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From reporting channels to process integrity

Whistleblower gaslighting as a litmus test for governance, quality management and oversight in the healthcare sector

The first MVF article (02/26) on whistleblower gaslighting described mechanisms, consequences of stress and support options (Niederlohmann, 2026). This follow-up article asks a more specific question: How can an organisation tell whether its reporting process is actually working? The focus is therefore not on individual stress dynamics, but on governance, quality management and oversight. In the healthcare sector, staff are often the first to notice discrepancies between the mission statement and actual care practice: hygiene shortcomings, medication risks, understaffing, gaps in documentation or dysfunctional processes. Such reports constitute safety-relevant information. At the same time, the speak-up literature has long described how problems are often not raised when negative consequences are anticipated or when reports are perceived as ineffective (Morrison & Milliken, 2000; Okuyama et al., 2014).

Scope of inquiry and narrow definition

>> A narrow conceptual definition is crucial for this article. “Speak-up” refers to the situation-specific raising of safety-related risks within a team or the hierarchy; “whistleblowing” refers to formalised internal or external reports to bodies that can take action (Near & Miceli, 1985; Van Dyne et al., 2003). The term ‘whistleblower gaslighting’ is used here only when four elements are present: (1) a report relating to safety, quality or compliance, (2) a reaction that shifts the focus from the facts to the person, (3) a blocked, delayed or incomprehensible investigation of the facts, and (4) a deterrent or punitive effect on further reporting behaviour. Not every harsh, delayed or poorly communicated response meets these criteria.

Conceptually, this narrow definition is compatible with work on gaslighting, epistemic injustice and institutional betrayal (Abramson, 2014; Fricker, 2007; Smith & Freyd, 2014; Ahern, 2018). For clinical practice, the term is only useful if it is not used as a clinical diagnosis or a moral battle cry, but rather as an observable pattern comprising epistemic devaluation, blocked clarification and organisational deterrence. Methodologically, this is a narrative conceptual contribution. The text does not claim to provide a systematic synthesis of evidence nor causal attributions regarding the question of ownership; its added value lies in translating scattered literature into an auditable governance logic. Reprisal and institutional gaslighting may coincide, but they are not synonymous. Reprisal refers to thesubsequent act of retaliation; gaslighting refers tothe communicative and procedural devaluation that may precede, accompany, or even generate a chilling effect without formal sanctions.

Summary

Introduction: Reporting channels only protect patient safety if reports are objectively investigated, acknowledged in a timely manner and

processed without deterrence. This follow-up article on whistleblower gaslighting therefore shifts the focus from the consequences of stress to process integrity. It develops a narrow definition of the term, a verifiable governance pathway and a few applicable indicators for clinical practice, quality management and supervision.

Methods: A narrative conceptual paper with a literature review on speak-up/whistleblowing, gaslighting, epistemic injustice, patient safety, governance standards and legal sources (including the Whistleblower Protection Act (HinSchG), the Occupational Safety and Health Act (ArbSchG), Book V of the Social Code (SGB V), the Quality Management Guidelines (QM-RL), ISO 37002 and ISO 37301).

Results: Whistleblower gaslighting is defined in the narrower sense as a pattern in which a safety- or compliance-related report is devalued in a person-centred manner, the factual investigation is blocked or delayed, and further reporting behaviour is deterred. What is decisive is not so much the form of ownership as the way in which conflicting objectives are handled. Robust countermeasures include reporting and audit trails with clearly defined roles, documented triage, independent review, protection against reprisals, audits that reflect day-to-day practice, and visible learning loops.

Discussion: In healthcare practice, it is not enough simply to provide reporting channels. Reporting processes only become verifiable when their process integrity, protective effect and learning outcomes are regularly monitored.

Keywords

Whistleblowing; Speak-up; Gaslighting; Patient safety; Quality management; Whistleblower protection; Governance; Organisational learning

Crossref/doi

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Abgrenzung für die Praxis: Wovon hier genau die Rede ist		
Begriff	**Woran erkennbar?**	**Primäre Antwort**
Institutionelles Gaslighting nach Hinweisgabe	Sicherheits- oder Compliance-Hinweis wird personenzentriert umgedeutet; Klärung bleibt blockiert, verzögert oder intransparent; weiteres Hinweisverhalten wird abgeschreckt.	Person und Sache trennen; unabhängige Prüfung; Schutz und dokumentierte Rückmeldung.
Konflikt / Dissens	Sachlicher Streit ist beidseitig benennbar; Metakommunikation und Verhandlung sind grundsätzlich möglich.	Moderation, Rollenklärung, Vereinbarungen mit Follow-up.
Bullying / Mobbing	Wiederholte negative Handlungen, Ausgrenzung oder Sabotage; Hinweisbezug ist möglich, aber nicht zwingend.	Beschwerdeweg, Schutzmaßnahmen, Anti-Bullying-Intervention.
Faire Leistungsrückmeldung	Transparente Kriterien, konkrete Beispiele, Korrekturmöglichkeit; nicht an einen Hinweisfall gekoppelt.	Standardisiertes Performance-Management.
Repressalie (HinSchG)	Nachteilige Maßnahme wegen Meldung, z. B. Versetzung, Degradierung oder Projektentzug.	Rechtliche und interne Prüfung; Dokumentations- und Begründungspflicht.

Table 1: **Delineation for practice: What exactly is being discussed here. Author's own representation.**

Note on language: For the sake of readability, gender-neutral terms (e.g. whistleblowers, employees, managers) are predominantly used.

Where process integrity breaks down

A verifiable reporting process comprises at least six steps: access to the channel, acknowledgement of receipt, triage, substantive review, feedback and organisational learning. At each of these stages, the focus can shift from the issue to the individual. Typical points of failure include framing the issue as an isolated case, personalisation ("mindset", "team spirit"), conflation with disciplinary procedures, investigations marred by conflicts of interest, and ritualised processing without comprehensible follow-up measures. The channel then remains formally intact, but functionally it loses its protective effect. The fact that organisational context is particularly significant for retaliation was described early on in the context of whistleblowing (Mesmer-Magnus & Viswesvaran, 2005).

Economic and reputational pressures can exacerbate such vulnerabilities. However, the literature on ownership does not provide a basis for blanket attributions of blame. In Germany, efficiency gains have also been reported following privatisations (Tiemann & Schreyögg, 2012). At the same time, international reviews report quality risks under certain forms of privatisation and particularly under private equity ownership, albeit with heterogeneous evidence and without allowing for straightforward inferences regarding individual institutions (Devereaux et al., 2002; Borsa et al., 2023; Goodair & Reeves, 2024). For the purposes of this paper, therefore, a modest conclusion suffices: the more that key performance indicators, financial or reputational considerations dominate the handling of reports, the higher the risk that safety information will be framed as an operational disruption rather than an opportunity for learning.

For governance and oversight, therefore, it is not so much the form of ownership itself that is decisive, but rather the logic governing the handling of conflicting objectives. This applies across all organisations: specific loyalty frameworks, as well as profit or reputation targets, must not frame reports as disloyalty when the recovery and continued health of patients and staff are at stake.

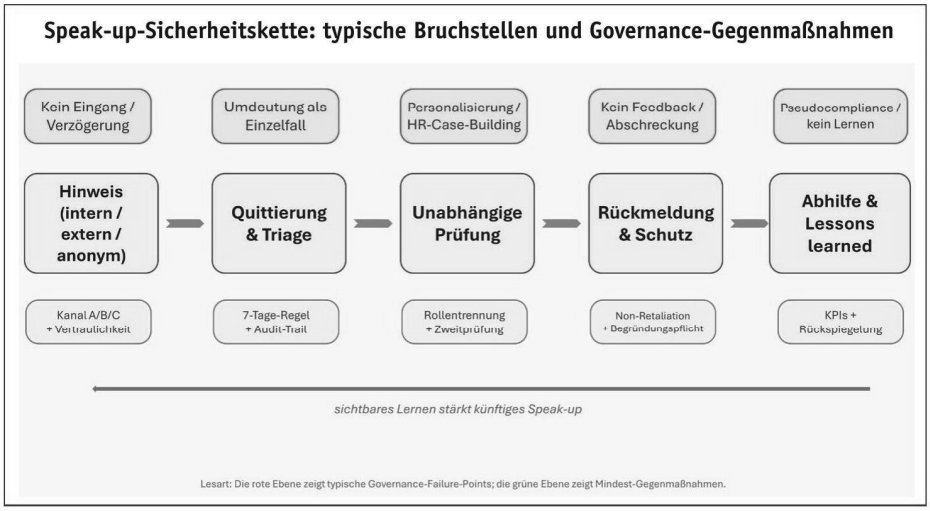


Fig. 1: **Speak-up safety chain: typical points of failure and governance countermeasures. Own illustration.**

The situation becomes critical when personnel files and whistleblowing cases overlap, when the hierarchy potentially affected by the report also controls the investigation, or when audits examine only documents rather than actual practice. From a patient safety perspective, this is not a cultural detail but a process risk.

Figure 1 summarises this logic of breakdowns as a speak-up safety chain: at every stage of the reporting pathway, typical governance failure points are matched by specific minimum countermeasures.

Minimum standards for a verifiable reporting process

Legal minimum requirements, governance recommendations and good practice should be clearly separated. Of particular legal relevance are the procedural obligations under the Whistleblower Protection Act, the consideration of psychological stress in occupational health and safety, and the quality-related obligations under SGB V and the QM Directive. On the governance side, this is supplemented by audit trails with clearly defined roles, independent review structures and additional secure reporting channels. Finally, best practice concerns the specific design of language, audits, feedback and learning routines.

The Whistleblower Protection Act requires, amongst other things, an acknowledgement of receipt within seven days and a response in principle within three months (Section 17 HinSchG). At European level, Directive (EU) 2019/1937 sets minimum standards for internal and external reporting channels, confidentiality and protection against reprisals. Occupational health and safety law requires psychological stress to be taken into account in risk assessments (Section 5 ArbSchG). Section 135a SGB V and the G-BA's QM Directive enshrine the obligation to systematically ensure quality and make risks manageable. However, these standards do not in themselves answer the question of how an institution prevents reports from being informally dismissed. This is precisely where governance comes in.

International standards and models provide a useful process framework for this. ISO 37002 structures whistleblowing around the stages of receive, assess, address and conclude; ISO 37301 embeds this within a broader compliance management framework. The Three Lines Model makes it clear why the operational line, the risk/compliance function and independent audit should not be part of the same decision-making chain (International Organization for Standardization, 2021a, 2021b; Institute of Internal Auditors, 2020). The UK's 'Freedom to Speak Up' approach also demonstrates the value that visible protection roles and additional secure reporting channels can offer to staff (Francis, 2015; Hughes, 2019).

Implementation in clinical practice, quality management and oversight

At the organisational and leadership levels, an effective design begins with explicit non-retaliation, separation of roles and clearly assigned responsibility at the organisational or senior management level. During ongoing audit processes, transfers, postponements of appraisals or withdrawal from projects should only be possible on the basis of documented, objective logic unrelated to the reported incident. In this respect, ethical leadership is not merely a guiding principle, but a predictor of whether internal whistleblowing is perceived as safe at all (Cheng et al., 2019).

Prüffähiger Hinweisprozess: Prozessschritte, Failure Points und Nachweise			
Prozessschritt	**Häufige Entwertung**	**Mindeststandard**	**Auditierbarer Nachweis**
Zugang zum Kanal	Kanal ist unklar, nur über Vorgesetzte erreichbar oder faktisch abschreckend.	Mehrgleisige interne und externe Wege; bekannte Zuständigkeiten; Vertraulichkeit.	Policy, Intranet, Schulungsunterlagen, Mitarbeiterinterviews.
Eingangsbestätigung / Triage	Keine Reaktion; Hinweis wird als Einzelfall oder Konflikt abgebogen.	Bestätigung binnen 7 Tagen; fallbezogene Zuordnung und Priorisierung.	Zeitstempel, Fallnummer, Triage-Log.
Sachprüfung	Personalisierung, Interessenkonflikt, fehlende Evidenzbasis.	Definierte Prüfzuständigkeit, Rollentrennung, dokumentierte Belege.	Prüfplan, Rollenmatrix, Sachstandsdokumentation.
Schutz während der Klärung	Rotationen, Projektentzug, Bewertungsverschiebungen oder isolierende Maßnahmen.	Non-Retaliation; getrennte Freigabewege für personenbezogene Maßnahmen.	Freigabe- und Begründungslog; Monitoring auffälliger Maßnahmen.
Rückmeldung	Schweigen oder formelhafte Antwort ohne Bezug zur Prüfung.	Rückmeldung binnen 3 Monaten; Information über Maßnahmen und Gründe.	Rückmeldeschreiben, Case-Closure-Summary.
Lernen / Audit	Fall bleibt im Einzelfall; Papierlösung ohne Veränderung.	Dokumentierte Folgemaßnahmen, Lessons Learned, praxisnahe Review-Schleifen.	Maßnahmenlog, Teamrückmeldung, Auditbefunde.

Table 2: **Verifiable reporting process: process steps, failure points and evidence. Own representation.**

In quality management, speak-up should not be treated as an afterthought, but rather as a safety process. This includes documented triage, defined responsibilities for review, an audit trail, fixed feedback channels and a separation of factual review and personnel procedures. A standardised, fact-based approach to wording is helpful: not “We need to talk about your mindset”, but “Two specific incidents and the underlying standard will be discussed; the discussion may take place with a trusted representative”. Such linguistic precision reduces scope for interpretation and makes it harder to personalise the case. Team-based measures such as debriefings, standardised escalation procedures and routines for psychological safety remain important, but must not replace governance gaps (Edmondson, 1999; Okuyama et al., 2014).

For supervision, certification and external quality assurance, this implies that not only the existence of a reporting channel, but also its usability and process integrity should be assessed. Practical or unannounced audit components can help to make the gap between documentation and actual practice more visible than mere file audits; relevant studies from other settings suggest that unannounced procedures are more sensitive, even if they do not directly examine reporting processes (Klerks et al., 2013; Ehlers et al., 2017; Barnett et al., 2017). Confidential staff interviews, plausibility checks of processing times and the review of aggregated lessons learnt are also useful.

In addition, mystery patient or mystery shopper procedures may be considered in clearly defined, low-risk test areas, for example to assess accessibility, wayfinding, quality of information or standardised basic processes from a user perspective. However, their informative value is limited: They reflect isolated experiences, can undermine trust, and cannot replace unannounced audits or the objective investigation of specific complaints. For many issues, patient-led validations are more representative of everyday practice and less intrusive, such as randomised short surveys after discharge, secure digital feedback channels, or the comparison of announced or documented services with the care actually received. It is crucial that such tools are not used for covert individual monitoring of staff, but are evaluated in an aggregated, learning-oriented manner and within clear ethical guidelines (Adams et al., 2015).

Kernindikatoren für Klinik, QM und Aufsicht	
Dimension	**Beispielindikator**
Zugang und Nutzung	Anteil der Beschäftigten, die einen Meldeweg benennen können; Verteilung der Meldungen nach Kanaltyp.
Prozessintegrität	Anteil der Fälle mit 7-Tage-Bestätigung, dokumentierter Triage, definierter Prüfzuständigkeit und vollständigem Audit-Trail.
Schutzwirkung	Anteil der Fälle ohne Repressaliensignal; Sentinel-Indikatoren wie Versetzung, Projektentzug oder auffällige Bewertungsverschiebung nach Meldung.
Lernen	Anteil der Fälle mit dokumentierter Folgemaßnahme, Prozessänderung oder Rückspiegelung an Teams.
Klima	Psychologische Sicherheit, Speak-up-Klima und wahrgenommene Futility, z. B. über SUPS-Q oder kurze Teamklima-Instrumente.
Praxisnähe des QM	Abweichungen zwischen Dokumentenlage und beobachteter Praxis, insbesondere in praxisnahen oder unangekündigten Prüfungen.

Table 3: **Key indicators for clinical practice, quality management and supervision. Author's own presentation.**

The MVF readership benefits above all from relevant audit questions: Do staff know the channels through which reports can be made? Is receipt actually confirmed within the specified timeframe? Is the reviewing body independent? Are follow-up measures and feedback documented? And can deterrent signals be identified in aggregated form following a report? For healthcare providers, payers and patient representatives, such process indicators are more useful than individual case narratives because they allow governance to be assessed without breaching confidentiality.

Indicators and research needs

The difference between appeals and governance lies in measurability. A few robust key performance indicators are sufficient for hospital management, quality management and supervisory bodies.

Such key figures do not replace case analysis. However, they enable trend monitoring, ward comparisons and governance discussions without disclosing individual reports. The Speaking Up About Patient Safety Questionnaire (SUPS-Q) provides a practical tool for measuring the speak-up climate (Richard et al., 2021).

For research and healthcare management, three gaps are particularly relevant: Firstly, there is a lack of prevalence studies that clearly distinguish gaslighting-specific patterns from conflict, bullying and legal reprisals. Secondly, evaluations of ombudsman/guardian models, role separation and audit-based study designs are needed. Thirdly, reporting processes should be more closely linked to outcome data on patient safety, staff retention and absenteeism.

Conclusions

Whistleblower gaslighting is a particularly useful concept for healthcare provision when used in a narrow and verifiable sense. The added value of the concept lies not in moralising about difficult leadership in general terms, but in highlighting a recurring pattern: safety information is devalued in a person-centred manner, factual investigation is slowed down or blocked,

and further whistleblowing behaviour is deterred.

The real litmus test is therefore not the reporting channel itself, but the process integrity of the entire reporting pathway. Where acknowledgement, triage, independent review, protection against reprisals, feedback and learning demonstrably work together, the likelihood that reports are translated into improvements increases. Where this chain breaks, pseudo-compliance arises. For relevant stakeholders from clinical practice, quality management, regulatory bodies, payers and patient advocacy who read MVF, the value of this article lies in a simple, auditable question: Can the organisation demonstrate that it not only receives reports but also processes them fairly, securely and in a way that facilitates learning? For health insurers, regulators and certifiers, the focus should be less on individual cases and more on the aggregated process quality of the feedback channel as the actual subject of control. <<

From Reporting Channels to Process Integrity: Whistleblower Gaslighting as a Test Case for Governance, Quality Management and Oversight in Health Care

Introduction: Reporting channels protect patient safety only if concerns are reviewed on their merits, feedback is timely, and further speaking up is not deterred. This follow-up concept paper therefore shifts the focus from individual burden to process integrity and develops a narrow definition of whistleblower gaslighting, a testable governance pathway, and a small set of indicators for hospitals, quality management, and oversight.

Methods: Narrative concept paper synthesizing research on speak-up and whistleblowing, gaslighting, epistemic injustice, patient safety, governance standards, and relevant German and European legal sources.

Results: Whistleblower gaslighting is used here in a narrow sense for cases in which a safety- or compliance-related concern is redirected from the issue to the person, factual review is blocked or delayed, and future reporting is chilled. The key determinant is less ownership as such than the way organizations handle target conflicts. Robust countermeasures include separated reporting and review functions, documented triage, independent review, non-retaliation, practice-near audits, and visible learning loops.

Discussion: Reporting channels become meaningful only when their process integrity, protective function, and learning effects are routinely monitored.

Keywords

whistleblowing; speak-up; gaslighting; patient safety; quality management; whistleblower protection; governance; organizational learning

Statements

Data Availability Statement: This article develops a conceptual framework and does not report a new empirical dataset.

Ethics Statement: Not applicable. No human participants, identifiable patient data or secondary clinical data were used. Author Contributions: EN conceived the article, conducted the literature review and drafted the manuscript.

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Author's declaration

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Immunotherapies for non-small cell lung cancer: balancing innovation and cost-effectiveness

Current situation and assessment of potential for Germany

With around 40,000 new cases annually, non-small cell lung cancer (NSCLC) is the most common form of lung cancer, accounting for approximately 79% of all lung cancers in Germany [1]. A significant proportion of patients are only diagnosed at advanced stages of the disease, which limits therapeutic options and underscores the importance of innovative systemic treatment approaches [2]. In recent years, immuno-oncology therapies – particularly checkpoint inhibitors – have fundamentally expanded the range of treatment options for NSCLC. These drugs open up new prospects in terms of response rates and survival probabilities, but at the same time present the healthcare system with new challenges [3]. Their use is associated with considerable treatment costs, which impact both the budget planning of hospitals and general practitioners, as well as the expenditure of statutory health insurance schemes. Against this backdrop, the question arises as to how medical progress can be reconciled with economic viability.

>> In accordance with the 'principle of economic efficiency' under Section 12 of the German Social Code, Book V (SGB V), a treatment must be assessed not only on the basis of efficacy and medical necessity, but also from a (health) economic perspective (system perspective). On the other hand, service providers in both inpatient and outpatient care operate as commercial enterprises and are therefore also subject to business management principles (service provider perspective).

Whether a treatment is also "economically justifiable" can only be answered by considering both the system and the service provider perspectives. Whilst, for example, medical decision-makers in hospitals or private practices focus primarily on clinical benefit, a hospital's (medical) controlling function looks at budgetary implications, reimbursement and cost structures. The hospital pharmacy complements this view with aspects such as purchase prices, procurement processes/logistics and contractual framework conditions. This results in a necessary multi-level perspective on the treatment decision. Only an integrated approach allows for a well-founded assessment and joint decision-making. Against this backdrop, those therapies in oncology that are of high clinical relevance and have the potential to impact budgets are becoming particularly significant. This is relevant, for example, in the case of immune checkpoint inhibitors, the use of which in the treatment of NSCLC has become the therapeutic standard. Within this class of drugs, pembrolizumab and cemiplimab, for example, play a central role [4]. As treatment can take place in both the inpatient and outpatient sectors, and different care and reimbursement mechanisms

apply in each case, these differences have a direct impact on cost-effectiveness, budgetary burden and the options available to healthcare providers.

Zusammenfassung

Einleitung: Das nicht-kleinzellige Lungenkarzinom (NSCLC) ist die häufigste Form des Lungenkarzinoms. Immuncheckpoint-Inhibitoren haben die Therapie in den letzten Jahren grundlegend verändert, sind jedoch mit hohen Arzneimittelkosten verbunden. Vor dem Hintergrund des Wirtschaftlichkeitsgebots rückt die ökonomische Vergleichbarkeit therapeutischer Alternativen in den Fokus.

Methoden: Es erfolgte ein Vergleich der Arzneimittelkosten am Beispiel von Pembrolizumab und Cemiplimab unter Berücksichtigung der Dosierungsschemata und der geltenden Arzneimittelpreise.

Ergebnisse: Cemiplimab weist im Vergleich zu Pembrolizumab geringere Arzneimittelkosten auf (ca. 600 Euro pro Gabe bzw. rund 10.000 Euro pro Patient:in und Jahr). Hochgerechnet auf die Zielpopulation ergibt sich ein potenzielles Einsparpotenzial im Millionenbereich.

Diskussion: Auch bei vergleichbarer klinischer Wirksamkeit können unterschiedliche Arzneimittelpreise erhebliche wirtschaftliche Konsequenzen haben. Eine integrierte Bewertung von Wirksamkeit und Wirtschaftlichkeit ist erforderlich, um Therapieentscheidungen im Sinne des Wirtschaftlichkeitsgebots nachhaltig zu gestalten.

Schlüsselwörter

Lungenkarzinom, NSCLC, Wirtschaftlichkeit, Immunonkologie

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Comparison of drug costs

Recording annual treatment costs enables an assessment of the economic risks associated with cost-intensive therapies and consequently allows for an economic evaluation of treatment options and potential alternatives.

The example of the two immune checkpoint inhibitors, cemiplimab and pembrolizumab, both of which are used, among other things, as first-line monotherapy for NSCLC, illustrates this tension between clinical benefit and economic viability particularly clearly.

Arzneimittelkosten im Überblick

Wirkstoff	Dosierung	Kosten pro Gabe/Zyklus	Anzahl Zyklen pro Jahr	Jahrestherapie-kosten
Cemiplimab	350mg alle 3 Wochen	4.076,16 Euro	17	69.294,72 Euro
Pembrolizumab	200mg alle 3 Wochen	4.680,39 Euro	17	79.566,63 Euro

Table 1: **Drug costs per patient. Author's own presentation.**

Both active substances are administered at three-week intervals, resulting in 17 treatment cycles per year with continuous treatment. The dosage is 350 mg for cemiplimab and 200 mg for pembrolizumab per cycle [5],[6]. Taking into account statutory discounts, the cycle costs amount to €4,076.16 for cemiplimab and €4,680.39 for pembrolizumab. With 17 cycles per year, the annual treatment costs amount to €69,294.72 for cemiplimab and €79,566.63 for pembrolizumab (see Table 1).

The difference in drug costs of €600 per patient per dose and around €10,000 per patient per year takes on considerable significance at the population level in the context of growing patient numbers.

When considering the entire target population, there is significant potential for savings at the population level. According to the benefit assessment by the Joint Federal Committee (G-BA), the target population for treatment with cemiplimab as monotherapy in first-line treatment of NSCLC is 3,697 to 4,919 statutory health insurance patients annually [7].

Multiplying this number by the drug costs per patient per dose results in a difference between the two treatment options of 2.2 to 2.9 million euros (see Fig. 1).

The fact that, according to calculations, pembrolizumab was the top-selling oncology drug in Germany in 2023 with a turnover of around 1.57 billion euros illustrates the scale of the potential economic effects and underlines the importance of cost-effectiveness analyses [8]. Against the backdrop of rising patient numbers and a continuing expansion of the areas of application, this aspect is becoming increasingly relevant and can represent an important economic lever for the healthcare system.

Reimbursement of innovative therapies in the DRG system

In addition to considering drug costs from a system perspective, the steering function from the service provider's perspective is of great practical importance. To this end, reimbursement and payment arrangements, as well as potential sector-specific (mis) **incentive systems,** must be examined in greater detail.

In Germany, the inpatient treatment of patients with NSCLC is reimbursed via the flat-rate system of Diagnosis Related Groups (DRGs). Each DRG is assigned a relative weight, which reflects the average resource consumption of a treatment case. The reimbursement for an inpatient case is calculated by multiplying the relative weight by the respective state base case value [9].

Within each flat-rate payment, corresponding amounts to cover drug-related costs are already factored in, with these being reflected in the cost category groups '4a' (overhead costs for drugs) and '4b' (direct costs for drugs). However, when innovative medicines are used, there is often a discrepancy between the actual costs incurred and the pre-calculated share for medicine costs [10].

To avoid this shortfall, supplementary remuneration instruments are available in the form of additional fees (ZE) and fees for so-called new examination and treatment methods (NUB). Additional fees are generally triggered via specific OPS codes and are listed annually in the flat-rate fee catalogue updated by the Institute for the Hospital Fee System (InEK) [11]. A fundamental distinction is made between valued and unvalued additional fees. Valued ZEs have standardised euro amounts applicable nationwide, whereas unvalued ZEs are to be agreed upon individually by each hospital. The legal basis for ZEs is found in Section 6(1), first sentence, No. 1 of the Hospital Remuneration Act (KHEntgG).

A direct comparison of the two immunotherapies reveals a different representation in the remuneration system. For cemiplimab, an unvalued ZE (ZE2026-218) is listed, whereas for pembrolizumab, ZE171 is a nationally valued ZE. Whilst the assessed ZE is fixed for the DRG year, potential price adjustments can be incorporated into the remuneration for the ZE to be negotiated individually with the health insurance funds, thereby

providing greater flexibility [11].

Medicines in outpatient hospital care: System under Section 129a of the German Social Code, Book V

Different billing mechanisms apply to outpatient care in hospitals than in the DRG system – both in terms of doctors' fees and the medicines used in outpatient settings. If oncological immunotherapy is administered on an outpatient basis in a hospital (e.g. via IV administration), the medication is billed in accordance with the provisions of Section 129a of the German Social Code, Book V (SGB V). These provisions govern the pricing of medicines dispensed by hospital pharmacies at the expense of statutory health insurance.

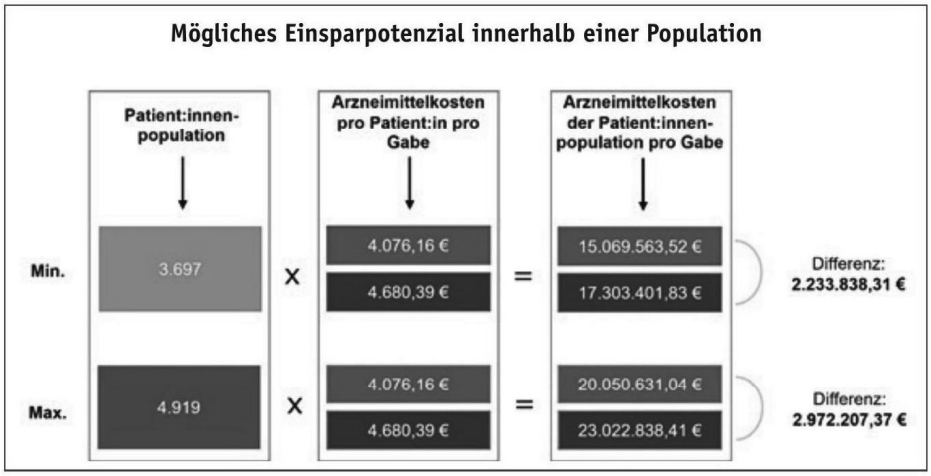


Fig. 1: **Potential savings within a population. Author's own illustration.**

Modellhafte Beispielberechnung des Arzneimittelabrechnungsbetrags (in Euro)		
	Cemiplimab (i.v.)	Pembrolizumab (i.v.)
Abgabepreis des pharmazeutischen Unternehmers (ApU) / Herstellerabgabepreis (HAP)	3.478,65	4.001,48
+ Großhandelshöchstzuschlag (3,15% auf ApU, max. 37,80 Euro) + 0,73 Euro)	+ 38,53	
= Apothekeneinkaufspreis (AEP) / ApoEK / Taxe-EK	= 3.517,18	= 4.040,01
+ Kompensationszuschlag auf AEP/ApoEK/Taxe-EK gem. § 129a SGB V	+ 19%	
+ Herstellungspauschale / Arbeitspreis gem. § 129a SGB V	+ 100,00	
Rezeptabrechnungsbetrag	= 4.285,44	= 4.907,61
- Gesetzliche Zuzahlung des Versicherten (10% vom Brutto-AVP, mind. 5 Euro und max. 10 Euro pro Packung)	Onkolog. Patienten meist von Zuzahlung befreit	
- Gesetzlicher Herstellerabschlag (7% vom ApU) gem. § 130a SGB V	- 243,51	-280,10
= effektive Ausgaben der GKV (exkl. ggf. Rabattvertrag)	**= 4.041,93**	**= 4.627,51**

Table 2: Model example calculation of the drug billing amount in accordance with Section 129a of the German Social Code, Book V (SGB V), as of February 2026. Own illustration.

The billing method under Section 129a of the German Social Code, Book V (SGB V) is based on the pharmaceutical company's selling price, supplemented by the wholesale mark-up on the pharmacy purchase price. The compensation surcharge and the manufacturing flat rate or labour cost are then added to this, resulting in the prescription billing amount. After deduction of the statutory co-payment and the manufacturer's discount, the effective statutory health insurance expenditure per dose is obtained, without taking into account any discount agreements (see Table 2).

A comparison of the example prescription billing under Section 129a of the German Social Code, Book V (SGB V) for cemiplimab and pembrolizumab, in each case without taking into account any discount agreements, reveals a difference of over 500 euros in statutory health insurance expenditure.

Therapeutic decisions caught between efficacy and cost-effectiveness

The health economic evaluation and management of immuno-oncological therapies for NSCLC demonstrate that the selection of a specific active substance extends far beyond purely medical considerations. The example shown is representative of numerous therapeutic fields in which a nuanced assessment must be made between cost-saving effects from a system-wide perspective and sector-specific reimbursement and payment effects.

For healthcare providers working in clinical practice, the primary focus is on the benefit to patients. Nevertheless, it is becoming increasingly clear within the healthcare system that economic aspects must also be taken into account, for example when selecting therapies and medicines.

In controlling, the focus is increasingly on cost manageability, whilst revenue management primarily addresses coding and reimbursement issues, thereby supporting the financial security of the services provided.

Particularly with high-cost therapies, differences in the choice of medicines have a noticeable impact on budget planning and case costs. Decisions regarding medicines are therefore relevant not only from a medical perspective but also from a business management perspective.

Hospital pharmacies also face complex challenges. Purchase prices, availability, discount agreements and sector-specific billing rules influence the actual cost-effectiveness of a treatment. The pharmacy thus becomes a key player in treatment planning when it comes to the practical feasibility of using medicines.

In view of rising overall expenditure in the healthcare sector, resources must be deployed in a targeted and responsible manner. This is not only the case with NSCLC, but also with many other indications involving innovative, cost-intensive medicines. Against this backdrop, it is all the more important that medical, pharmaceutical and economic perspectives work closely together and take each other into account. It is crucial that the various professional groups take joint responsibility and that cost-effectiveness and science are brought into harmony. Only through collaboration can care that is both guideline-compliant and economically viable be secured in the long term. <<

Authors' declaration

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Immunotherapies for non-small cell lung cancer: between innovation and cost-effectiveness – status quo and potential

assessment for Germany

Introduction: Non-small cell lung cancer (NSCLC) is the most common form of lung cancer. Immune checkpoint inhibitors have fundamentally changed treatment in recent years, but they are associated with high drug costs. Against the backdrop of economic efficiency requirements, the economic comparability of therapeutic alternatives is coming into focus.

Methods: A comparison of drug acquisition costs was carried out using the example of pembrolizumab and cemiplimab, taking into account dosage regimens and current drug prices.

Results: Cemiplimab has lower drug costs than pembrolizumab (approximately €600 per dose or around €10,000 per patient per year). Extrapolated to the target population, this results in potential savings running into the millions.

Discussion: Even with comparable clinical efficacy, different drug prices can have significant economic consequences. An integrated evaluation of effectiveness and cost considerations is therefore necessary to support sustainable treatment decisions in line with the principle of economic efficiency.

Keywords

Lung carcinoma, NSCLC, economic efficiency, immuno-oncology