

The Dutch lock procedure for reimbursement works as intended

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The Dutch lock procedure intends to prevent uptake of ineffective drugs and to negotiate the price of effective drugs to regulate the impact on the healthcare budget¹



Situation:

The **lock procedure** was introduced in 2015 to **prevent uptake of ineffective drugs** and to **negotiate the price** of effective drugs to regulate the impact on the healthcare budget¹

Challenge:

Potential **loss of health** as drugs are unavailable to patients during the lock procedure*



Research question:

What are the **effects of the lock procedure** on population health and the healthcare budget?

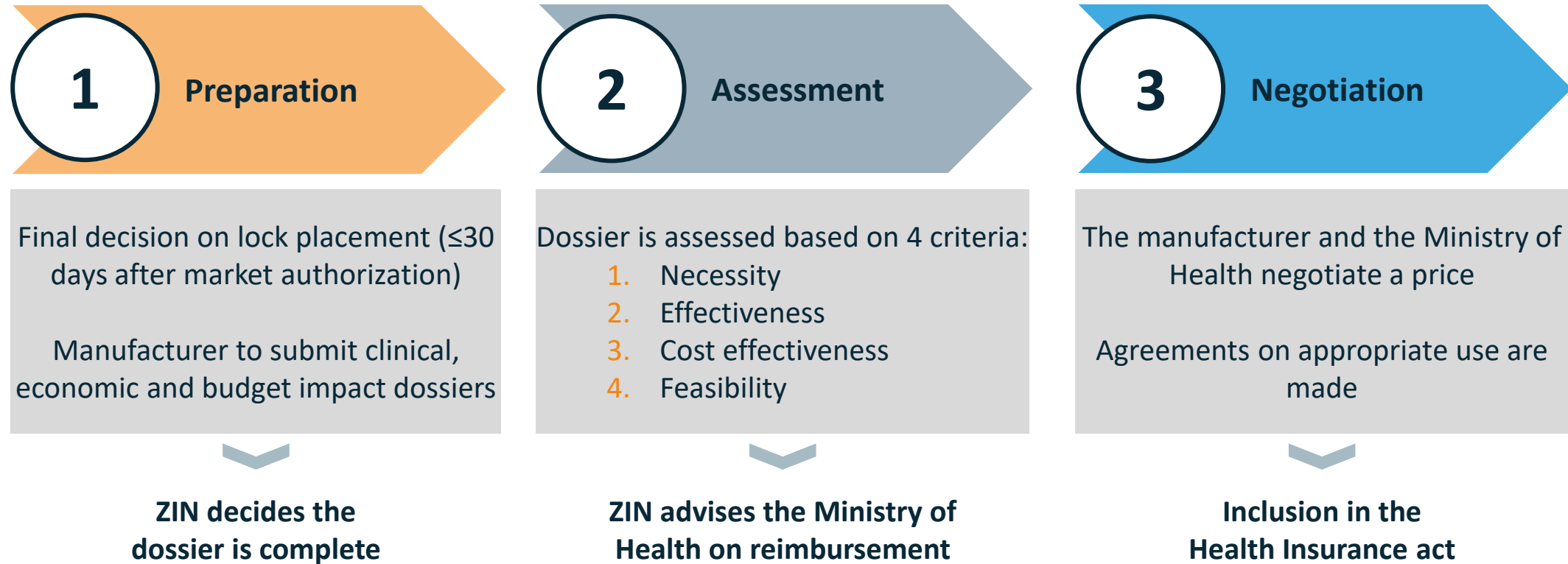
Aim:

Technical analysis of a policy instrument, which can be used to assess the impact of reimbursement procedures

1. Staatsblad van het Koninkrijk der Nederlanden - 15 May 2018 - <https://zoek.officielebekendmakingen.nl/stb-2018-131.html>

* Exemptions are made for clinical trials and compassionate use

The lock procedure consists of three distinct phases: preparation, assessment and negotiation



We assessed the effects for all drug indication combinations with a pharmacoeconomic dossier completing the lock procedure before the end of 2022

Drug indication combinations



* 6 drug indication combinations were declined based on the quality of the evidence and/or model. We assume that these would have been declined in the alternative route as well, and this is therefore not a specific effect of the lock procedure.

We compared the lock procedure with a comparative route of reimbursement which is completed faster

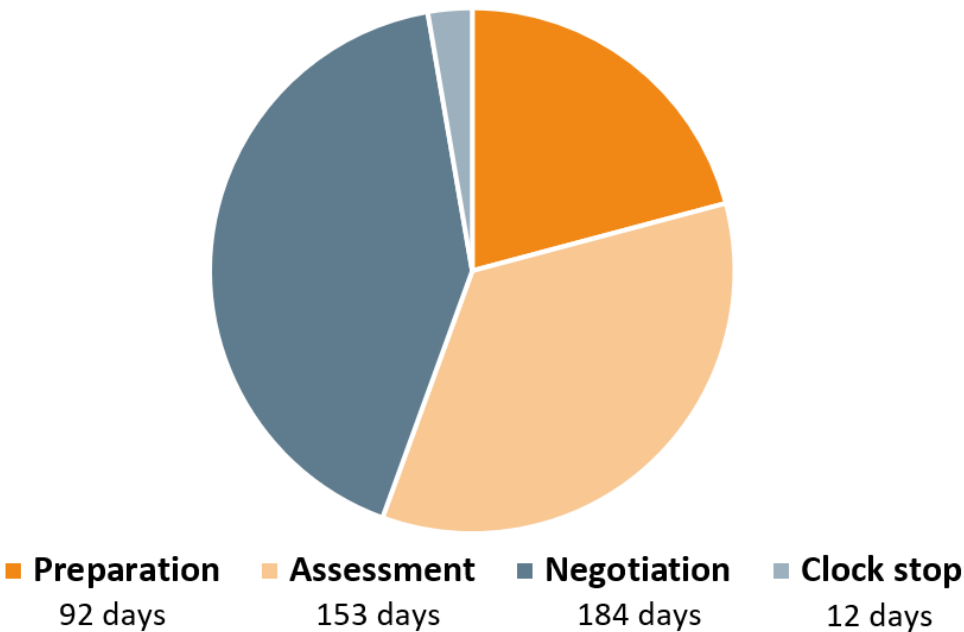
440 days

was the average duration of the lock procedure

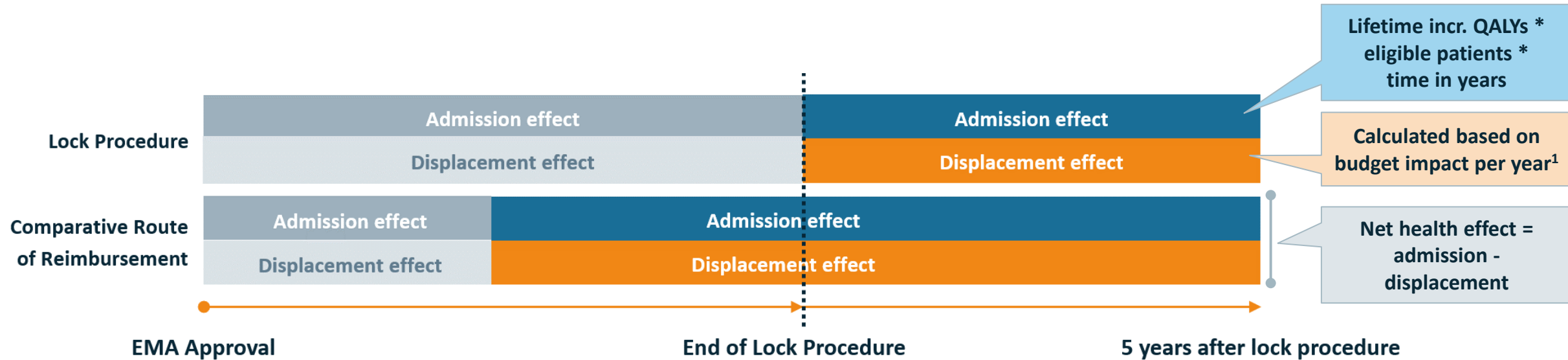
134 days

We compared the lock procedure with a different route of reimbursement which takes 134 days on average

Average number of days of the Lock Procedure



We developed a model to assess a net health effect and a budget effect



- \ **The admission effect** is caused by the health benefits gained because of the new drug.
- \ **The displacement effect** models health lost in other healthcare caused by the reallocation of funds. We assume a fixed healthcare budget, which means that the funding for the new treatment leads to displacement elsewhere.
- \ During the lock procedure, the new drug is **excluded**, and the potential health benefits and losses are not capitalized.
- \ And we assessed the impact on the **healthcare budget** caused by the price negotiations

1. We use previous research to estimate displacement (verdringing). Source: POINT 1.0 – Verdringingseffecten zichtbaar maken. IQ Healthcare.

<https://www.iqhealthcare.nl/nl/kennisbank/tools/point-10-verdringingseffecten-zichtbaar-maken/>

The modelling study is based on assumptions relating to the lead times, negotiated discounts, time horizon, and displacement



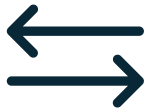
Lead times: We use a scenario lasting 134 days for the comparative route



Discount: We apply the list price for the comparative route and use a scenario based on the average discount that year for the lock procedure



Time horizon: After the lock procedure, a fixed 5-year time horizon is applied



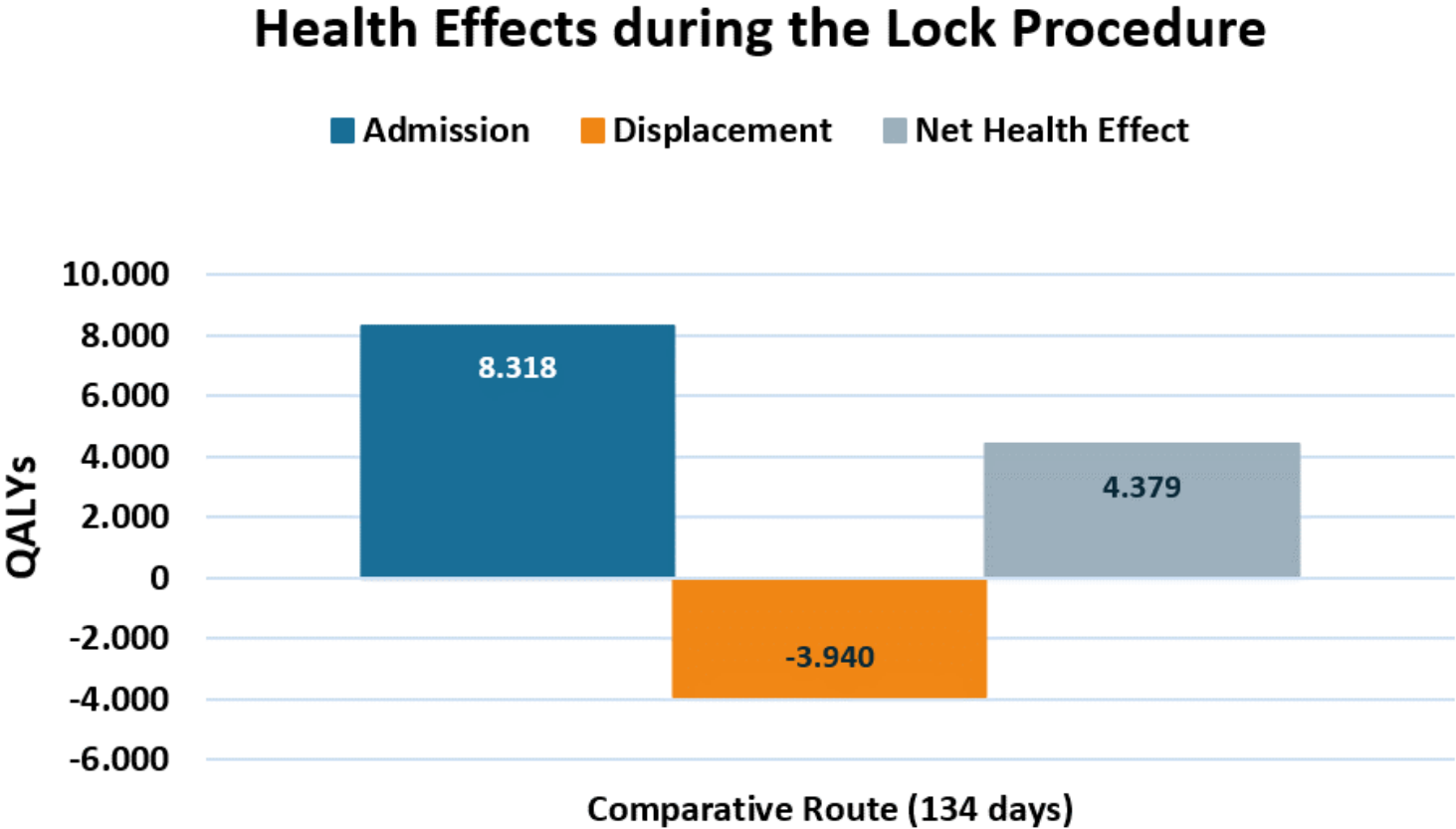
Displacement: Based on existing research¹ which used 2012-2014 data, only displacement within specialised hospital care is taken into account



All assumptions are used consistently; both during and after the lock, and for both the lock and the comparative route.
The results provide insight in the order of magnitude of the effect of the lock.

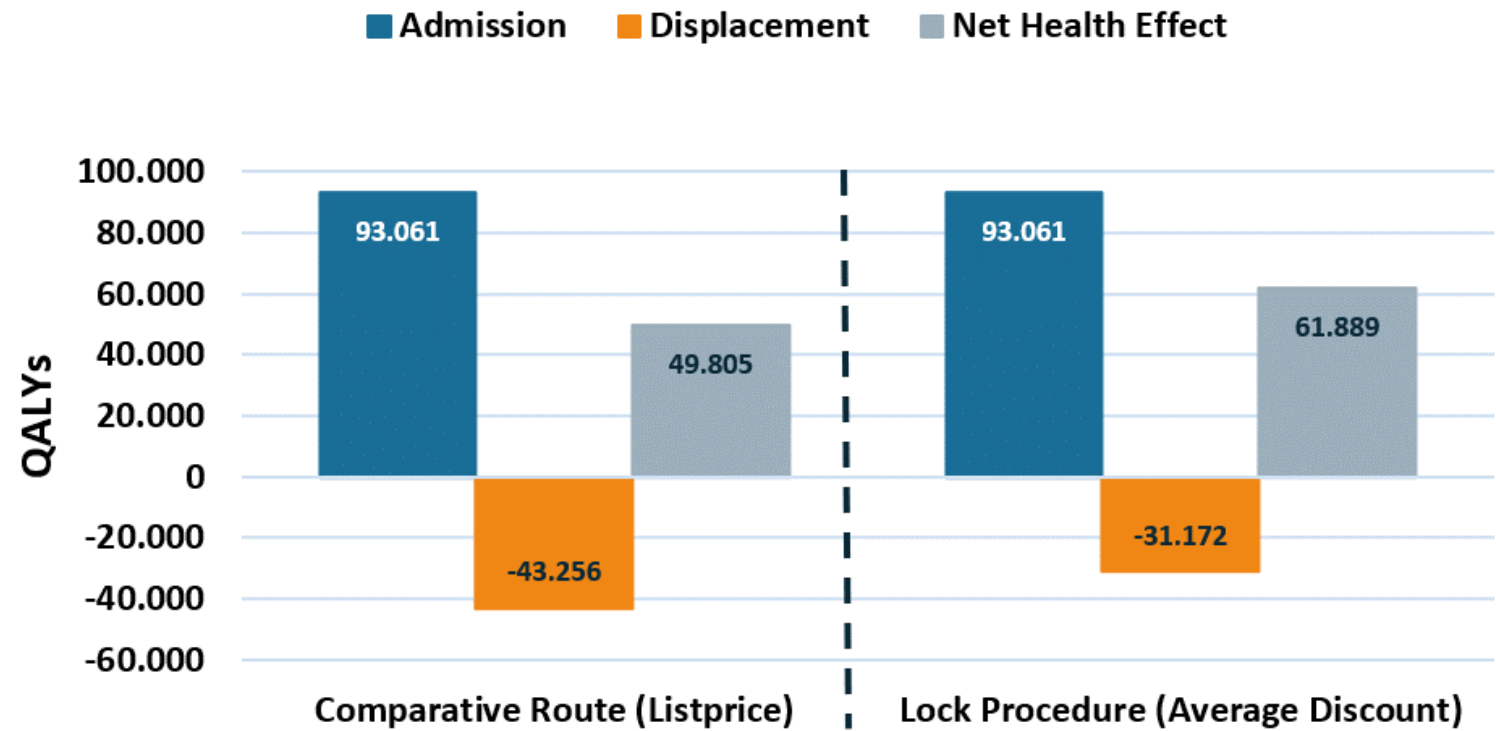
1. POINT 1.0 – Verdringingseffecten zichtbaar maken. IQ Healthcare. <https://www.iqhealthcare.nl/nl/kennisbank/tools/point-10-verdringingseffecten-zichtbaar-maken/>

During the lock procedure there are no admission effects and no displacement, but there would have been effects if the new drug would have been available earlier



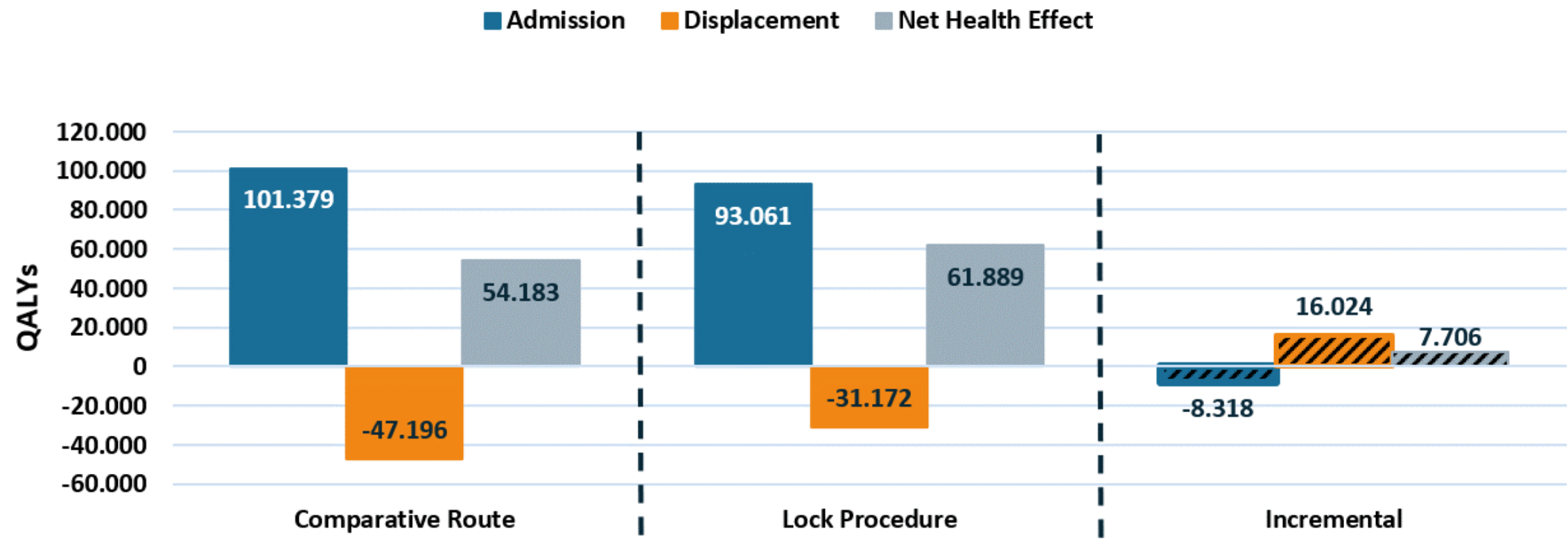
In the 5 years after the lock procedure, price negotiations limit the loss of total population health through displacement

Health Effects 5 years after the Lock Procedure

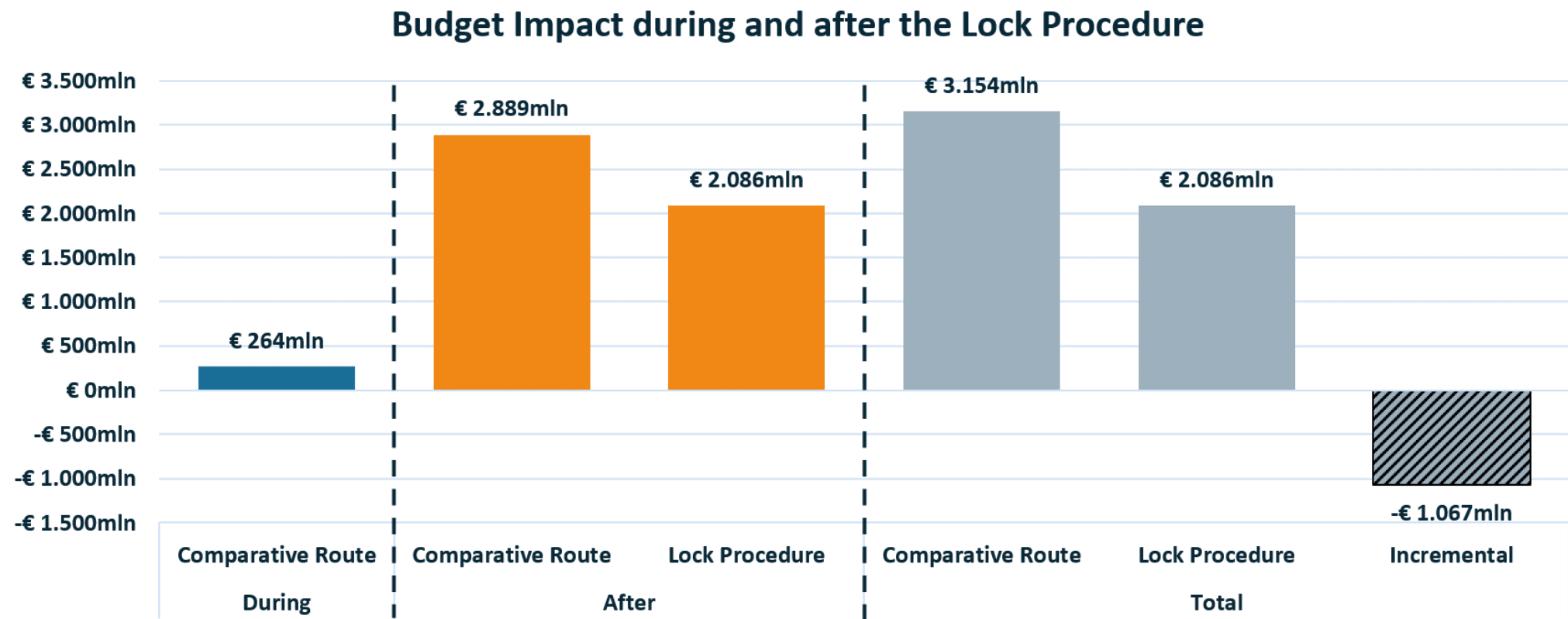


The investment of exclusion during the lock procedure is compensated in the 5 years after, leading to a positive incremental result

Total Health Effects for the Lock Procedure vs the Comparative Route



The lock procedure reduces the budget spent on new expensive drugs during and 5 years after the lock procedure



The total effects of the lock procedure are a balance between health not gained during the lock procedure and health not displaced in the 5 years after the lock procedure



Results are dependent on the health benefits of the new drug, the duration of the lock procedure, and the negotiated price



The lock does not capitalize on the potential health benefits of new innovative drugs in the short term, but limits health loss in the long term

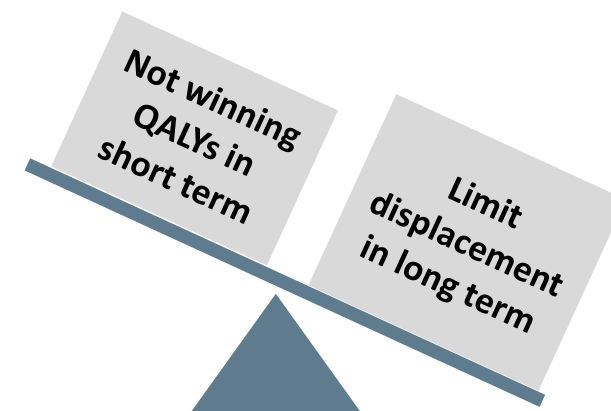


Price negotiations compensate the effects of exclusion during the lock procedure



We suggest further research into:

- quantifying displacement
- alternative routes of reimbursement for cost-effective drugs
- the extent of financial arrangements for the comparative route



We provide a framework for further development and to facilitate discussion about the lock procedure



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