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Specialist outpatient care (ASV) in the context of current health policy reforms

The outpatient specialist medical care in the context of current health policy reforms

Background: In the German health care system, uncoordinated, sometimes competing care structures lead to breaks in care, false incentives and wrong supply with avoidably higher costs. The degree of outpatient treatment also lags behind comparable countries. Outpatient specialist medical care (ASV) should overcome these drawbacks. Reforms are currently being implemented again, which, among other things, are intended to promote outpatient treatment.

Methodology: Within the framework of the research study GOAL-ASV with funding by the innovation fund the status quo and obstacles to implementation in ASV were analyzed and suggestions for further development provided by a multi-perspective mixed- methods study. The current legislative initiatives were analyzed based on the published content of the government commission and the paragraphs already included in SGB V.

Results: The ASV has now established itself as a new outpatient, cross-sectoral form of care. In the last analyzable period, the first quarter of 2023, 182.918 patients were quarterly treated by 39,000 doctors in 20 indications in over 800 teams. However, the development is hampered by bureaucratic hurdles and over-regulation. The current health policy legislative initiatives to improve outpatient care appear to be uncoordinated with the ASV.

Conclusion: The data suggest that there is currently no harmonization in the care landscape either, the models do not contribute to a continuous cross-sectoral patient path.

Keywords
Health care structures, outpatient care, patient journey

For many years, experts have been calling for the historically developed sectoral boundaries and the associated misaligned incentives with breaks in care and misuse of care in the German health care system to be addressed and eliminated (SVR 2012; SVR 2018; Nagel et al. 2017). The care areas of medical care centres (MVZ) implemented for this purpose in the Fifth Social Code (SGB V) according to § 95, day-clinical treatment according to § 115, pre- and post-inpatient treatment according to § 115a, outpatient surgery according to § 115b, authorisation according to § 116, outpatient treatment at the hospital (ABK) according to § 116b old version, university outpatient clinic according to § 117, the socio-psychiatric outpatient clinics under § 120, the affiliated physician system under § 121, the disease management programmes under § 137f, the formerly integrated and now special care under § 140a SGB V, to name but a few, have not led to the elimination of parallel care structures, the dismantling of sectoral boundaries or the levelling of differences between urban and rural areas (Dengler et al. 2018; Jacobs 2019; Wolf 2020). Since there was hardly any coordination or harmonisation between these systems, these individual measures, which did not work together synergistically, did not contribute to the urgently needed harmonisation of the health care landscape and a degree of outpatient care that is adequate in an OECD comparison (OECD 2021), but rather made the structures even more complex and more opaque for many stakeholders - health care providers and patients. With the amendment of § 116b SGB V and the implementation of outpatient specialist care (ASV), a renewed attempt was made on 1.1.2012 to bring about interdisciplinary and cross-sectoral treatment, at least for patients with rare diseases and those with a special or complex course of disease (Deutscher Bundestag 2011).

>> The ASV is gradually replacing the ABK with a transition period of three years. For the first time, it contains a uniform regulatory framework for hospitals and practices in outpatient care with regard to participation, quality assurance and remuneration. In this article, the development of ASV over time is presented. For this purpose, data from the evaluation study GOAL-ASV, which was conducted on behalf of the Federal Joint Committee (G-BA) within the framework of the Innovation Fund (G-BA 2022a), are reported and the further development that has taken place since then is presented. On the other hand, the current health policy activities with regard to outpatientisation, i.e. the new day inpatient treatment in hospitals, the further development of outpatient surgery and inpatient interventions as well as sectoral remuneration are presented and discussed. The observation is made in particular with regard to implementation, harmonisation between the constructs and the patient pathway.

ASV as an interdisciplinary and cross-sectoral care model

Contents and structure

ASV was anchored in § 116b SGB V on 1.1.2012 (German Bundestag 2011). It can be considered for patients with diseases with a special course of disease (e.g. tumour diseases, rheumatological diseases) as well as rare diseases or diseases with a low number of cases (e.g. cystic fibrosis, haemophilia). So far, regulations for twenty indication areas have come into force (G-BA 2023); the G-BA is successively transferring two more indication areas from the ABK to ASV every year. The care structure consists of interdisciplinary teams with a team leader, a core team and physicians to be consulted; the details are defined by the G-BA in a guideline (ASV-RL) (G-BA 2013). Hospital physicians and contract physicians can participate. Participation must be reported to the regional extended Land committees (ELA). In the process, personnel (qualification, minimum quantities) and structural (cooperation, team structure, emergency care) requirements must be proven, on which the possibility of participation depends. There is no admission procedure in the narrower sense and no demand planning. Remuneration is currently unbudgeted in accordance with the standardised evaluation scale (EBM).

Evaluation of the development and status quo of ASV

As part of the GOAL-ASV health services research study, ASV was evaluated from 2019 to 2021 by a research consortium consisting of the FOM Hochschule für Oekonomie & Management, the Leibniz In-

stitute for Prevention Research and Epidemiology, the Scientific Institute of Haematologists and Oncologists in Private Practice and the German ASV Association. The aim was to examine the current status, hurdles and obstacles as well as the utilisation and to develop recommendations for further development or optimisation. The report on the results has now been published on the G-BA website (G-BA 2022a). We present partial results of the study here, and also add updated data that were collected after the evaluation was completed.

The study was based on the data of the ASV Service Centre, the advertisement forms of all 17 ELAs, the answers to a structured survey of the ELAs, interviews with ASV team leaders and patient representatives, surveys of physicians and hospital managers as well as patients. Furthermore, anonymised SHI routine data of the GKV-Spitzenverband as well as from the German Pharmacoepidemiological Data Base (GePArD) (Pigeot and Ahrens 2008), incidence and prevalence figures of the Robert Koch Institute (ZfKRD 2020), of the Institute of the Evaluation Committee (InBA 2021), which are evaluated within the framework of the adjustment according to § 87 SGB V para 1, as well as figures determined within the framework of the bureaucratic cost estimate from the supporting reasons of the G-BA (G-BA 2019).

Results

Status quo, development, access procedures

The number of authorised ASV teams has been steadily increasing in most indications since the first concretisation came into force in 2014, and was 799 in quarter 1/2023. Often, a significant increase in ASV teams can be noted at the time of termination of the old authorisations (ABK). Fig. 1 shows the overall development across all indications.

Between the entry into force of a concretisation for an indication area and the establishment of the first teams, between four and 36 months pass. A large variance was found with regard to the size, composition and sector of the ASV teams. On average, 44 physicians are organised in a team. 95% of all teams are cross-sectoral, the share of contract physicians across all indications is 42%. For rheumatism (adults) and sarcoidosis, the majority come from the panel doctor sector. Of the team leaders, 86% work in a clinic, 9% in a practice and 5% in an MVZ. The evaluation of the advertisement forms of the 17 ELAs available on the Internet revealed a clear heterogeneity with regard to the requirements for the documents to be submitted. This concerns the designation of the physicians to be consulted (by name or institutionally), the type and scope of the documents to be submitted (certificates, organisational requirements), the minimum quantities (self-declaration, patient lists) as well as the possibility to authorise the ELA to inspect the KV physician register. There were also significant differences in the rejection rates as well as the justifications per ELA. The duration of the procedure was between one and twelve months.

Since the beginning of ASV, up to and including quarter 1/2023, a total of 1,871,544 quarterly patients (patients for whom services were billed by at least one ASV doctor in the quarter) have been cared for by approx. 39,000 doctors in ASV (the individual „head count“ of patients is lower, as treatment usually extends over several quarters; the number of individual doctors is also lower, as the same doctors can participate in more than one ASV team). In the last four quarters available for analysis, 182,918 insured persons were in ASV per quarter. The teams, numbers of doctors and patients are distributed very differently depending on the federal state or KV region (Fig. 2), with the highest numbers per 1 million inhabitants in Schleswig-Holstein, North Rhine, Hesse and Berlin, the lowest penetration to date is found in Rhineland-Palatinate, Saxony-Anhalt, and in Mecklenburg-Western Pomerania not a single team has yet been established. The differences are probably due, among other things, to the varying testing practices of the ELA, the extent of the ABK determinations as well as an insufficient number of potentially participating specialists. The proportion of patients in the total potential population is shown in Figure 3. Penetration is markedly heterogeneous depending on the indication.

The expenditure volume has meanwhile (as of Q4 2022) reached a volume of 130,561,759 euros for ASV services by participating panel doctors and 300,942,555 euros for services by ASV-eligible hospitals (incl. the still existing provisions under the ABK) (BMG 2022).

Motivation and hurdles

Those not yet participating in ASV stated that the most frequent potential motivation was an improvement in the areas of bridging sector boundaries, interdisciplinary care, cooperation with other specialists, patient care and billable services. With regard to barriers and obstacles, those not (yet) participating in ASV and hospital managements mainly cited the high organisational effort and the lack of strategic or financial benefit.

Those participating in ASV mainly saw patient benefit, interdisciplinarity and strategic competitive considerations as motivation. The abolition of the old authorisation (ABK) was also an important motivation for a majority of respondents from the hospital sector. Monetary aspects were rated as important or very important more frequently among the general practitioners than among the participants from the clinics. The ASV participants described the prescribed specialties, the provision of all necessary services of the number range, the necessary quality certificates as well as the distance regulation of 30 minutes to the location of the team leader as hurdles within the framework of the notification procedure. Overall, the majority rated the notification procedure as inappropriately time-consuming and poor or very poor. For almost a quarter of the team leaders surveyed, it took up to four months from the start of processing the notification form to the positive decision, for slightly less than half between 5 and 12 months and for 15% longer than a year. According to the respondents, the administrative and documentation workload is a major obstacle during ASV participation; in addition, an inadequate remuneration spectrum - especially for rare diseases - was also mentioned.

Recommendations

For the further development and optimisation of ASV,a series of recommendations for the adaptation of the ASV-RL were made in the results report of thestudy. For example, consultation and adoption of the specifications should be accelerated, which would be possible by dispensing with the detailed number ranges in the appendices. New EBM figures should also be transferred more quickly to ASV. The notification procedure would have to be simplified considerably, made less bureaucratic and a nationwide electronic notification form would be advantageous. As quality assurance documents for clinicians, existing evidence such as certificates, further training authorisations and existing certifications should also be recognised. The type and scope of the evidence should be defined by the G-BA in a uniform

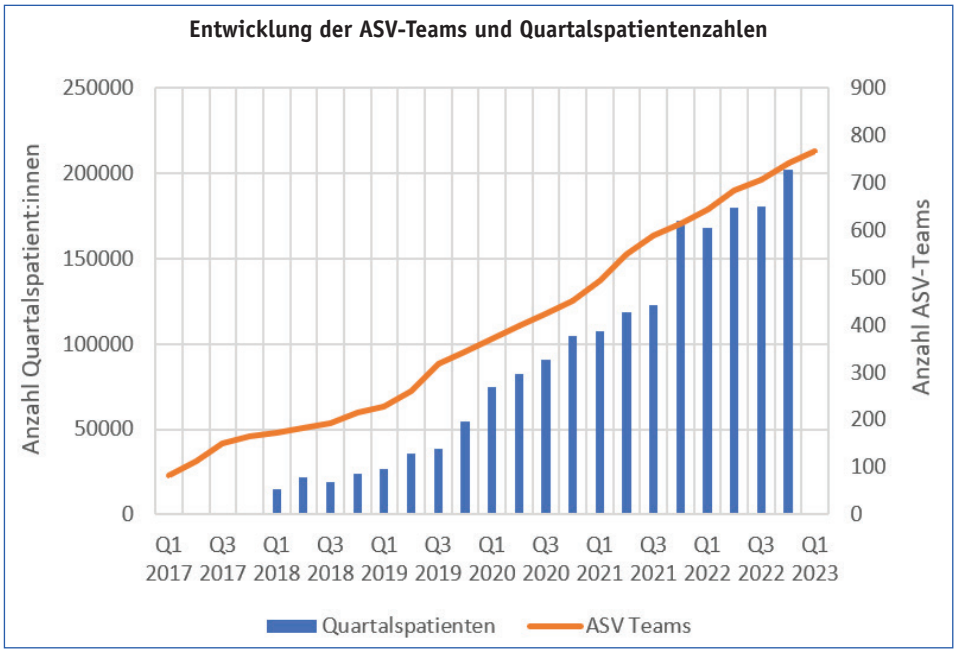


Fig. 1: Development of ASV teams and patient numbers/quarter (Source: ASV-Servicestelle, as of Q1/2023, G-BA 2023a, as of Q4/2022). Own representation. Data prior to Q1 2017 are not shown, as the numbers were negligible until then).

manner throughout Germany. The current distance rule of 30 minutes from the location of the team leader should be dropped in order to favour the establishment of ASV teams in rural regions as well.

Current reforms to intensify outpatient treatment

Outpatient surgery and inpatient interventions (AOP) according to § 115b SGB V

By amending Section 115b SGB V in the Act for Better and More Independent Audits (MDK Reform Act), the legislature had initiated a comprehensive revision of the AOP catalogue as of 1 January 2020 (German Bundestag 2019). Pursuant to Section 115 b (1) SGB V, the GKV-Spitzenverband (GKV-SV), the Deutsche Krankenhausgesellschaft (DKG) and the Kassenärztliche Bundesvereinigung (KBV) then agreed on a new version of the billing and uniform remuneration for hospitals and contract physicians (AOP contract) as of 1.1.2023 and, as an annex, on a further development of the catalogue based on an expert opinion by the IGES Institute (Albrecht et al. 2022). The experts proposed 2,476 new services on the basis of 208 OPS codes (operation and procedure codes), an increase of 86% to a total of 5,355 services. Most of the services proposed for expansion, about 60% (1,482 services), are operations. The second most common service, with 546, is diagnostic procedures such as endoscopies. These services were provided around 15 million times as full inpatient services in 2019. In the new area of inpatient-replacing (e.g. conservative) treatments, the experts recommend 65 DRGs (diagnosis-related groups) for inclusion in the AOP catalogue, including DRGs in the area of radiotherapy and conservative tumour treatments. These services accounted for a total of 632,786 annual inpatient hospital treatments in 2019. In order to be able to define the potential for outpatient treatment, so-called context factors were named (e.g. general condition, severity of illness, ventilation days, etc.) that require inpatient care. (Albrecht et al. 2022).

Day treatment in hospitals according to § 115e SGB V

With the Hospital Care Relief Act (KHPflEG) passed on 2.12.2022, the so-called day inpatient treatment came into force on 1.1.2023 with the amendment of § 39 SGB V and the introduction of § 115e SGB V on 1.1.2023. Since then, in medically appropriate cases and with the patient's consent, authorised hospitals can provide day inpatient treatment with at least six hours of treatment without an overnight stay instead of full inpatient treatment. The billing is done according to DRG coding on the basis of the applicable case flat rate catalogue by the Institute for the Hospital Remuneration System (InEK). For the overnight costs not incurred, a lump-sum deduction from the total charges calculated for the full inpatient stay is to be made, corresponding to 0.04 valuation ratios (approx. 150) per night, whereby the deduction may not exceed a share of 30% of the charges for the stay as a whole. Treatments of less than six hours are not reimbursed as day inpatient treatment, but are to be billed as outpatient treatment in accordance with the system of § 39 SGB V. In accordance with the guiding principle of „outpatient before inpatient", services that were previously provided on an outpatient basis in hospital and could be remunerated according to the EBM or by means of flat rates agreed at regional or local level may not be billed as day inpatient services. The maximum lengths of stay are applied in the same way as for treatment with overnight stays. Days on which patients were not in hospital are not taken into account when determining the length of stay and the remuneration.

Sectoral remuneration according to § 115f SGB V

The introduction of a special sector-equivalent remuneration according to § 115f SGB V (so-called hybrid DRG) for service complexes identified in the IGES report, which can in principle be provided on an outpatient basis according to § 115b SGB V, is planned within the framework of the KHPflEG (German Bundestag 2022). So far, the pricing between EBM and DRG is - as already mentioned - very different. For example, outpatientservices in DRG group R with Major Diagnostic Category - MDC 17 Haematological and solid neoplasms, are currently remunerated on average at Euro 267 according to EBM (chapter 31), but in the DRG system at Euro 1,897 per patient and quarter, corresponding to a difference by a factor of 7.12 (Albrecht et al. 2022). The new system is to regulate remuneration in the same sector, i.e. regardless of whether the service is provided in an inpatient or outpatient setting or in a hospital or a panel doctor's practice. For this purpose, parallel to the expansion of the AOP catalogue, a concrete proposal has been presented within the framework of a project funded by the Innovation Fund entitled „Uniform, Cross-Sector Remuneration (ESV)" under the consortium leadership of the Hamburg Center for Health Economics at the University of Hamburg (Schreyögg et al. 2022). Here, a calculation from service complexes,

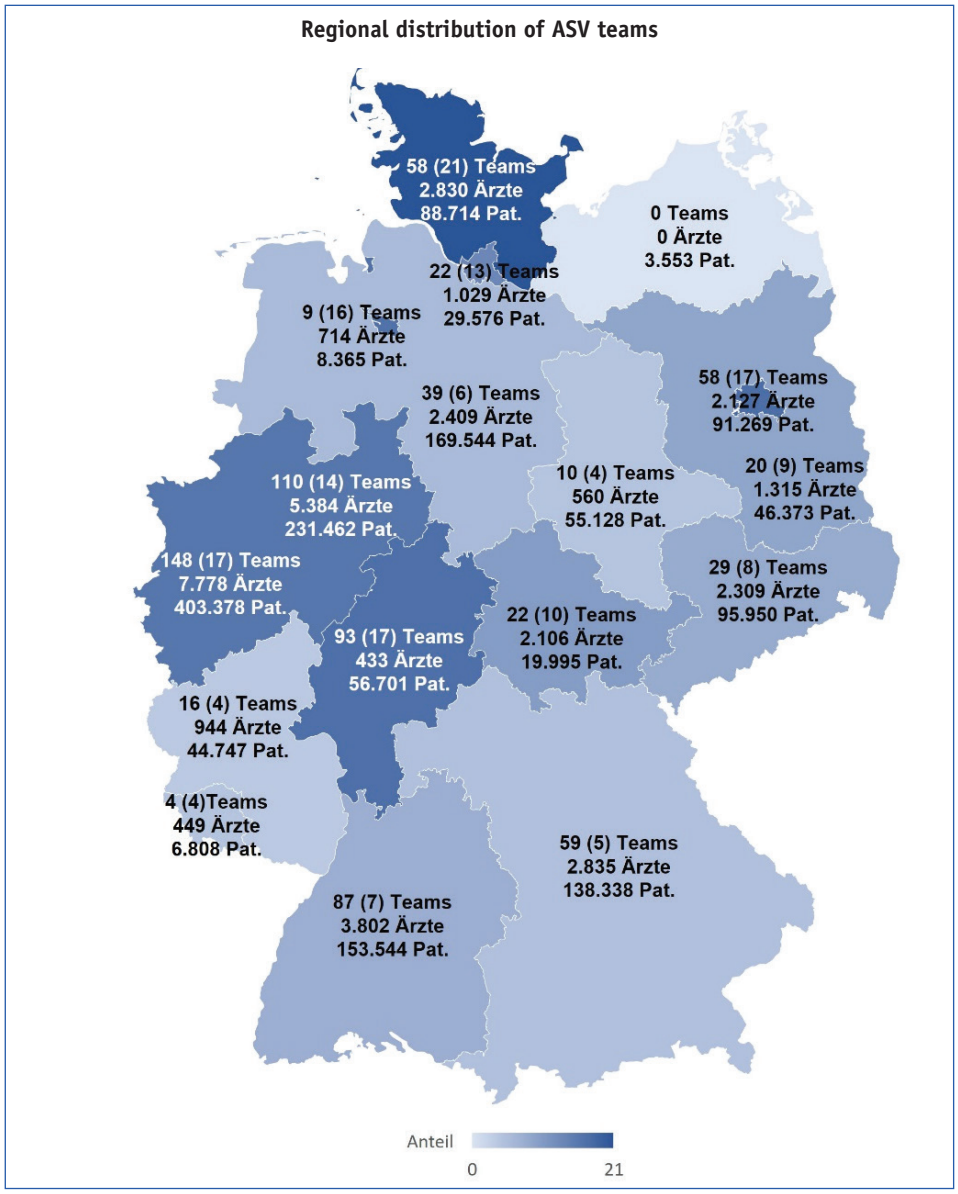


Fig. 2: Regional distribution of ASV teams in absolute terms, per 1 million inhabitants (in brackets), as well as participating physicians and quarterly patients treated (absolute figures in each case) in the individual Länder or KV districts. The intensity of the blue colouring corresponds to the number of teams per 1 million inhabitants. Data source: G-BA 2023a; Federal Statistical Office 2022. Own representation. As of Q 1/2023.

e.g. radiology, surgery, anaesthesia, etc., was proposed. According to the ESV expert opinion, the severity level should take into account the PCCL (patient clinical complexity level) established in the inpatient DRG system. Patient sever ity levels in theindividual federal states or io. Inhabitants. Data source: . or PCCL values of 0 - 1 (non-complex situations with no or low severity) would speak for outpatient care, PCCL from 2 or 3 for inpatient care. The level of remuneration should take into account, among other things, the current degree of outpatientisation. Consequently, this should be oriented closer to DRG flat rates for services that have so far been performed predominantly on an inpatient basis and closer to EBM for procedures that have so far been performed predominantly on an outpatient basis. In a first stage, remuneration is to be in the form of a flat rate. In a second step, a differentiated calculation is to take place according to the modular principle with convergence to the AOP catalogue. The identified DRGs will be removed from inpatient care and can then no longer be billed in the DRG system. The adjustment of the morbidity-related total remuneration is planned for the following year.

The legislator had commissioned the KBV, the GKV-SV and the DKG to select services from the AOP catalogue by the end of March 2023 that could be remunerated with sector-equivalent flat rates and to agree on the amount and content of the flat rates. The negotiations on this then failed. Currently (as of 1.8.2023), the BMG is therefore defining a corridor for services and remuneration within the framework of the substitute measure.

Discussion

From a health care perspective, the participation of service providers from clinics and practices, the interdisciplinarity and the team structure of ASV are unique in the health care system. Moreover, many aspects of ASV (sectoral access requirements, quality requirements and remuneration) already contain the preconditions for an increase in outpatientisation, (Dengler et al. 2022, Froschauer and Straub 2023). In the meantime, ASV has established itself in everyday health care and will continue to gain in importance through the expansion by two indication areas per year.

However, GOAL-ASV has shown that the intentions of the legislator, such as the reduction of access barriers, regional differences, preservation of treatment continuity, etc. (Deutscher Bundestag 2011), are overshadowed by bureaucratic formalities. The relatively high cost of notification hinders the participation of physicians in private practice, as shown by the low proportion of ASV teams led by physicians in private practice. For some of the service providers, especially among the specialists to be consulted and in the segment of rare diseases, the billable number range leads toan unfavourable cost/income ratio due to the low number of patients and the lack of economies of scale(Diel and Mertsch 2019, Dengler et al. 2022).

The low number of ASV teams for the rare diseases, which in some cases fall short of the provisions within the framework of the SHI (Marfan syndrome, cystic fibrosis, Wilson's disease), could indicate that the access procedure within the framework of the SHI was less complex and the treatment spectrum and remuneration possibly more adequate. Since ASV does not include a guarantee aspect, there is a risk of underuse for some of the patients with rare diseases.

It is evident that with regard to the proportion of ASV patients in the potential total population, there is no clear temporal connection to the entry into force of the concretisation (see Fig. 3). The reasons for this can only be speculated at present; they could be due to delays in the formation of ASV teams because, for example, the re-

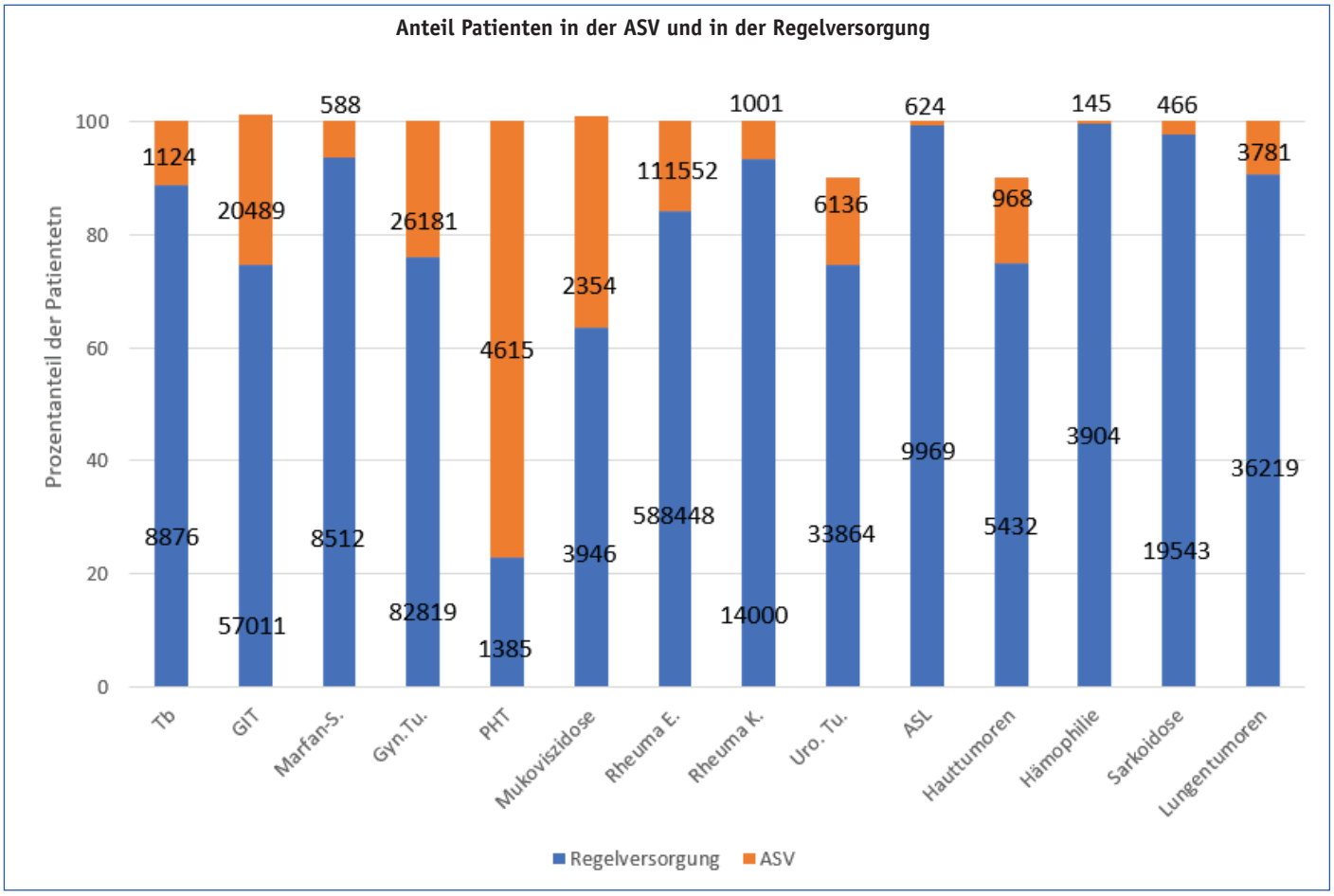


Fig. 3: Proportion of patients in ASV and in standard care in percent as well as estimated absolute patient numbers. The indication areas are listed from the first in 2014 (TB) to the last in 2019 (lung tumours) from left to right. Legend: GIT = gastrointestinal tumours. PHT = pulmonary hypertension. ASL = selected rare liver diseases. Data source: G-BA 2023a; Dengler et al. 2022). Status Q 1/2023.

quired specialist groups cannot be found (Dengler et al. 2022). Furthermore, in the case of ASV teams that have already been formed, there could be false incentives that favour inpatient care, such as in the indication area of tuberculosis (Diel and Mertsch 2019). Health services research studies could provide more clarity here.

The remuneration system for ASV services provided for by law (Section 116b (6) sentence 3 SGB V) has also not yet been developed. This impairs the establishment of ASV as a genuine nationwide health care solution.

ASV is also limited in its development by the many neighbouring, partly competing, outpatient and acute inpatient care areas, which means that eligible patients do not always find the right form of care for them (Froschauer and Straub 2023). This is mainly due to the fact that ASV was integrated into an existing system without taking into account, „thinking along" with and further developing the neighbouring care structures and sectors. For example, there is no harmonisation with the system of affiliated physicians according to § 121 SGB V, and in the recently enacted amendment to § 117 SGB V (university outpatient departments), it was stipulated that the service area according to Para. 1 S. 1 No. 2 is on an equal footing with other forms of service provision (in particular with § 116b SGB V).

Some recommendations from GOAL-ASV have since been taken into account, including the deletion of multimodal therapy as a prerequisite for patient inclusion in oncological indications. The required adjustment of the service-specific quality requirements was also made in order to make it easier for clinicians to provide evidence of the required documents (G-BA 2023a).

In the update of the appendices of March 2023, new billing codes were also taken into account, e.g. for consultation services for cystic fibrosis patients. In order to ensure that billing according to the valid EBM is also adjusted in ASV as promptly as possible, the G-BA is currently discussing a restructuring of the procedure for the annual appendix update (G-BA 2023b).

With regard to the current reforms to intensify outpatientisation, the question of whether the expansion of the AOP catalogue within the framework of § 115b SGB V will actually lead to a relevant additional outpatientisation will depend above all on which services are defined in the second step of the expansion of the AOP catalogue planned for 1.1.2024 and what the remuneration will look like within the framework of § 115f SGB V (hybrid DRG). The expansion of the AOP catalogue alone will „.... not have any relevant effect on the fundamental implementation difficulties" (BMG 2022b). An increased outpatientisation of these services can only be expected when the corresponding DRG services are removed from inpatient care or purged and transferred to § 115 f of the German Social Code, Book V. It is also decisive which hospitals carry out the remaining inpatient treatments and at what level of quality. It is to be hoped that the quality requirements currently being prepared will lead to an adjustment here.

In the case of day inpatient treatment in hospitals in accordance with the new § 115e SGB V, it remains to be seen to what extent the hospitals will use this voluntary option. The prerequisites for day

treatment are so vague that a large number of legal disputes about their existence in individual cases can be expected (G-BA 2022). The decisive criterion of „at least six hours of medical or nursing treatment" is likely to lead to uncertainties and disputes in practice and jurisprudence, not only with regard to the demarcation from full inpatient care, but also with regard to other forms of treatment such as partial inpatient care, inpatient interventions in accordance with § 115b SGB V and all outpatient forms for which the EBM provides for billing options of more than six hours. In addition, there are risks under liability law (G-BA 2022b, Sehy & Riese 2023). The explanato-

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ry memorandum in § 115e rightly points out that no day inpatient treatment can be provided for patients for whom the necessary home care cannot be ensured overnight. This also implies the necessity for the hospital to obtain a picture of the home care situation, which in practice can only be done through the information provided by the patients. This necessitates a comprehensive informative discussion (Sehy & Riese 2023).

In addition, the hospital's decision not to care for patients overnight is likely to be regularly associated with a high logistical effort, which would tie up the staff that could potentially be released due to the lack of an overnight stay. Patients have to be discharged daily and readmitted the following day. In addition, staff must be kept on hand to readmit patients with problems at night after discharge.

Conclusion

In summary, it is unfortunately once again apparent that the clear cut with a fundamental reorientation and harmonisation of the existing structures, which is actually necessary and has been demanded by most experts for years, is still lacking. In any case, the constructs now introduced are not coordinated with the many already existing outpatient models, including ASV. This leads to even more heterogeneous and confusing care structures, which even compete with each other. This also increases the danger that the competition for patients will be geared to money and not to the quality of treatment. The „jungle" of outpatient treatment options will become even more complex and opaque with the addition of further small-scale offers, especially from the patient's point of view.

Moreover, the possibilities of expansion for hospitals to provide outpatient care, as contained in §§ 115b, e and f SGB V, often encounter existing hospital processes that are not designed for large-scale outpatient and, in this respect, resource-saving service provision. Therefore, in many cases, the processes and infrastructure in the hospital need to be adapted, which takes time.

In a consistent development towards cross-sectoraland interdisciplinary care in the sense of a patient pathway without breaks, service areas such as ASV should therefore not be considered in isolation, but embedded in a superordinate overall concept. In the course of the currently initiated reforms at the interface of outpatient and acute inpatient care, the ASV approach could be usefully strengthened and further developed as a cross-sectoral model.

Limitations

In the GOAL ASV study, the estimation of the number of insured persons potentially qualifying for ASV was fraught with imponderables due to the limited availability of data on the reality of health care, especially from health care areas outside of standard care, such as pre- and post-inpatient care (§ 115a SGB V), university outpatient clinics (§ 117 SGB V), special care (§ 140a SGB V), etc. The data from the GOAL ASV study were not available. In the completed surveys among the service providers, an imbalance was found between the physicians participating in ASV and those not participating, which is due to the different response rates. <<

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