

Executive Summary

Health data as the basis of outcome-based price agreements

Outcome-based price agreements are not new – so why are they not used to a greater extent?

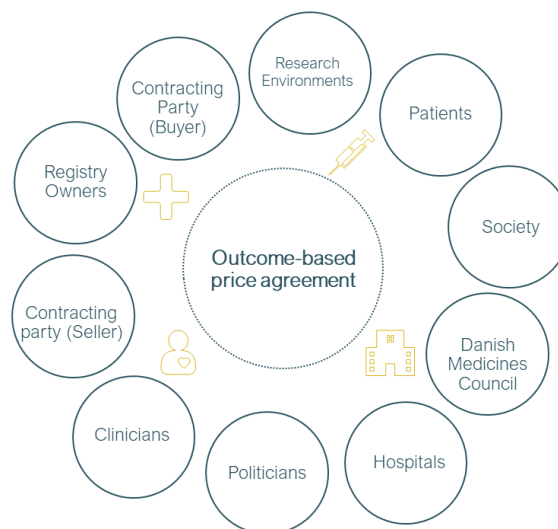
Life Science Insights Centre has explored attitudes, possibilities and barriers for a greater dissemination of outcome-based price agreements among a wide range of stakeholders in the field:

The study is driven by the Life Science Insights Centre's interest in supporting the stakeholders in avoiding deadlocks when new drugs are ready for market introduction, and therefore price, value, uncertainties, etc. must be agreed upon. Outcome-based price agreements are one way to go about such agreement models. Regardless of interests and positions, the ability of being able to follow up on the clinical effect of a specific treatment is key. Therefore, the question of which health data is available has a special place in the study.

Method

The study is based on a three-step approach. First, desk research has led to a mapping of models for outcome-based price agreements. Next, a series of qualitative interviews with stakeholders have uncovered their perspectives on such models: Contracting Party (Seller), Contracting Party (Buyer), Clinicians, Registry Owners & Research Environments, Patient Representatives, Ethics & Politics. Finally, the results of steps 1 and 2 have been discussed with the stakeholders at a workshop. The findings are shared in this

report and summarised in this Executive Summary.



Possibilities: A positive position on greater use of outcome-based price agreements

The potential of outcome-based price agreements is acknowledged across the stakeholder groups, and all groups wish to gain more experience with them. The greatest potential is seen where existing documentation is limited and in specialised areas, such as medicines for small and rare diseases as well as personal medicine.

Generally, it is concurred that all stakeholders in an agreement do not need their own access to data – a key point which helps to solve ethical and competition issues in relation to outcome-based price agreements.

The interviews made it clear that there is a strong wish to include PRO and 'quality of life' data as a supplement to the objective data,

so that together they form the basis for evaluation and monitoring of outcome-based agreements. The introduction of QALY is seen as a contributing factor in this context.

Barriers: Prerequisites for outcome-based price agreements to be implemented in practice

Stakeholders highlight both practical and ethical barriers. It is stated that an outcome-based price agreement must not put the doctor or patient under pressure to deliver "the right" clinical results. This is further complicated by the fact that often the effect of a treatment cannot be assessed in a binary manner, but can also rest upon a subjective assessment of, for example, increased quality of life.

In the more practical end of the scale, the stakeholders mention the amount of time it will require of all parties involved in a specific price agreement to define relevant, measurable effect goals as well as finding health data that supports the given agreement. Stakeholders therefore express concern that the administrative part of outcome-based price agreements will be so heavy that they will not be implemented despite their potential.

In addition, it is a challenge to access health data that can actually support these price agreements: Despite the fact that Danish health data are unique in an international perspective, it is not a given that the data is practically applicable to the specific goals of a given agreement. RKKP and the clinical quality databases are mentioned by many stakeholders as a possible source of data, but no current data sources are a perfect fit, and in many cases additional data will have to be collected for the specific agreement. This supports the concern for the administrative

part of outcome-based pricing agreements - and the use of PRO and 'quality of life' data could potentially make this even heavier.

The way forward for outcome-based price agreements in the Danish healthcare system?

The study clearly shows that there is an interest in and willingness to try to incorporate outcome-based price agreements in the Danish healthcare system with the common purpose of making new treatments available to patients in a sound socio-economic manner.

With regard to the data critical for outcome-based price agreements, there is also a possibility of progress: Stakeholders agree that in Denmark we have access to many potential data sources. Additionally, there is agreement that the handling and analysis of data should be carried out by public actors, preferably an independent third party.

There are no easy solutions or templates for outcome-based pricing agreements. The agreements must be well considered, and all stakeholders must be involved when a specific outcome-based price agreement is being set up. It will be time consuming, and the processes underpinning the agreements must reflect that. Stakeholders recommend taking a closer look at experiences from abroad if outcome-based price agreements are to be disseminated in the Danish healthcare system.