (somewhat) disappointing results with various waiting time/list initiatives dating back to 1993, central government chose a different track – much to the dismay of the counties.

Additional funding was earmarked to increase elective surgery above a defined base level of surgical activity to ensure that hospitals had provided what was expected within their normal budget. Furthermore, the free choice of hospital law of 1993 was extended. If a patient had waited for elective surgery for more than two months, the patient now has the right to choose either a private (for-profit) hospital or go to Germany or Sweden – fully paid by the home county except for travel costs.

3.2 Services from GPs, practising specialists, physiotherapist etc.: priority setting via the fee schedule

The above examples (3.1.1-3.1.3) all concern hospital treatment. The mechanism for services provided by for instance general practitioners or physiotherapists is somewhat different because they are private entrepreneurs working on contract with the county health service. The range of services provided depends on the fee schedule. The fee schedule establishes which services will be paid in full or partially by the county. In many respects then, the decision about which services to include on the various fee schedules amounts to a priority setting process.

The fee schedule is negotiated nationally between the various unions, e.g. the union of general practitioners and the counties. The final contract has to be approved by the minister of health. Hence, 'priority setting via the fee schedule' is a fairly controlled process and governed primarily by fiscal considerations.

New services are only added slowly, often in connection with a 'trial period' of for instance one to two year, in part to gauge the expenditure effects, in part to provide documentation about the health effects.

Providers are free to offer services outside the fee schedule, but then with 100% co-payment from patients. In practice this option is not used.

3.3 Public Health

In many respects priorities for public health (prevention and health promotion) are established nationally. The primary vehicle are government plans for the area. The two last plans carried the titles: 'the Danish Government Programme on Public health and Health Promotion 1999-2008' and the current government in 2002 published 'Healthy throughout Life'. In these plans a number of diseases are targeted, e.g. heart disease, and important risk factors identified for modification (reduction), for instance tobacco, diet, or alcohol.

However, here again the decentral structure of the Danish health sector shows. Central government rarely set aside substantial amounts to implement the plans, but consider the plans as 'indicative plans' to be used by the counties (and the municipalities) in the activities in this area. So far such plans have not be negotiated as part the annual negotiations between central government and the Association of Counties. This means that actual priority setting is left to the counties as part of their annual budgetary processes. Experience indicate that public health has a hard time to compete with acute somatic and psychiatric care.

3.4 Pharmaceuticals

The decision about reimbursement of a particular drug is made centrally by the Danish Medicines Agency based on the legislation passed by the Danish Parliament (section 7 of the law about public health insurance). Hence, reimbursement decisions – and in essence priorities given to the various available pharmaceuticals – take place nationally, and very unusual based on explicit politically established criteria. See [14] for examples of this process. The Medicines Agency in most cases bases it reimbursement decisions on recommendations from a standing committee on reimbursement composed of 7 persons with a medical or a pharmaceutical background appointed for four years.

The pharmaceutical companies apply to the Medicines Agency for reimbursement from the public health insurance (a universal and tax funded system financing drugs, practising physicians outside hospitals, adult dental care etc.). Fairly explicit guidelines exist for required information in the application from the drug companies, procedures and standards for analysing these and other available data[12], and explicit criteria, but not weights, for deciding on reimbursement [11]. As such there is considerable transparency surrounding the decision to reimburse, but the process is not totally predictable due to vagueness of the criteria used and the (maybe continually changing) unknown weights applied to the set of criteria.

There are five types of reimbursement

- General reimbursement
- And four types of individual reimbursement (patient specific, based on individual applications)
 - o single reimbursement
 - o reimbursement for the chronically ill
 - o reimbursement for the dying
 - o increased reimbursement

General reimbursement is the dominating and the most attractive form for reimbursement, both for the pharmaceutical companies and the consumers because, once granted, it applies without limitations to the drugs in question.

For general reimbursement the two primary criteria are: whether the drug has a documented safe and therapeutically valuable effect for well defined medical indications, and that the price of the drug has a reasonable relationship to the therapeutic value. Documents indicate, e.g.[10], that the first criterion is the more important one.

For drugs with new chemical entities the standing committee on reimbursement receives a medical opinion from the medicines agency focusing on clinical effect compared to other drugs for the same or roughly the same indication, side effect profile compared to existing drugs, and – somewhat surprisingly as part of the medical opinion – the degree of improvement in clinical effect and/or side effect profile compared to the 'economic burden imposed by the new drug'. In connection with the latter the Medicines Agency makes a price comparison where a price per DDD is calculated and compared to the DDD prices for comparable marketed drugs. Specific administrative procedures exist for this comparison. In available sources 'economic burden' is not specified, but one is probably not wrong in guessing that it undoubtedly includes budgetary effects on the public health insurance.

General reimbursement is *not* granted if the drug has a broad indication. In addition to this there are nine other instances where general reimbursement is not granted. For instance, that prescribing requires special diagnostic procedures, i.e. usually something that takes place in a hospital setting,

or that treatment takes place in hospital. Other examples are that there is a risk that the drug will be used outside of the officially claimed indication ('indication creep'), or that there is a risk that the drug will be used as first choice despite that the Medicines Agency finds this unfounded, or that it is unclear whether and when the drug is a first choice drug. Clinically undocumented drugs cannot receive general reimbursement. In addition there is a rubber-clause saying that if the drug in question solely or mainly is used for purposes where it is not reasonable to expect reimbursement from the public health insurance. However, there is no documentation of what exactly is meant by 'reasonable to expect' – neither in legislation or government executive orders.

Reimbursement decisions essentially are about priority setting in the health care sector, and undoubtedly are one of the most important ongoing priority issues in health care. A single positive decision on reimbursement usually involves subsequent public and private expenditures running into several millions Euros. It is obviously very difficult to sell a drug without general reimbursement (however, see the section on single reimbursement below). At the same time, drugs increasingly innovate or improve treatment modes, but at a cost – and come from what some observers somewhat distrustful call commercial pharmaceutical companies. For these and a host of other reasons it is therefore important that the criteria used for deciding on reimbursement are transparent and well-argued. Overall the Danish criteria are fairly transparent and furthermore grounded in legislation and explicated in government executive orders, but most politicians probably do not realize the type of priorities they establish by means of this set of criteria. To them it is probably mainly a technical issue and not an equally important political priority setting issue. In addition, the applicable criteria are formulated in somewhat imprecise terms, leaving considerable interpretative leeway for the standing committee on reimbursement and the Medicines Agency, i.e. the implicit weights and interpretations attached to the individual criteria.

As an aside it should be noted that drugs dispensed by hospitals are free to the patient, and that the decision about introducing drugs in a hospital setting is a separate process taking place at the county level. Hence, the criteria surrounding introduction of hospital based drugs are more unclear than for reimbursable drugs, because it is left at the discretion of the respective county councils.

Annually the Medicines Agency receives between 20-25 applications for general reimbursement for new chemical entities or new dispensation forms. The rejection rate for 1999-2001 was 58%, 65%, and 38% respectively [12]. The most frequent reason for rejection was (too high a) price. In view of this it is somewhat surprising that economic evaluations are not used more and/or apparently play a minor role.

4. Turning theory into practice

This question to a considerable extent been answered in section 3 above and partially in section 1. In the Danish context it should be noted that although considerable theorising has taken place, much of the debate has been tied intimately to 'real issues', i.e. how the counties can improve the priority setting as part of the budget process. Therefore, no large gap exists between theory and practice. The process has been characterized by considerable pragmatism by all parties involved.

It is worthwhile to summarize which mechanisms are used.

• for *hospital services* priority setting takes place through the annual budget process nationally and at the county level. Revenues (desired tax level) and expenditures (desired expenditures) are equilibrated in this process. It is a political process based on inputs from professionals and analyses like health technology assessments or economic evaluations. However, the process in no way abounds with documentation for various new treatments or

phasing out of existing treatments. However, in a longer time perspective – for instance 2 to 3 years health technology assessment may provide the platform on which new proposals are entered into the budget process.

Due to the fact that the Danish health sector is tax financed, tight national control and fiscal ceilings combined with annual negotiation with the counties the total level of health expenditures are controllable, and the total level is established through a fairly ordered process.

- for services from *provider outside the hospitals*, e.g.GPs, the priority setting mechanism is the (re)negotiation of fee schedules, where new services are added or existing services taken out. The setting and change of the fee schedule is based on a combination of fiscal considerations along the professional advice on desirable services. In this area few technology assessments are used as part of the process. The same holds for economic evaluations.
- for *public health* national plans from central government provides indications of desirable areas for activities. However, due to lacking central funding, the real priority setting takes place in the counties and the municipalities as part of their budget process.
- for *pharmaceuticals* priority setting takes place nationally and is an integral part of the decision about reimbursement status of particular products. In many respects it is the most transparent priority process and is based on written expert input.

5. Maintaining explicit priority setting in the long term

In one sense it would be wrong to say that priority setting has taken root if it is understood as being based on some ideal principles developed by experts. In another sense priority setting has taken root, namely that the need for priority setting is (almost) universally accepted, also by most physicians.. Furthermore, important mechanisms are in place, for instance the macro and micro budget processes. However, it would be wrong to describe these process and transparent and very data/analysis based. By the very nature (tax funding, public hospitals being owned by the funding body) it is a rather political process. In addition the use of health technology assessment as decision aids is also accepted in many quarters.

For obvious reasons the budgetary process in entrenched and the reliance on health technology assessments is increasing. The idea of using very clear cut priority setting criteria like those set down in the Norwegian 1987 white paper [12] never took root, although several counties tried in the min 1990ies.

The long-term issues concern a more general issues, namely to what extent the Danish welfare system, including the health sector, still can be tax financed. A Commission on Welfare has been established to study this issues. Hence, the overall priority setting issue in the health care sector is embedded in a more general question about the welfare state.

6. Recommendations

Some of the things that have been successful in Denmark can only be transferred to Germany with great difficulties. The most important difference concerns the financing system: a unified tax based system in Denmark with politicians clearly in control compared with the German system of 400+ Krankenkassen and a far more complex regulatory system (Krankenkassen, Länder and the Federal level). like that in place in Denmark. These important differences influence on the way in which priority setting can be put in place.

However, with some caution it is suggested that

- look at the Danish priority setting for pharmaceutical
- develop health technology assessment, HTA, including economic evaluation. Make sure, however, that this is tied closely to the important priority setting bodies. Maybe consider legislating about the use of HTA (I realize that the German Institute for Medical Documentation and Information already has been established. I am calling here for mechanisms ensuring that the results are integrated into core decision processes).
 - it must be emphasised that decision tools/aids like HTA never can provide priority setting! It requires responsible politicians, boards of Krankenkassen etc.. In other words, decision processes where the parties accept the need to establish priorities and want to use for instance HTA in this process.
- establish (without providing the answer her) fiscal limits (ceilings) for hospital services. The process leading to these ceilings will turn into a priority setting process supported by for instance HTA.

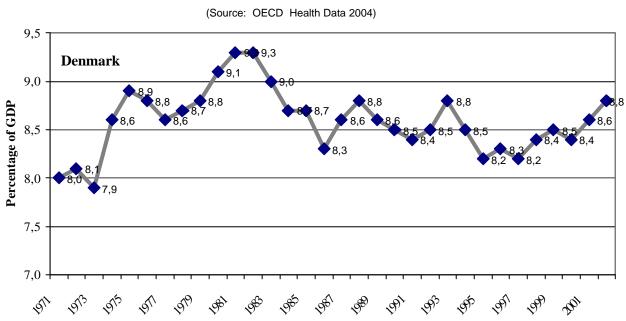
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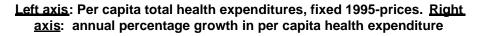
Figures

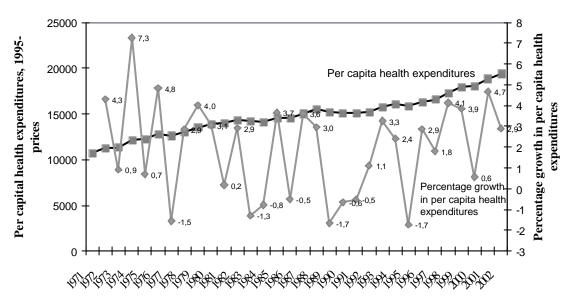
FIGURE 1.



Comment on Figure 1: 1. 1975-1977: adjustment to the oil-crisis, **2**. 1977-1983: the Danish economy partly out of control, **3**. 1983-1993: Period of fiscal austerity ('resurrection of the Danish economy'), **4**. 1994 – 2002: steady economic growth, health expenditures on average grow by about 2.5% annually in real terms

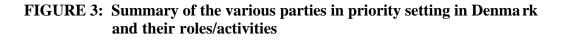
FIGURE 2





Total health expenditures as percentage of Gross Domestic Product

Comments on figure 2: Per capita health expenditures have increased by an average annual rate of about 3% from 1971 to 2002, but with periods of negative growth, in particular in the 1980ies. The highest growth rates were in the 1970ies.



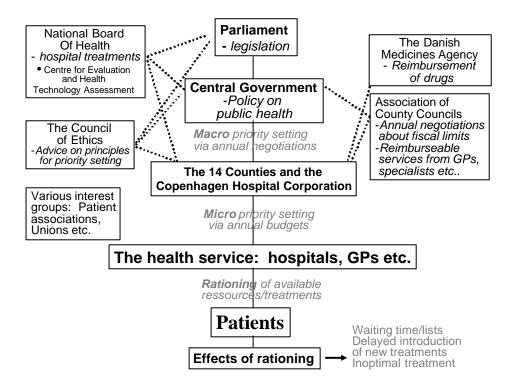


FIGURE ¤4

Fehler! Es ist nicht möglich, durch die Bearbeitung von Feldfunktionen Objekte zu erstellen.