Drug Initiative Saxony-Thuringia

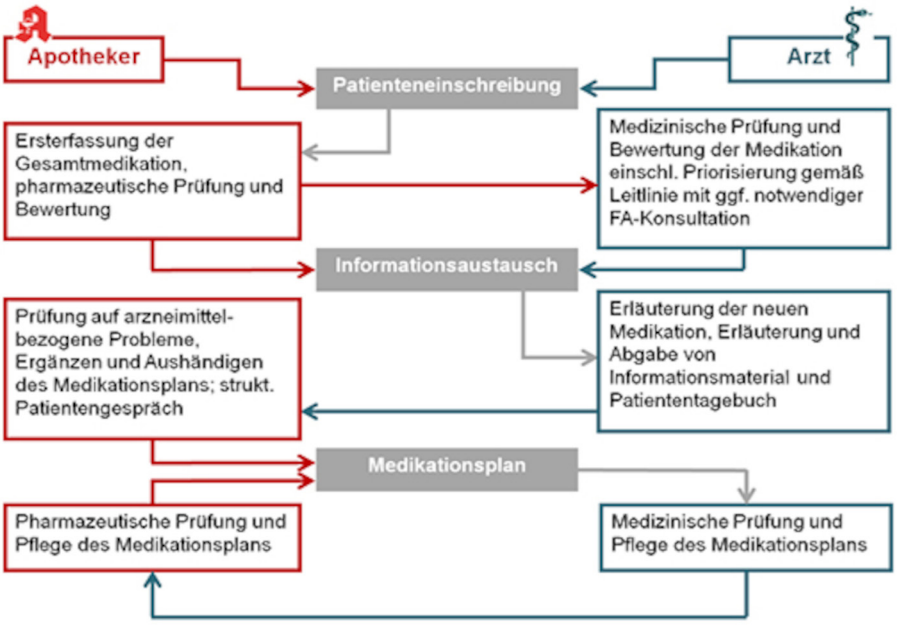
ARMIN is dead if politicians do not react now

With the end of the legally maximum possible term of eight years, the model project ARMIN, the Medicines Initiative Saxony-Thuringia, was terminated on 30 June 2022. This means that a promising and meanwhile even positively evaluated approach to care, which promotes and interlinks the interprofessional cooperation between doctors and pharmacists for the benefit of the jointly cared for patients, is about to come to an end. No wonder that the actors involved used the opportunity of the presentation of the evaluation data to initiate political demands to maintain the positive effects of ARMIN beyond the end of the project and possibly even to develop them further, for which, however, in the opinion of the ARMIN project partners, the necessary legal foundations must first be created.

>> ARMIN was a project that created something very special in the participating federal states: a new reality of inter-professional health care for multimorbid patients who take five or more active substances on a permanent basis, based on clear rules and coordinated processes. Rainer Striebel, Chairman of the Board of AOK PLUS, put it in a nutshell at the press conference to present the current evaluation data: ‚Currently, there is no legal framework in standard care that promotes and interlocks interprofessional cooperation between doctors on the one hand and pharmacists on the other'. However, according to Striebel, the possibility of continuing this care approach by means of selective contracts also falls away. When asked by ‚Monitor Versorgungsforschung', the head of AOK-Plus stated that the complexity of the project was so great that he did not consider §140 selective contracts to be a ‚relevant basis' with which not only the lowest possible enrolment hurdles but also the participation of other health insurance funds could be made possible. Therefore, Striebel continues, his health insurance fund with high market shares in Saxony and Thuringia is increasingly moving away from selective-contract regulations, as ‚what works well should be made available to all people in the regions'.

By ‚works well', the head of the fund certainly means ARMIN, which has managed to become a piece of standard care in Saxony and Thuringia over the eight-year course of the model. The results of the evaluation of Module 3, interprofessional medication management, were particularly good. Here, Prof. Dr. sc. hum. Hanna Seidling from the Department of Clinical Pharmacology and Pharmacoepidemiology at the University Hospital of Heidelberg, who was engaged for the evaluation together with the aqua-Institut in 2019. This late timing is already a problem in itself: although the evaluation could still take place during the term of the model project, it started much later at a time when it had actually already been implemented in routine care. The second problem results from the study design chosen - due to the time lag - with the help of a retrospective allocation of a control group by means of a propensity score matching. According to Seidling, this means that possible selection effects cannot be completely ruled out, which could also distort the overall effect. Likewise, due to the study design, no causal or mechanistic conclusions could be drawn that could show what actually triggered individual effects.

Nevertheless, important results could be shown in the comparison of the patients from the intervention and the control group



The steps to the medication plan: The pharmacist records the total medication and creates a preliminary medication plan. Then the doctor evaluates the medication and completes the medication plan. Finally, the medication plan is completed in the pharmacy. Source: https://www.kvs-sachsen.de/armin/die-drei-module/Darstellung).

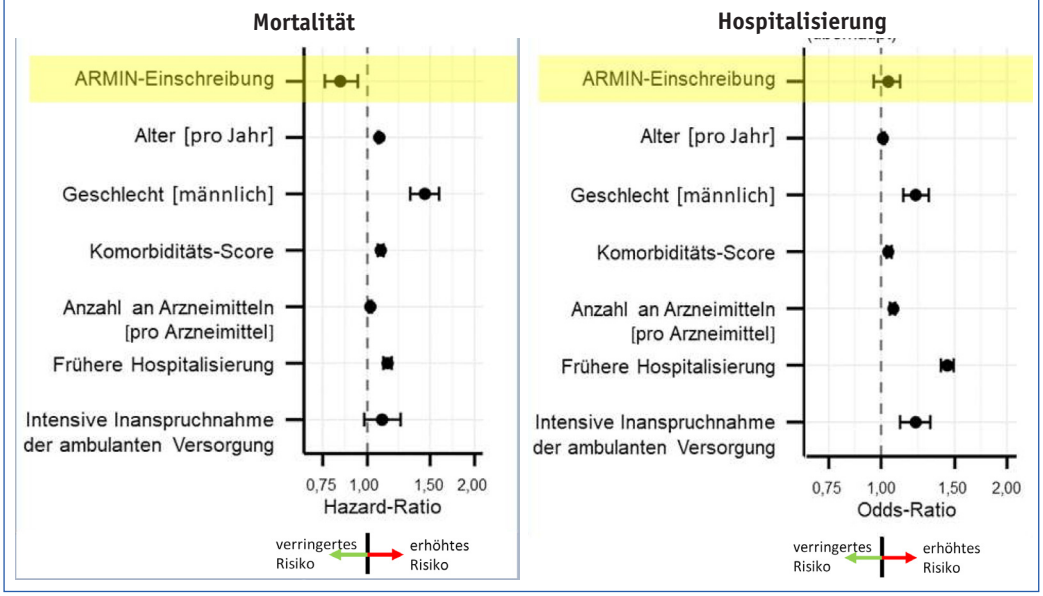
ARMIN - Medication Initiative Saxony-Thuringia

The model project is based on the ABDA-KBV model, the ‚Future Concept for Pharmaceutical Care'. In 2011, the National Association of Statutory Health Insurance Physicians (KBV) and the Federal Association of German Pharmacists (ABDA) developed a concept for the supply of medicines. With the Statutory Health Insurance Structure Act (GKV-Versorgungsstrukturgesetz), which came into force on 1 January 2012, the legislator opened up the possibility of implementing the concept in a pilot project for patients with statutory health insurance through the then newly created § 64a SGB V (Social Code Book V). The Saxon and Thuringian State Pharmacists' Associations and the two Associations of Statutory Health Insurance Physicians in Saxony and Thuringia as well as the AOK PLUS then decided to implement this concept and concluded an ‚Agreement on a model project according to § 63 SGB V for the optimisation of pharmaceutical care in Saxony and Thuringia (ARMIN)'. This came into force on 1 April 2014 and was implemented in stages. The ARMIN pharmaceutical initiative was intended to increase the quality and efficiency of pharmaceutical care. Further information: www.arzneimittelinitiative.de

until the end of the individual follow-up period. For example, the main endpoints were the risk of dying and the risk of being hospitalised within the next two years. During the follow-up period, 9.3% of the patients in the ARMIN group died, compared to 12.9% in the control group. According to Professor Seidling, the risk of death in the ARMIN group was 0.84 times greater and thus significantly lower than in the comparison group in the adjusted analysis (here the allegedly higher age in the control group was excluded). Seidling: ‚This corresponds to a covariate-adjusted absolute risk reduction of 1.52%, which in turn translates into a number-needed-to-treat of 66.'

Of particular political importance is the number 0.84. This means nothing other than that the patients who participated in ARMIN medication management had a 16% reduced relative risk of dying compared to the retrospectively matched control group! With regard to hospitalisations, however, no difference was found between the ARMIN and control groups - the proportion of patients hospitalised within two years was the same in both groups. According to Seidling, it should also be noted that hospitalised ARMIN patients were hospitalised earlier and more frequently than those patients who were hospitalised in the control group. The reasons for this could not be analysed due to the study design, but Seidling ventured the interpretation that earlier hospitalisations were probably a sign that closer monitoring of the intervention group took place, which might have made it possible to recognise and react to certain situations more quickly. Seidling: ‚However, this is purely hypothetical and would only be one possible interpretation of the data.' It should also be noted that the hard endpoint mortality has so far been examined relatively rarely in the course of the analysis of medication management programmes and even more rarely with positive results. Here, the health services researcher sees a reason for further consideration and discussion of the results. From a scientific point of view, the data should also be used to plan further and then prospective studies. With such study designs, it could then be investigated much more precisely where the triggers of such effects can be located, which intervention componentsare particularlysuccessful and informative and above all: which patient groups could particularly benefit from structured medication management

Ergebnisse der Evaluation des Moduls 3 (Medikationsmanagement)



Mortality: 9.3% of ARMIN patients (N = 469/5,033) and 12.9% of control patients (N = 1,300/10,039) died. Hazard ratio (HR) 0.84 (95% CI [0.76-0.94], P = 0.001). Source: Heidelberg University Hospital, Department of Clinical Pharmacology & Pharmacoepidemiology, April 2023 ARMIN-PK presentation of evaluation results on 18.04.2023.

Hospitalisation: During a two-year follow-up period after inclusion, 52.4% of ARMIN patients (N = 2639/5033) and 53.4% of control patients (N = 5359/10039) were hospitalised at least once. Odds ratio (OR) 1.04 95% CI [0.96-1.11], P = 0.347

Three demands of the ABDA

Gabriele Regina Overwiening, President of the Federal Association of German Pharmacists, ABDA for short, could only agree with this statement. One of the biggest problems in the long-term treatment of diseases, ac-



f. l.: Dr. med. Annette Rommel (1st Chairwoman of the Board of KV Thuringia), Prof. Dr. sc. hum. Hanna Seidling (Department of Clinical Pharmacology and Pharmacoepidemiology of the University Hospital Heidelberg), Rainer Striebel (Chairman of the Board of AOK PLUS) and Gabriele Regina Overwiening (President of ABDA - Federation of German Pharmacists' Associations).

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cording to the ABDA President, is limited adherence or compliance with medication or therapy. ‚Medicines that patients do not take cannot work,' Overwiening said. But every patient has the right to decide freely about his or her treatment. However, according to the ABDA head: ‚This decision does not only concern one's own health. If medicines are left in patients' cupboards, this causes enormous additional costs for the health system. Therefore, an important result of the ARMIN model project is that the adherence of participating patients has been demonstrably improved. In her opinion, the structured and repeated discussions with the patients were certainly an important building block for this. However, the time and content of such detailed counselling sessions went beyond the counselling provided in standard care. In addition, many patients found it positive that their medication plan was checked and updated by doctors and pharmacists, but also that they had a better overview of their current, complete and correct medication plan. Overwiening: ‚ARMIN has clearly shown that joint care by doctors and pharmacists has many advantages for patients. We have to bring this into standard care.'

For this reason, the ABDA head put three demands on record:

- Firstly, all patients with polymedication should be entitled to an annual review of their entire drug therapy. This review of the drug therapy should be carried out jointly by doctors and pharmacists - according to clear rules and in coordinated processes. The paid medication analysis on the part of pharmacists has already been introduced with pharmaceutical services in June 2022, but this does not go far enough. ‚In AR- MIN we have learned that doctors and pharmacists can and should work more closely together. Now the responsibilities of doctors and their fees must be defined for the review of overall medication,' demanded the ABDA President, who thus clearly sided with the medical profession.
- Secondly, if the annual joint medication analysis at the discretion of the doctor or pharmacist is not sufficient, patients in standard care should be entitled to continuous joint care by doctors and pharmacists. According to Overwiening, this would correspond to ARMIN medication management, which has shown such great benefit. The ABDA boss: ‚We have learned from ARMIN, and this is also confirmed by other studies, that simply printing out a medication plan is not enough to generate a benefit for the patient'.
- Therefore, the third demand was: If one of the focal points of the measure is to be adherence to medication, the medication plan must be explained verbally to the patients according to their individual knowledge .

For all these demands it is true that all patients who use several medicines need individually tailored support services. Overwiening: ‚The benefit is greatest where doctors and pharmacists work hand in hand for the benefit of their patients. ARMIN has proven that this can be implemented in everyday care.

KV: pro standard care

‚This was not a study, it was standard care. With these words, Dr. med. Annette Rommel, the 1st Chairperson of the Board of KV Thuringia, who has regarded the model project from the beginning ‚a bit like my little son', which has grown very slowly, clarified what ARMIN is all about: the patient benefits that have now become clearly visible. According to the head of the Thuringian KV, it was not a selection of people who were particularly interested in their health who took part in ARMIN, but the clientele that was cared for in the GP practices - a large number of chronically ill patients who had to take five or even more medicines at the same time. Therefore, the topic of compliance, but also the topic of interaction and avoidance of undesirable side effects is enormously important. She knows this from her own experience as a general practitioner and especially as a rural doctor, because she has a lot to do with patients who find themselves in exactly such situations. Rommel: ‚That is why it was a very special concern for all of us to enter into cooperation with the pharmacists in Thuringia and Saxony.' Rommel went on to say that cross-sectoral care is often a nice buzzword, but here one can clearly see that the regulated and targeted cooperation of professionals can enable an improvement in patient care.

Rommel also spoke of problems and stumbling blocks. For example, the industry producing practice management systems had not worked as ‚we had wished' and had not implemented ‚our modules 100 per cent'. Some colleagues who wanted to participate in the ARMIN model were disappointed because the practice software providers backed out of the project. Rommel: ‚This is a huge issue in Germany. Our digitalisation in the health sector is also suffering from this.

Despite everything, the head of the KV clearly pleads for the continuation of the project approach, as long as the corresponding legal framework for standard care has been created by the federal legislator. Then ARMIN would also be applicable nationwide in the Federal Republic. However, she rejected Overwiening's demand for an annual review of the entire drug therapy. She did not believe that it was really necessary to regulate a patient's entitlement to an annual medication check. This would depend too much on the individual patient. What is clear, however, is that pharmacists and doctors must have clearly defined tasks regarding medication management, the medication catalogue and the prescription of active substances. Rommel: ‚We also need a digital solution for the medication plan. And an obligation for the software industry to introduce the necessary modules. Last but not least, there needs to be adequate remuneration for the additional services provided by doctors and pharmacists. <<

By: MVF Editor-in-Chief Peter Stegmaier