

'We need a strategy to pr mote the pilot systems'

Im Interview: Prof. Dr oec. Leonie Sundmacher MSc, Technical University of Munich, Chair of Health Economics

'From my point of view, it would be useful if further evidence were collected on the effectiveness of selective contracts.' In the cover interview with 'Monitor Versorgungsforschung', experienced healthcare researcher Prof Dr Leonie Sundmacher is not surprised that the 'Cardiolotse' innovation project was not recommended for transfer to standard care. However, in her opinion, this decision cannot be based on a lack of evidence. Her assumption is that the Innovation Committee 'apparently shies away from recommending this labour-intensive intervention for standard care as long as its effectiveness and cost-effectiveness are not confirmed by other projects'.

>> Let's use our conversation to place the topic of pilots - based on the evaluation of the 'Cardiolots' innovation project carried out by you and your team - in a wider context. Here I refer on the one hand to the results (1), the evaluation report (2) and the G-BA decision (3) of the 'Cardiolotsen' innovation project, and on the other to the article 'Patientenlotsen: Optimierte Versorgung oder Orientierungshilfe - im immer komplexer werdenden Gesundheitssystem brauchen Menschen Unterstützung. Reflections on the future of patient guides', published in June 2024 in the Deutsches Ärzteblatt (4), written by Marie Coors, Wolfgang Greiner, Lorenz Harst, Jochen Schmitt and yourself. Let's start with the 'Cardiolotsen' innovation project to move from the smaller point to the larger one: In its decision on the 'Cardiolotsen' innovation project, the Innovation Committee, which is based at the G-BA, does not make a recommendation, but 'based on positive trends' forwards the results to five designated bodies, which can do what they want with them, but do not have to. Were you surprised by the outcome of the decision? How do you categorise the wording of the decision?

As an evaluating institute, we work closely with the team carrying out the intervention right from the start. At the same time, we always withdraw to neutral ground, as we take the independence of the evaluation seriously and want to categorise the evaluation results objectively. From this, yes, somewhat distanced perspective, the decision did not shake me. I recognise that the G-BA only rarely makes a recommendation for standard care, as the requirements for nationwide implementation are high, particularly in the case of diseases with a high public health relevance. However, we could not understand why the Innovation Committee lacked informative evidence.

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Could you please explain this assessment?

The project established a pilot model for patients with cardiovascular disease after discharge from inpatient care. With the training of pilots, the focus was on addressing patients directly. The pilot was to remain the point of contact for patient care after hospitalisation. The RCT was conducted in an organised manner. After 12 months, we were able to demonstrate a lower rehospitalisation rate and a favourable cost-effectiveness ratio. The G-BA criticised the fact that the statistical significance of the primary endpoint was not given in all adjustment and evaluation procedures. This is also correct, but places high demands on the evidence of a complex intervention. I cannot imagine that all recommended projects have cleared this hurdle. Furthermore, it was - correctly - criticised that the patient population in the trial was more severely ill than originally assumed. This is also true, but this does not call into question the analysability of the more severely ill population.

In your personal opinion, how did this non-recommendation come about?

I gathered from the subtext that the Innovation Committee, which is part of the G-BA, is apparently reluctant to recommend this labour-intensive intervention for standard care until its effectiveness and cost-effectiveness have been confirmed by further projects. In addition, it is presumably still uncertain which pilot models should be prioritised and in what form. In my opinion, this could have been written in the same way instead of just relativising the evidence. In order to assess the quality of the evidence, I would find it helpful if the Innovation Committee, which is part of the G-BA, would allow the evaluators to comment briefly on the recommended decision. Not to relativise or question the recommendation, but to support the scientific community in classifying the results. This would correspond to the exchange of arguments within a peer review process.

By forwarding the decision to, among others to the associations of health and long-term care insurance funds at federal level and the German Hospital Association (DKG), as well as from a passage in the text of the resolution (quote: 'Due to the recognisable positive trends, however, the option remains to implement the cardio pilot concept on a selective contractual basis, depending on the local needs, resources and implementation options'), one could assume that a type of selective contractual mandate in accordance with Section 140a SGB V can be derived from this, with which the 'cardio pilots' can be deployed outside of standard care. Is that also your assessment of the decision? And let me ask you: do you assume that there will soon be cardiologists not only in the three north-eastern federal states of Germany?

Yes, that's how I read the decision. The contractual partners, AOK Nordost and Vivantes, are effectively being asked to continue the project as part of a selective contract following the positive evaluation.

Which they are doing, by the way.

That's a good thing. This will have the positive effect that more experience can be gathered on the pilot projects as part of this or further selective contracts. Existing weaknesses can also be addressed: For example, the communication between the cardio pilots and doctors in private practice did not work smoothly during the project. Even the pilots had problems overcoming sector boundaries. From my point of view, it would also be useful if further evidence on the mode of action were collected along the selective contracts. Since an RCT is already available, these could also be quasi-experimental analyses.

I can also imagine that health insurance funds and hospital net-

works in other regions will find this model of direct approach attractive in our difficult-to-navigate healthcare system. However, there should be a resubmission point at which the G-BA decides, based on the available evidence on pilot projects, for which diseases and for which settings pilot activity in standard care can be useful. The obvious advantage is that all patients can then benefit regardless of their health insurance affiliation.

Your evaluation report on the 'Cardiolotsen' project states that 'the evaluation results to date indicate that the new form of care has added value for patients'. Why was the wording 'indicate' chosen, although the ICER value (note: incremental cost-effectiveness ratio) of 2,664 euros is quite clearly in favour of the 'Cardiolotse' intervention? Is the wording 'suggest' intended to indicate that this is a result with a very low level of evidence? What was the reason for this cautious wording?

The wording results from the distanced view as a neutral, independent evaluator already mentioned at the beginning. The cost analysis showed a significant reduction in hospital costs during the follow-up period, but there was no statistical significance when looking at the overall costs. There is also the challenge that the calculated ICER reflects the costs saved per potentially prevented rehospitalisation. The costs saved must therefore be assessed proportionately for the reality of care, which should definitely be taken into account in the overall assessment. The study did not have a low evidence class.

Question: Why was there no statistical significance when analysing the total costs? What exactly is the reason for this?

It should be taken into account that the implementation and intervention costs of the Cardiolots were included in the analysis of the total costs, which reduced the significant difference in the previously analysed care costs.

In the article 'Patient pilots: optimised care or guidance' (4), you write as co-author that the 'evidence available to date is insufficient' to differentiate the extent to which the effect of pilots differs depending on the disease and setting, which for you raises the question of whether 'pilots should be used for specific indications' (for example, in the scope of case management and the associated remuneration) or 'to what extent more general concepts for pilot activity are possible'. With this statement, you are certainly not only referring to the evaluation of the 'Cardiolotsen' project that you carried out, but probably also to other analyses published to date on various pilot projects: What needs to be done from a healthcare research perspective in order to close the evidence gap that is apparently becoming apparent at this point?

There are already a number of published final reports on pilot projects supported by the Innovation Fund. The Innovation Committee has yet to make a concrete recommendation for the transfer to standard care. The use of social care nurses in the OSCAR project, for example, led to an improvement in the health-related quality of life of oncological patients within the first six months and to a reduction in overall costs. The Cardiolotsen project came to a similar conclusion, with shorter hospital stays and lower hospital costs. Furthermore, patient satisfaction with the pilots is rated as high by the majority of completed projects. The STROKE OWL project, on the other hand, found that the care of stroke patients was more closely aligned with the guidelines, but there were no differences in mortality and recurrence rates. We therefore recognised in the article you mentioned that an isolated consideration of the individual project results does not make sense. At the point of resubmission, it is necessary to sort out which evidence is available to what degree and to what extent. Which patient populations benefit in particular and whether there are possible synergy effects between pilot projects.

When would be an appropriate time for the resubmission you mentioned, which is not provided for in the Innovation Fund?

The Innovation Committee has approved a wide range of projects with pilots for different indications and settings and has presumably also attached expectations to them. Once the largest ongoing projects have been completed, a review can be carried out. It is simply important that we learn systematic lessons from the evidence we have gathered and do not let this opportunity pass us by.

'An isolated analysis of the individual project results is not meaningful'

Furthermore, the aforementioned article (4) states that it could also be useful to 'define specific target groups within the disease groups that could potentially benefit most from the intervention, which would increase the cost-effectiveness of the intervention'. However, an 'evidence-based identification of the care and indication areas with increased potential for improvement and coordination for a targeted use of the pilots is therefore still outstanding'. Here, too, the question is: Wouldn't it make more sense to answer the questions you have addressed than to promote yet another pilot project? Because you will surely say 'yes': What could a corresponding study setting or even a corresponding theory look like? Would you rather see another innovation fund application as sensible or is there another approach that would be more suitable from your point of view? Should a corresponding pilot project perhaps be launched in a region?

We don't always need more: classic subgroup analyses in the ongoing RCTs already provide useful insights into the benefiting patient populations. Of course, the RCTs are powered for the primary endpoint, so that subgroup results without significance do not allow a final judgement. But the subgroup analyses that show significant improvements are of informational value.

I am also currently interested in whether the pilot scheme works in rural areas with a lower density and intensity of care and with smaller hospitals, or how the models would have to be adapted to meet the needs of the population.

'Although there are initial indications of cost savings for sta-

tutory health insurers for cardiological patients, other health economic perspectives, such as from the point of view of society as a whole or other payers, are insufficiently represented,' the DÄB article also states (4). This is 'an essential research gap that urgently needs to be closed', particularly with regard to the intended cross-sectoral and cross-lawbook impact of patient pilots. What health economic perspectives from the point of view of society as a whole or other payers are you referring to here? And: How could you imagine closing this evidence gap?

The perspective of the statutory health insurers is essential for the reimbursement decision. In addition to costs that are borne directly by patients, care and pension funds are also important stakeholders/payers for certain indications, for example, and should be included in a cross-regulatory solution.

Let's now move on from the micro to the meta level, as you are not only head of the Department of Health Economics at the Technical University of Munich and as such also an evaluator, among other things. You are also a member of the German Advisory Council on Health and a member of the Government Commission for Modern Hospital Care at the Federal Ministry of Health and several other councils: As a designer of healthcare systems with a primarily scientific background, what advice do you give to politicians, health insurance funds, KVs and hospital associations at federal and state level on how they should deal with the issue of locums - also in view of the increasing problems of care in the age of double demographics and the shortage of skilled labour - in the interests of better care and, above all, for the benefit of patients?

This has already been mentioned above. I can understand that the decision to make a recommendation is not made for each individual pilot project in isolation. Rather, a strategy is needed to promote and finance this care complex.

The decision should be made largely on the basis of the available evidence, but at the same time it is important to consider the impact that the establishment of pilots will have on the local skilled labour situation. Positions are often created for pilots that need to be filled by trained staff. Potentially favoured working hours away from shift work could make the pilot profession an attractive alternative to everyday practice and clinic work. However, this also means that trained specialists will have to be replaced elsewhere. In the last report by the German Council of Economic Experts, we arrived at a differentiated analysis according to which Germany has a relatively large number of employees per inhabitant in an international comparison. Nevertheless, the high number of cases per patient results in a high workload in the healthcare system. Our recommendations therefore centred on eliminating the structural weaknesses of the healthcare system and reducing medically unnecessary cases as far as possible. Simply increasing the supply of specialists overlooks the fact that we are giving up a great deal of efficiency in favour of cumbersome structures and is not realistic in view of demographic change.



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Lots:innen therefore tie up personnel capacities on the one hand, but at the same time promise to increase efficiency.

In my opinion, the calculation only works if the use of patient pilots is not an interim solution on the way to a fundamental reorganisation of sectors and sector boundaries, but offers additional benefits for vulnerable patient populations.

Isn't there an unanswered, because rather uncomfortable, question behind all this: Should patients be controlled or should they be left to their own devices in the spirit of the primus of individual freedom? And, on the other hand, shouldn't the stakeholders in our healthcare system be obliged to act in the best interests of patients instead of establishing outcome-based care instead of single-service-based care?

The question is no longer as uncomfortable as it was ten years ago. The discussions at this year's Medical Conference in Mainz and in the doctors' associations and trade unions are characterised by the desire for more patient control. As a health economist, I can agree with this assessment.

In this year's expert report, we also made it clear that the German healthcare system is too complex and no longer meets people's needs. In my opinion, the fact that four out of five people in Germany have difficulties navigating the healthcare system is not evidence of a strikingly low level of health literacy, but rather the result of a high-

ly fragmented system. We don't have pronounced quality deficits at the level of individual doctors and nurses, but we don't manage to guide patients quickly to the most effective and efficient care for them. This results in poorer outcomes than would be possible with coordinated care. Effective patient management now requires more commitment on the part of patients as well as clear patient pathways and decision-making rules between providers: it is an overall task. In our innovation fund project 'Pathway' (5), for example, a survey of Techniker Krankenkasse policyholders revealed that many people consider a reliable contact person for their health problems more important than quick access to a large number of providers. That was surprising for me and is encouraging.

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How can we make faster progress?

With the will to change and certainly also a new culture of cooperation in healthcare. This requires targeted steps not only to increase the health literacy of patients, but also to invest in the management skills of stakeholders.

Wouldn't it be a task for healthcare research, or even one that healthcare researcher Prof Sundmacher could take on, to set up a kind of university spin-off institute to run seminars for regional healthcare managers in order to increase the chances of establishing pilot projects in rural areas in particular?

I'll give that some thought. A new culture of cooperation is best learnt from peers. But we are happy to provide the evidence for this.

'Services must be sufficient, appropriate and economical; they must not exceed what is necessary. Insured persons cannot claim benefits that are unnecessary or uneconomical, service providers may not provide them and health insurance funds may not authorise them.' You know Section 12 SGB V inside out: will we ever achieve an entitlement to better, if not the best, care in Germany if the evidence is available?

Evidence is decisive. However, I am not aware of any healthcare system in which decisions are purely evidence-driven. In this respect, a certain amount of piecemeal work is priced in. Alongside evidence, transparency in decision-making is therefore the most important criterion on the way to efficient utilisation of our resources

Prof Sundmacher, thank you for the interview <<

The interview was conducted by MVF Editor-in-Chief Peter Stegmaier

Literature

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Links to scientific papers 'Cardiolotse ':
https://pubmed.ncbi.nlm.nih.gov/39428539/
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