



ABSTRACTBAND

32. Jahrestagung

13. bis 14. November 2025

Jena

Gesellschaft für Arzneimittelanwendungsforschung
und Arzneimittelepidemiologie e. V.



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Sehr geehrte Damen und Herren,
liebe Kolleginnen und Kollegen,

im Namen des Vorstandes der GAA heiÙe ich Sie ganz herzlich bei unserer 32. Jahrestagung willkommen.

Wie schon im vergangenen Jahr starten wir am Donnerstagvormittag vor der gewohnten Abfolge der Tagungssessions wieder mit einem Pre-Conference-Workshop: Thema sind Maßnahmen der Apotheke des Universitätsklinikums Jena zugunsten der Arzneimittelsicherheit von Patientinnen und Patienten. Danach stehen wieder verschiedene Sessions zu aktuellen Themen rund um unser Leitmotiv »Arzneimittelanwendungsforschung und Arzneimittel epidemiologie« auf dem Programm. Einzelheiten zu den Themenblöcken und dem Pre-Conference-Workshop entnehmen Sie bitte diesem Flyer.

Besondere Höhepunkte werden erneut die Einführungsvorträge unserer Key-Note-Speaker zu den verschiedenen Sitzungen sein. Unsere klassische Postersession wird auch in diesem Jahr wieder anhand gedruckter Poster durchgeführt werden; der Tradition folgend werden die drei besten Poster prämiert und eine Geldprämie gewinnen. Am Abend werden wir den ersten Veranstaltungstag in gemütlicher Runde ausklingen lassen.

Wir hoffen, wir konnten auch in diesem Jahr wieder ein attraktives und faszinierendes Tagungsprogramm für Sie zusammenstellen, das unsere Tagung erneut zu einem lohnenden gemeinsamen Erlebnis macht.

Wir freuen uns sehr über Ihre Teilnahme und möchten unsere Mitglieder sowie alle interessierten Gäste auch zu unserer Mitgliederversammlung am 14. November 2025 einladen.

Für den Vorstand der GAA e.V.
Prof. Dr. med. Holger Gothe

Während der Veranstaltung werden Foto- und ggf. Filmaufnahmen erstellt, auf denen auch Teilnehmer/innen erkennbar sein können. Mit der Teilnahme an der Veranstaltung willigen die Teilnehmer/innen ein, dass diese Aufnahmen zur Dokumentation, Nachberichterstattung und Öffentlichkeitsarbeit der GAA e.V. zeitlich, räumlich und inhaltlich unbegrenzt verwendet und veröffentlicht werden dürfen. Sämtliche Nutzungsrechte an den im Rahmen der Veranstaltung entstehenden Aufnahmen gehen auf die GAA e.V. über.

Haftungsbeschränkung: Die Teilnehmer/innen nehmen auf eigene Verantwortung an der Veranstaltung teil. Für Unfälle, Schäden oder Verluste, gleich welchen Ursprungs, an Sachen und Personen haftet weder der Veranstalter noch der Vorstand. Sollten einzelne Bestimmungen dieser Klauseln ganz oder teilweise unwirksam sein oder werden, bleibt die Wirksamkeit der übrigen Bestimmungen hiervon unberührt.



Pre-Conference-Workshop

AMTS-Instrumente „live“ aus der Apotheke des Universitätsklinikums Jena

Ort:

Universitätsklinikum Jena (UKJ), Am Klinikum 1, 07747 Jena

Treffpunkt: Gebäude F5, Konferenzraum („Oval Office“)

Anreise vom Stadtzentrum mit der Straßenbahnlinie 5 Richtung Lobeda Ost, Haltestelle „Platanenstraße“, Gebäude F5 liegt direkt gegenüber auf der anderen Straßenseite

Donnerstag, 13. November 2025

10:00 – 11:30

Pre-Conference-Workshop

AMTS-Instrumente „live“ aus der Apotheke des Universitätsklinikums Jena (UKJ)

Closed Loop Medication Management (CLMM) gewinnt bei der Gewährleistung einer sicheren und effektiven Arzneimitteltherapie zunehmend an Bedeutung und revolutioniert die Arzneimitteltherapie durch digitale und automatisierte Prozesse. Im Rahmen des Workshops erhalten Sie die Möglichkeit, bei einer Führung durch die Apotheke des UKJ das integrierte System zu sehen. In einem „Room of Horror“, der für konkrete Gefahren der Patienten-sicherheit sensibilisieren soll, haben Sie Gelegenheit, praxisnah verschiedene typische und häufige Gefahren für die Patienten-sicherheit in diversen Szenarien zu entdecken und gemeinsam zu diskutieren.

Inhaltliches Konzept:

PD Dr. Katrin Farker (UKJ)

Programm Pre-Conference-Workshop:

- Begrüßung PD Dr. Katrin Farker (UKJ)
Anschließend parallel in zwei Gruppen Führung durch die Apotheke des UKJ mit
- Closed Loop Medication Management (CLMM) (Andreas Iffland, UKJ)
- „Room of Horror“ (Christine Keßler, UKJ)



Wissenschaftliches Programm der 32. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie e. V. (GAA)

Tagungsort:

Rosensäle Friedrich-Schiller-Universität Jena, Fürstengraben 27, 07743 Jena

(In runden Klammern sind jeweils die vortragenden Autor/inn/en namentlich genannt.)

Donnerstag, 13. November 2025

13:00 – 13:15 **Begrüßung und Einführung** in die Tagung (Gothe H, GAA)

13:15 – 13:30 **Grußwort** Prof. Dr. T. Kamradt, Wissenschaftlicher Vorstand und Dekan der Medizinischen Fakultät, Universitätsklinikum Jena (UKJ)

Themenschwerpunkt 1:

Über-, Unter- und Fehlversorgung in der Arzneimitteltherapie

Vorsitz: Gothe H, GAA

13:30 – 14:05 **Key Note:** Unangemessene medizinische Leistungen im deutschen Gesundheitssystem – arzneimittelbezogene Ergebnisse des IndiQ-Projektes (Vogt V, Jena)

14:05 – 14:20 Unterschiede in der Verschreibung von Opioiden auf Kreisebene in Deutschland (2023): Ergebnisse einer bevölkerungsbezogenen Studie (Enners S, Berlin)

14:20 – 14:35 Herpes zoster – Impfquote und Inzidenz der Erkrankung (Lappe V, Köln)

14:35 – 14:50 Anwendung von Pembrolizumab im realen Versorgungsgeschehen in Deutschland: Patientencharakteristika und Überleben (Scholle O, Bremen)

14:50 – 15:20 **P a u s e**

Themenschwerpunkt 2:

Innovative Arzneimittel und Therapieoptionen

Vorsitz: Farker K, UKJ

15:20 – 16:00 **Key Note:** FRESCO-Studie – Herstellung und Einsatz einer innovativen Therapieoption zur Behandlung der Colitis ulcerosa (Hartmann M und Stallmach A, Jena)

16:00 – 16:15 **P a u s e**

Themenschwerpunkt 3:

AMTS und interprofessionelle Zusammenarbeit

Vorsitz: Schmiedl S, GAA

16:15 – 16:50 **Key Note:** Fehlermanagement in CIRS-NRW (Schwalbe O, Münster)

- 16:50 – 17:25 **Key Note:** Chancen und Herausforderungen in der interprofessionellen Zusammenarbeit zwischen pflegerischem und pharmazeutischem Personal im Kontext der Verblisterung für Heime (Schmid T, Kempten)
- 17:25 – 17:40 Medikationsfehler - Ein relevantes Thema in der Ausbildung von Pflegefachkräften (Hagedorn M, Wadersloh)
- 17:40 – 17:55 Pharmakotherapie bei Parkinson Psychosen: Eine Mixed-Methods-Studie (Rose O, Salzburg)

Ende des wissenschaftlichen Teils des ersten Tages

Abendveranstaltung

Ab 18:30 Uhr erwartet uns das Restaurant Hofbräu am Johannistor, Johannisplatz 29, 07743 Jena, <https://www.hofbraeu-am-johannistor.de/>, Essen à la carte auch vegetarisch/vegan.

Wir bitten um verbindliche Voranmeldung im Anmeldeformular zur Jahrestagung.

Freitag, 14. November 2025

08:30 – 10:05 Postersession

Vorsitz: Jobski K, GAA

1. Analyse der zum Schwangerschaftsabbruch verwendeten Medikamente in der ambulanten Praxis – Ergebnisse einer bundesweiten Online-Umfrage unter Ärzten (Rikl L, Witten)
2. Versorgungsrealität gynäkologischer Arzneimitteltherapien: Inanspruchnahmen der privaten Krankenvollversicherten 2019-2022 (Drebka A, Frankfurt a.M.)
3. Anticholinergic Exposure in the German National Cohort (NAKO): Prevalence and Drug Utilization Patterns in Real-World Settings (Könnecke J, Frankfurt a.M.)
4. ALERT - Analyse von unerwünschten Arzneimittelwirkungen und Medikationsfehlern bei Erwachsenen in Deutschland (Weal J, Bonn)
5. Arzneimitteltherapiesicherheit im Fokus - Fallberichte mit Methotrexat (Janke F, Jena)
6. Heat-dependent adverse drug reactions in patients under diuretic therapy – results from ADRED study (Berres J, Aachen)
7. Effect of a pharmaceutical intervention on the completeness of medication histories upon elective hospital admission in elderly patients (Schulz J, Krefeld)
8. Stärkung von Apotheken: Die Rolle unterstützter telemedizinischer Konsultationen bei der Verbesserung der patientenzentrierten COVID-19 Versorgung (Heydarpour R, Berlin)
9. Interprofessionelle Zusammenarbeit im Medikationsprozess: Eine Analyse der AMTS-Aktionspläne seit 2007 (Vogt B, Berlin)
10. Arzneimitteltherapiesicherheit in der Pädiatrie: Arzneimittelbezogene Probleme bei Patient:innen mit angeborenen Stoffwechselerkrankungen (Harings T, Leipzig)
11. Arzneimittelanwendung bei Kopfschmerzen bei Kindern und Jugendlichen: die Perspektiven der Patient*innen und deren Eltern (Neininger M, Greifswald)
12. Prognostizierte Kaliumkurven für die Risikoüberwachung bei ambulanten Patienten mit Herzinsuffizienz, Diabetes mellitus oder chronischer Nierenerkrankung (Scherkl C, Heidelberg)
13. Tocilizumab- und Ocrelizumab-bedingte Reaktionen bei Patienten mit seltenen Erkrankungen – eine Analyse spontaner Meldungen unter Verwendung der EudraVigilance-Datenbank (Himmel J, Witten)
14. Individuelles Pharmakotherapie-Management (IPM) identifiziert auch Leitlinien-assoziierte Risiken für die Arzneimitteltherapie- und Patientensicherheit (Wolf U, Halle)
15. Associations between health beliefs and the prevalence of adverse events after COVID-19 vaccinations (Bunila Yuwang F, Nürnberg)
16. Ginkgo biloba L. bei kognitiven Beeinträchtigungen im Zusammenhang mit Polypharmazie und anticholinergem Belastung – Real-World Evidenz aus dem Praxisalltag (Scholl A, Frankfurt a.M.)
17. Herstellung gefrorener, doppelt verkapselter fäkaler Mikrobiota als innovative Therapieoption für die FRESCO-Studie (Linhardt C, Jena)

18. Von der Herstellung bis zum Patienten: Sicherstellung der Stabilität und Integrität von gefrorenen fäkalen Mikrobiota-Kapseln während der Lagerung und des Transports im Rahmen der FRESCO-Studie (Thürmer M, Jena)
19. Einführung von Biopharmazeutika in Europa: Verteilungsmuster und Datenverfügbarkeit (Selke G, Berlin)

10:05 – 10:30 **P a u s e**

Themenschwerpunkt 4: Datenquellen und Auswertungstools (KI) für die Arzneimittelanwendungsforschung

Vorsitz: Lappe V, Meyer I, GAA

- 10:30 – 11:05 **Key Note:** Erhebung von Arzneimitteldaten in der NAKO-Gesundheitsstudie (Ebert N, Düsseldorf)
- 11:05 – 11:40 **Key Note:** (AI-Supported) Use of Observational Data in Regulatory Research (Wicherski J, Bonn)
- 11:40 – 11:55 Trends im Antidepressiva-Gebrauch 2018-2022 in 11 europäischen Regionen: Unterbrochene-Zeitreihen-Analyse des Einflusses der COVID-19-Pandemie (Selke G, Berlin)
- 11:55 – 12:10 Korrelationen und partielle Korrelationen im 10-Jahres-Trend zwischen Alter, Polypharmazie, Anzahl der Patienten pro Morbidity Related Group in Schleswig-Holstein mit einer Betrachtung zum Einfluss der Corona-Pandemie (Schuster R, Lübeck)
- 12:10 – 12:25 Das individuelle Pharmakotherapie-Management (IPM) mit definierten elektronischen Patienten- und Medikamenten-Scores verhindert weitreichende multidimensionale Risiken der Polypharmazie und ist mit KI-Unterstützung universell einsetzbar (Wolf U, Halle)
- 12:25 – 12:40 Use of targeted therapy in non-small-cell lung cancer patients in rural and urban areas of Saxony-Anhalt (2010-2023) (Wittenberg I, Magdeburg)

12:40 – 13:00 **Prämierung der Poster, Abschluss und Verabschiedung**
(Jobski K, Gothe H, GAA)

13:00 – 13:30 **M i t t a g s p a u s e**

13:30 – 15:00 **Mitgliederversammlung der GAA**
Gäste sind willkommen.

01

Heat-dependent adverse drug reactions in patients under diuretic therapy – results from ADRED study

Judith Berres, Kathrin Uhlig, Jakob Sommer, Katja S. Just
Institut für Klinische Pharmakologie, Uniklinik RWTH Aachen, Aachen, Germany

Background: The climate change causes an increasing number of hot days in Europe. Although evidence for a temperature-depending increase in adverse drug reactions exists, no concrete recommendations for dose adjustments of causative drug groups have been established to date. Likewise, no consistent definition of heat-associated symptoms exists.

Materials and Methods: For identification, the multicentric ADRED trial (Adverse Drug Reactions in Emergency Departments, DRKS-ID: DRKS00008979) served as basis, containing patients with a suspected adverse drug reaction in emergency departments, symptoms and medication including WHO-UMC causality assessments of all drugs taken. The cases were linked with temperature data of Germany's National Meteorological Service (DWD) at enrolment date and in three-day-mean before enrolment. Symptoms were visually identified using heatmaps, while relative frequency of symptoms in the group with causally accused diuretic (n = 1050) vs. not causally accused diuretic (n = 2330) were compared in dependence of daily maximum and mean temperature. Focus was set on summer days and hot days according to DWD (daily maximum temperature $\geq 25^\circ\text{C}$). A literature comparison was conducted for plausibility.

Results: The identified symptoms included vertigo (rel. frequency in subgroup with causally accused diuretics $\geq 25^\circ\text{C}$, n = 182: 17.6%), dehydration (14.3%), syncope (12.1%), electrolyte imbalance (11.5%), hypotonia (10.4%), fall (10.4%), peripheral oedema (7.1%), vomiting (7.1%), fatigue (7.1%). They showed both a higher relative frequency in the group with causally accused diuretics and temperature-dependency, especially at summer/ hot days. The difference between various temperature parameters was negligible. No unanticipated symptoms were observed.

Conclusion: The analysis showed clear association between identified symptoms and higher temperatures in real-world data and will be further used to develop recommendations for temperature-dependent dose adjustments.

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02

Versorgungsrealität gynäkologischer Arzneimitteltherapien: Inanspruchnahmen der privaten Krankenvollversicherten 2019-2022

Alexandra Drebka¹, Annika J. Scholl¹, Christian O. Jacke², Beatrice E. Bachmeier¹

¹Institut für Pharmazeutische Biologie, Goethe-Universität Frankfurt, Frankfurt am Main, Germany

²Wissenschaftliches Institut der Privaten Krankenversicherung (WIP), Köln, Germany

Hintergrund: Trotz verfügbarer medikamentöser Therapieoptionen sind menstruationsbedingte und klimakterische Beschwerden in Deutschland weiterhin hochprävalent. Dies wirft die Frage auf, ob die bestehenden pharmakologischen Standardtherapien (Hormonelle Kontrazeptiva und Hormonersatztherapie) nicht im erwarteten Maße zur Symptomlinderung beitragen oder nur eingeschränkt zur Anwendung kommen. Über die ärztliche Verordnung alternativer Ansätze, insbesondere pflanzlicher Arzneimittel, liegen bislang keine systematischen Daten vor. Analysen zur Inanspruchnahme sowohl synthetischer als auch pflanzlicher Arzneimittel bieten einen zentralen Zugang zur Versorgungsrealität.

Material und Methoden: Aus dem WIP-Arzneimittelprojekt der privaten Krankenversicherungen (pKVn) wurden die Inanspruchnahmen von Arzneimittelpackungen zur Behandlung menstrueller und klimakterischer Beschwerden analysiert. Eingeschlossen wurden alle verordneten Arzneimittelpackungen, die zwischen 2019 und 2022 in Anspruch genommen wurden. Die Daten wurden nach den ressourcenorientierten Methoden zusammengestellt [1].

Ausgeschlossen wurden männliche Versicherte und Frauen unter 12 Jahren sowie Arzneimittelpackungen, die nicht den ATC-Codes G03A, G03C, G03F oder G02CP zugeordnet werden konnten. Insgesamt wurden 2,8 Mio. Arzneimittelpackungen zur Behandlung gynäkologischer Beschwerden gefiltert und analysiert.

Ergebnisse: Von 2019 bis 2022 wurden überwiegend synthetische Hormonpräparate (G03; 91,5%) in Anspruch genommen und pflanzlichen Gynäkologika (G02; 8,5%) machten weniger als ein Zehntel aus. Während die Zahlen für synthetische Hormonpräparate nach einem Rückgang bis 2021 anschließend wieder nahezu das Ausgangsniveau erreichten, zeigte sich bei pflanzlichen Arzneimitteln ein durchgehend rückläufiger Trend.

Zur Behandlung menstrueller Beschwerden dominierten bei den 12-25-Jährigen die Hormonellen Kontrazeptiva (G03A; 92,2%), während die pflanzlichen Arzneimittelpackungen (G02CP01; G02CP02; G02CP05; G02CP07) lediglich 7,8%

ausmachten. Mit zunehmendem Alter stieg der Anteil pflanzlicher Arzneimittelpackungen kontinuierlich an (26-39 Jahre: 25,6%; 40-60 Jahre: 35,6%) und überstiegen erstmals bei Frauen über 60 Jahren den Anteil synthetischer Arzneimittelpackungen (59,2% vs. 40,8%).

Zur Behandlung klimakterischer Beschwerden nahmen in allen Altersgruppen mehr als 90% (12-40 Jahre: 98,5%; 41-65 Jahre: 91,2%; >65 Jahre: 97,2%) der Frauen Arzneimittel, die der Klasse der Hormonersatztherapie angehören (G03C, G03F) in Anspruch. Pflanzliche Arzneimittel (G02CP03; G02CP04; G02CP53) blieben altersübergreifend unter 10%, mit dem höchsten Anteil bei den 41-65-Jährigen (8,8%).

Schlussfolgerung: Zwischen 2019 und 2022 dominierten synthetische Hormonpräparate die medikamentöse Versorgung gynäkologischer Beschwerden deutlich gegenüber pflanzlichen Arzneimitteln, wobei sich altersabhängige Präferenzen zeigten.

Für den geringen Anteil pflanzlicher Arzneimittel sollten die KSB-Prinzipien (Kostenerstattungsprinzip, Selbstbehalte und Beitragsrückerstattungen) [1] der pKvN berücksichtigt werden. Dazu kommen pandemiebedingte Effekte, wie der deutliche Rückgang persönlicher Arzt-Patient*innen-Kontakte, der durch die eingeschränkte ärztliche Versorgung auch zu sinkenden Bezugswerten von Arzneimitteln geführt haben kann. Ebenso könnten fehlendes Wissen bezüglich alternativer Therapieoptionen auf Seiten der Patientinnen, beobachteten Trends beeinflusst haben.

Um den Versorgungsalltag besser zu verstehen und das Potenzial pflanzlicher Arzneimittel gezielter nutzen zu können, sind ergänzende Erhebungen von Patientenpräferenzen, Wirksamkeitserfahrungen, sowie die Gründe für Empfehlung oder Verschreibung aus Sicht der Apotheker*innen und Ärzt*innen empfehlenswert.

Literatur

1. Jacke CO, Schaarschmidt J, Begerow T. Das Auswahlverfahren von PKV-Daten bestimmt das Ergebnis: zum Unterschied zwischen Einreichungs- und Inanspruchnahmeverhalten. Gesundheitsökonomie & Qualitätsmanagement. 2025 Jul 17. DOI: 10.1055/a-2641-8957

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03

District-level differences in opioid prescribing in Germany (2023): results from a population-based study

Salka Enners¹, Andreas Schlotmann¹, Katrin Schüssel¹, Gabriela Brueckner¹, Kathrin Jobski², Irene Langner¹, Michael Thiede¹, Oliver Scholle³

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Background: Assessing regional variations in opioid prescribing is essential for understanding prescribing practices. Recent data on the extent of regional differences in opioid prescribing are lacking, particularly for non-cancer pain, where opioid use remains controversial. This study aimed to describe regional variations in the prescribing frequency of opioids for non-cancer pain in Germany.

Materials and Methods: This cross-sectional study utilized claims data from Germany's largest statutory health insurance (~27 million persons). We included persons without a cancer diagnosis. Users were identified as persons with at least one opioid outpatient prescription (ATC code N02A). For each district, we calculated the age- and sex-standardized prescription prevalence and incidence for the year 2023, both for all opioids and for high potency opioids.

Results: The study sample included at least 9,500 persons in each of the 400 districts. Across all districts, the prescription prevalence of opioids ranged from 35.32 to 69.38/1,000, with the 5th and 95th percentiles at 40.53 and 63.31/1,000, respectively (median: 51.68/1,000). For high-potency opioids, the prevalence ranged from 6.85 to 28.60/1,000, with the 5th and 95th percentiles at 9.64 and 21.88/1,000, respectively (median: 15.05/1,000). The opioid prescription incidence showed similar differences across the districts. For example, for high-potency opioids, it ranged from 3.10 to 12.53/1,000 (median: 6.19/1,000).

Conclusion: The prescribing frequency of opioids for non-cancer pain varied substantially across German districts, particularly for high-potency opioids. As the extent of these variations is unlikely to be driven by differences in morbidity, our results suggest potential for improving rational prescribing of opioids in certain regions.

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04

Associations between health beliefs and the prevalence of adverse events after COVID-19 vaccinations

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¹Klinikum Nürnberg, Paracelsus Medical University Nuremberg, Nürnberg, Germany

²Paracelsus Medical University Salzburg, Salzburg, Austria

Background: The Health Belief Model (HBM) describes the effects of health-related perceptions and beliefs on behaviour. It is based on the assumption that people are more likely to engage in health-promoting behaviour if they consider the respective measure to be effective and acceptable. The HBM can predict vaccination willingness. Vaccines are medicines that prepare the immune system of healthy people. This activation of the body's own defense mechanisms is similar to the effect of alternative (including homeopathic) remedies. However, the approval process of vaccines is analogous to that of conventional medicines for the acute treatment of diseases. In this study, we examine the health beliefs of healthcare workers and whether there is an association between health beliefs and the occurrence of side effects after COVID-19 vaccination.

Materials and Methods: This study evaluated adverse event (AE) rates after the first and second doses of mRNA vaccines (mainly Corinaty) from 982 health care workers (HCWs) of Nuremberg Hospital, one of the largest municipal hospitals in Europe (vaccinated between December 2020 and summer 2021). Moreover, we investigated health beliefs (e.g. about prevention and drugs, N=315) with a health belief questionnaire validated by Häussinger et al. [1]. Fisher's exact and Pearson's chi-square tests were used to analyse cross-tabulations. The significance level was set at 5%, no correction was made for multiple testing.

Results: Almost all vaccine recipients view vaccination as an important preventive measure (>95%), ensure that their vaccination status is complete, and have participated in vaccination to protect themselves (>97%), family members (>90%), and patients (83%). Around two-thirds expected significant side effects from the vaccination. Just over a quarter feared significant side effects. Approximately 40% assumed that conventional drugs have more side effects than alternative medicines. The latter suffered significantly more often from headaches after the first vaccination than those who did not assume this (p<0.01). Similarly, those who preferred alternative medicines suffered significantly more often from myalgia and headaches than those who did not tend toward alternative medicines (p<0.05).

Conclusion: Our sample shows a high willingness to be vaccinated. The found associations could indicate that vaccination, with its associated side effects, was perceived as a conventional medication. Detailed communication and education about the approval of the vaccines, their side effects, and the invasive measurement may have contributed to this. Experienced side effects are associated with reduced willingness to be vaccinated. To encourage vaccination and reduce potential nocebo effects, it may be helpful to highlight the characteristics of vaccines that are different to conventional drugs.

References

1. Häussinger C, Ruhl UE, Hach I. Health beliefs and over-the-counter product use. *Ann Pharmacother.* 2009 Jun;43(6):1122-7.
DOI: 10.1345/aph.1L547

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05

Medication Errors – a Relevant Topic for Nurses in Training

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Background: Due to the introduction of general nursing, the training of nursing professionals underwent fundamental changes in 2017 [1]. Since, from day one of learning in nursing schools the patient and his care setting are in focus. Basic subjects such as „medication in care“ are no longer taught. In outpatient facilities and geriatric care homes, specially trained nursing professionals, known as practice instructors, take over the practical part of the training using structured teaching situations.

Medication administration and medication management are among the tasks related to illness and therapy. Risk and error management is part of quality management. The handling of medication is part of the nursing process planning and is therefore a reserved task that may only be controlled by nursing professionals [2].

Practice instructors have to take part in 24-hours continuing education programmes every year. There is an effective space to discuss the role of nursing professionals in the medication process. Possible sources of medication errors are identified for each step. Frequent errors occur during storage, documentation or provision. As part of the overall concept of "Medication in Nursing Process Planning", two working aids for error analysis and error management are introduced [3].

Materials and Methods: Groups of about 12 practice instructors come together to perform error analyses and discuss error management during the workshops. The error analysis questionnaire asks about the type of error, whether the patient was harmed on a scale from A to I, evaluates which factors contributed to the event, and finally analyses whether and how a similar event can be avoided in future.

The second step focuses on error management and the implementation and transfer of solution ideas. Regular discussions during team meetings of particularly frequent or particularly dangerous errors are encouraged. The benefits for nursing staff, geriatric care homes and their operators are discussed in detail. The benefits for elderly people are described in the areas known to nursing staff: cognition and communication, mobility and agility, care, nutrition, urinary continence, pain, skin integrity, and oral health, as well as "safe handling of medication".

Results: Dosing errors and dispensing errors occur repeatedly in various workshop groups. Dispensing errors are related, for example, to delivery shortages, where 5 mg tablets are delivered instead of 10 mg tablets. Then, the correct labeling by the pharmacy is overlooked or misunderstood and therefor incorrectly implemented by the nursing staff. An example for a dosing error is resulting from a transcription error from the hospital discharge report to the family doctor's prescription. Instead of Haloperidol 2 mg, Haloperidol 20 mg was prescribed and administered for 2 weeks. A third example: a resident with a urinary tract infection did not receive the antibiotic medicines in time.

The participants are very willing to engage in error analysis and error management. However, achieving zero percent medication errors seems unrealistic at present. Too many similar errors occur repeatedly. The topic of medication is not required by law in education, training, or continuing education. Training with medication is provided once a year in inpatient settings by the supplying pharmacists. Given the complexity of the topic, this is far too infrequent. A nursing-based plausibility check of the dosage is only possible with years of practical experience. The CIRS-NRW reporting platform for medical errors is virtually unknown in geriatric care.

Conclusion: Practice instructors are sensitised to recognise medication errors during workshops. In structured teaching situations, they analyse them with nurses in training. Possible solutions are implemented during team meetings. The aim is to prevent medication errors in advance or to identify them as early as possible and resolve them in an interdisciplinary team. Practical instructors play a key role in the facilities: as experienced nursing professionals with a special understanding of complex issues, they are very well suited to act as multipliers within the team. Many providers are improve the quality of their practical training. Hence, sufficient time to carry out the training is often available.

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06

Medication Safety in Pediatrics: Drug-Related Problems in Patients with Inborn Errors of Metabolism

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Background: Pediatric patients with inborn errors of metabolism (IEM) are chronically ill and particularly susceptible to developing drug-related problems (DRPs) due to long-term medication use. The risk is further increased when additional

medication is used, for example to treat acute conditions. The aim of this study was to systematically assess the occurrence of DRPs in a cohort of pediatric patients with IEM [1].

Materials and Methods: The medications of 114 pediatric patients with IEM were analyzed, including medications for both chronic and acute conditions. Structured telephone interviews with their parents were used to record all medications available for the children at home, resulting in a total of 884 medications. Identified DRPs were classified according to type, clinical relevance, and preventability using the Pharmaceutical Care Network Europe (PCNE) classification system [1].

Results: Overall, 83 medications (9%) were associated with DRPs, affecting 50 patients (44%). Clinically relevant DRPs without safe therapeutic alternatives were found in 26 medications (3%) in 15 patients (13%), including 12 medications (1%) related to IEM. DRPs classified as clinically relevant and preventable due to the availability of safe therapeutic alternatives were identified in 20 medications (2%) in 24 patients (21%), with one medication (0.1%) related to IEM. DRPs classified as not clinically relevant in the context of these patients were found in 37 medications (4%) in 26 patients (23%), although they could be relevant in other populations. Of these, 3 medications (0.3%) were associated with IEM.

Conclusion: Nearly half of the pediatric patients were affected by DRPs. Notably, most preventable DRPs were not related to IEM or its specific therapy but rather occurred because the patients were children. These findings highlight the need for careful medication selection to improve pediatric medication safety.

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07

Empowering Pharmacies: The Role of Assisted Telemedical Consultations in Enhancing Patient-Centered COVID-19 Care

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Background: In recent years, it has become increasingly evident that the healthcare system faces numerous challenges. In particular, the shortage of medical professionals and the growing demand for modern working conditions - such as part-time models and remote work - are intensifying the pressure on primary care practices [1], [2], [3]. As a result, delays in patient care and unmet expectations are becoming more frequent, leading to missed opportunities for early disease detection and timely initiation of treatment. Patients may avoid seeking care due to long wait times in doctor's offices contributing to underdiagnosis and delayed interventions. These circumstances underscore the urgent need for innovative, sustainable and patient-centered healthcare delivery models.

With the enactment of the Digital Act 2024, a legal framework has been established to offer assisted telemedical consultations in community pharmacies [4]. This model allows pharmacies to expand their key role in patient care by facilitating remote access to medical expertise through digital technologies, within the familiar and accessible environment of the local pharmacy.

Pharmacies play a pivotal role in patient education and triage. They frequently encounter situations where a medical evaluation is warranted, yet patients may be unable to promptly consult a general practitioner. Reasons may include limited mobility, geographical barriers, or an out-of-hour's need [5], [6]. In such cases, assisted telemedical consultations offer low-threshold, effective alternative.

Pharmaceutical personnel are qualified to perform several routine medical tasks - such as point-of-care testing and blood pressure measurements [4], [7] - thereby expediting the diagnostic process. This highlights the feasibility and potential impact of assisted telemedical consultations, particularly given the substantial time currently spent in medical practices discussing test results. Empowering local pharmacies to conduct such consultations with their patients could enhance time-efficiency and support both doctors and patients in daily clinical practice.

In summary, assisted telemedical consultations offer substantial benefits for patients, pharmaceutical personnel, and the healthcare system at large [8], [9], [10]. Additionally, to alleviate the burden on general practices and emergency services, they facilitate earlier diagnosis and access to guideline-based therapies, ultimately improving patient outcomes.

The close interdisciplinary collaboration between pharmacists and physicians, combined with the strategic use of digital technologies, enhances healthcare delivery. Furthermore, this model reinforces the role of pharmacies as accessible, competent points of contact and contributes to the containment of infectious diseases.

As part of a nationwide initiative for COVID-19 prevention, an evaluation was conducted to assess the potential of pharmacies to raise patients' awareness of the risks of severe disease progression, inform patients about available treatment options, and evaluate the impact of assisted telemedical consultation on COVID-19 care.

Materials and Methods: The project was conducted across Germany via an online questionnaire from January 22nd to February 24th, 2025. It was implemented by DAP, DeutschesApothekenPortal; an online platform for pharmacists in Germany, in collaboration with Pfizer. The initiative aimed to raise awareness among at-risk patients regarding severe infections, testing options and available treatments. Participating pharmacies received training and educational material covering topics such as risk factors, burden of disease, therapeutic options, and the concept of assisted telemedical consultation. The materials were provided as downloadable PDFs for both internal use and patient distribution.

Subsequently, an evaluation was conducted to assess the current level of awareness among high-risk patients regarding COVID-19 and to explore the perceived utility of assisted telemedical consultations. The survey included 10 yes-or-no and multiple-choice questions and was completed anonymously by participating pharmacy staff.

Respondents received 400 DAP points as a benefit for participating in the survey. The survey evaluation was conducted by the DAP and reviewed by Pfizer.

Results: A total of 653 individuals participated in the survey, with 501 completing it in full.

Pharmacy staff engaged in patient consultations regarding individual risk for severe COVID-19. Specifically, 70.3% of staff consulted 10–20 patients, 22.5% consulted 21–30 patients, and 7.2% spoke to more than 30 patients. Following the consultations, 57.6% of patients reported being unaware of their individual risk prior to the consultation. Pharmacy staff provided recommendations regarding testing and therapy options, leading 83.2% of patients to indicate they would opt for COVID-19 testing in the presence of cold symptoms. Additionally, 81.4% of the pharmacy staff expressed willingness to offer COVID-19 tests and/or multiplex rapid tests in their pharmacy in the future, contingent upon appropriate reimbursement.

Regarding therapeutic options, 56.0% of patients were unaware of the availability of antiviral COVID-19 therapies. Nevertheless, after receiving a recommendation from the pharmacy staff, 78.5% of patients stated they would discuss these options with their general practitioner.

With respect to assisted telemedical consultations, 62.5% of pharmacy staff indicated a willingness to implement such services in their pharmacy in the future, provided adequate compensation mechanisms are in place.

Most participants (63.7%) recognized a clear added value of assisted telemedical consultation for COVID-19 care. According to the majority respondents, high-risk patients who test positive via rapid COVID-19 testing should ideally either consult their local general practitioner (50.9%) or utilize assisted telemedical consultation services within the pharmacy setting (35.5%).

Conclusion: The findings underscore the critical role of pharmacies in delivering patient-centered care, particularly in the context of COVID-19. A large proportion of patients lacked awareness of their individual risk for severe COVID-19. Compared to a similar initiative in 2023, self-awareness declined by 7.2% in 2025, highlighting the ongoing need for targeted patient education. Pharmacy consultations were shown to significantly enhance awareness and prompt concrete actions, such as testing or initiating discussions about antiviral therapy options with their general practitioners.

The strong willingness of pharmacy staff to engage in testing and assisted telemedical consultations reflects their potential as active healthcare providers. Pharmacies not only inform but also help assess the need for a medical consultation, enabling early diagnosis and timely intervention. The high level of trust patients place in pharmacy staff forms a solid foundation for the implementation of innovative care models. Assisted telemedical consultation is widely perceived as a valuable tool, particularly for at-risk patients requiring prompt medical attention.

Pharmacies are evolving beyond their traditional role as dispensaries to become integral components of a modern, prevention-oriented healthcare system. The Digital Act provides the legal basis for innovative care approaches. To fully realize its potential, it is essential to support pharmacy staff through appropriate training, infrastructure, and reimbursement mechanisms. By identifying risk factors, offering testing options and recommending evidence-based therapies, pharmacies can play a pivotal role in preventing severe disease progression and improving patient outcomes.

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08

Tocilizumab and Ocrelizumab-related reactions in patients with rare diseases – an analysis of spontaneous reports using the EudraVigilance database

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Background: In recent years, several advanced disease-modifying drugs (DMDs) have been approved for the treatment of rare autoimmune disorders. However, data on the safety and effectiveness of these novel DMDs outside the pivotal trials is limited. Hence, the CONTRIBUTE project aims to assess the effectiveness and safety of selected DMDs for rare rheumatic and neurological diseases in routine clinical practice. As part of the project, we analyzed spontaneous reports documented in the EudraVigilance database for selected DMDs and selected conditions (Giant cell arteritis (GCA) and Primary progressive multiple sclerosis (PPMS)).

Materials and Methods: We conducted a retrospective analysis of spontaneous reports from the authorization year (RoActemra®: 2009, Ocrevus®: 2018) to 2024. The database records reactions according to the MedDRA (Medical Dictionary for Regulatory Activities) terminology at the preferred term (PT-Term) level. Patients who received RoActemra® for treating GCA or Ocrevus® for treating PPMS were included in the analysis. All descriptive analyses were conducted stratified for the two DMDs using Python (Version 3.12.4) and Excel (Version 2506).

Results: For the DMD RoActemra® (Tocilizumab) n=1318 reactions including adverse drug reactions (ADRs) (n=319 (24.2%) serious ADRs) were identified. The five most reported PT-Terms were 'off label use' (n=53, 4.0%), 'headache' (n=28, 2.1%), 'intentional product use issue' (n=23, 1.7%), 'neutropenia' (n=20, 1.5%), and 'diverticulitis' (n=18, 1.3%). The three most frequent System Organ Classes (SOC) terms were 'General disorders and administration site conditions' (n=185, 14.0%), 'Injury, poisoning and procedural complications' (n=146, 11.0%), and 'Gastrointestinal disorders' (n=135, 10.2%).

For female patients 982 PT-Terms (74.5%) were reported. Patients over 65 years of age accounted for most reactions (n=634, 48.1%) whereas in n=566 (42.9%) reactions the age group was not specified.

The administration of Ocrevus® (Ocrelizumab) for the treatment of PPMS led to n=2455 reactions including ADRs (n=553 (22.5%) serious ADRs). The five most frequent PT-Terms were 'multiple sclerosis' (n=72, 2.9%), 'fatigue' (n=57, 2.3%),

'gait disturbance' (n=53, 2.1%), 'urinary tract infection' (n=48, 1.9%), and 'COVID-19' (n=42, 1.7%). Regarding SOC-Terms the three most common categories were 'General disorders and administration site conditions' (n=453, 18.4%), 'Nervous system disorders' (n=299, 12.1%), and 'Infections and infestations' (n=242, 9.8%).

The sex distribution presented itself more evenly distributed with n=1305 (53.1%) female patients. Most reported reactions were for patients between age 18-64 (n=1270, 51.7%). 37.7% (n=927) of all reactions were not specified regarding age of the patient.

Conclusion: Our findings highlight the multitude of spontaneous reports for newly approved DMDs used in two rare diseases providing a deep insight into the safety profile of these drugs after approval. Within the project, we will further compare the safety of selected DMDs using data from clinical trials and secondary data to provide a comprehensive picture of potential side effects in a real-world healthcare setting.

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09

Focus on drug therapy safety – case reports with Methotrexate

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Background: Drug therapy safety is defined as the entirety of measurements aimed at ensuring an optimal medication process, with the aim of reducing medication errors and thereby minimizing preventable risks to patients during pharmacotherapy.

The admission of patients from outpatient to inpatient setting can be a critical phase in the medication process, as this transition may be particularly prone to medication-related problems (MRPs). A common source of error could be the incorrect transfer of outpatient long-term medications into the hospital electronic patient record. This presents an especially high risk with drugs that have a narrow therapeutic range, such as high-risk medication like Methotrexate (MTX).

MTX is used at high doses as a cytostatic agent functioning as an antimetabolite, inhibiting DNA synthesis. However, at lower Doses MTX, acts as an immunosuppressant and is used as a disease-modifying antirheumatic drug (DMARD).

Case reports describe potential sources of error that may lead to intoxication from overdose. In particular, incorrect dosing intervals can lead to an overdose with potentially serious adverse events. As a DMARD, MTX is typically administered once a week. However, dosing interval errors, such as multiple administrations within a single week, can cause serious adverse events, including anaemia, pancytopenia, bone marrow depression, or agranulocytosis. Even with rapid intervention and appropriate treatment, such an intoxication may be fatal.

With that in mind, EU-wide risk minimisation measures were introduced as early as 2018. Those include visual warnings on the packaging, changes to the product information and introduction of online-accessible educational materials.

As part of an ongoing project, two recent patient cases were identified in which MRPs occurred due to incorrect MTX dosing intervals. This highlights the importance of continuously raising awareness among all professionals involved in the medication use process

Materials and Methods: As part of INTERPOLAR (INTERventional POLypharmacy – drug interAction – Risks) medication analyses are carried out in various departments of the University Hospital Jena (UKJ). The aim in the ongoing project is to identify potential MRPs early and address them through interdisciplinary collaboration. The medication analyses are based on essential patient information, including medical history, diagnoses, current medications, clinical data, and laboratory results.

Results: As part of the conducted medication analyses, two recent patients in different departments of the UKJ were identified with MRPs related to incorrect MTX dosing intervals.

The first case involved a 64-year-old patient with rheumatic arthritis, who had been prescribed MTX as a DMARD. Instead of the intended weekly application on Mondays, a daily dose interval was documented in the electronic patient record.

Similarly, a 64-year-old patient with non-systemic vasculitic neuropathy, had also been treated with MTX as a DMARD in off-label-use. According to the outpatient medication plan, MTX was intended to be administered once weekly on Tuesdays. However, a twice-weekly dose interval was documented in the electronic patient record.

Both MRPs were identified in time during the chart reviews and corrected in consultation with the treating physicians. As a result those MRPs did not reach the patients.

Conclusion: Medication reviews are essential for ensuring optimal patient care and drug therapy safety. Based on the presented case reports, interdisciplinary collaboration between clinical pharmacists and physicians should be established, particularly during the transition of outpatient to inpatient care, to achieve safe and effective pharmacotherapy. Special attention should be given to high-risk patients and medications with a narrow therapeutic range, in order to identify and resolve potential MRPs before they can impact the patient.

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10

Anticholinergic Exposure in the German National Cohort (NAKO): Prevalence and Drug Utilization Patterns in Real-World Settings

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Background: Anticholinergic drugs inhibit muscarinic acetylcholine receptors and are used to treat a variety of conditions, such as COPD, depression, Parkinson's disease, overactive bladder, and irritable bowel syndrome [1], [2], [3]. At the same time, they are associated with adverse effects, including an increased risk of cognitive decline, falls, and mortality [2], [4], [5].

However, despite the clinical relevance of assessing the anticholinergic burden (AB) as the additive effect of medications with varying anticholinergic potencies [6], national data on real-world exposure and utilization patterns, particularly including over-the-counter (OTC) use, remain scarce for Germany.

Materials and Methods: Using baseline data (2014–2019) from the German National Cohort (NAKO; >200,000 individuals) [7], [8], we conducted a preliminary, descriptive pharmacoepidemiologic analysis of anticholinergic medication use. AB was calculated as the sum of individual drug ratings using a validated scoring system adapted to medications available in Germany (German Anticholinergic Burden Scale, GABS), mapping prescribed and OTC drugs to graded burden scores from 0 (no anticholinergic effects) to 3 (strong anticholinergic effects) [9], [10].

Results: In our dataset, 17.1% of participants were exposed to anticholinergic medications, with 2.9% reaching a GABS score ≥ 3 . Mean burden was higher in women than in men (0.31 ± 0.83 vs. 0.24 ± 0.69) and increased with age (0.12 in those aged 20–29 years to 0.47 in those aged ≥ 70 years). Medications from the nervous system, cardiovascular system, and alimentary tract/metabolism ATC classes contributed most to overall AB. OTC drugs accounted for 12.6% of all anticholinergic agents.

Conclusion: Our findings reveal anticholinergic exposure in a large German cohort, highlight demographic differences, and underscore the importance of considering OTC medications in burden surveillance. These insights can inform future association- and outcome-focused research.

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11

Herpes zoster – vaccination coverage and incidence of disease

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Background: Herpes zoster is caused by the reactivation of the varicella-zoster virus after a primary infection, which manifests itself as chickenpox. The disease causes a painful rash. Complications include potentially long-lasting nerve pain, postherpetic neuralgia (PHN), and zoster ophthalmicus, which can lead to blindness. An inactivated vaccine has been available on the German market since May 2018. Following its recommendation as a standard vaccination for people aged 60 and over by the Standing Committee on Vaccination (STIKO) [1], it has been reimbursed by statutory health insurance funds since May 2019. Two vaccinations at intervals of two to six months are required for complete vaccination protection. The aim of the study was to investigate the incidence of the disease, the frequency of inpatient treatment, the rate of complete vaccination, and differences in vaccination rates between medical practices.

Materials and Methods: Database: data from adult BARMER insureds from 2017 to 2023 [2]. Definition of the incidence of herpes zoster (ICD-10 code B02), zoster ophthalmicus (B02.3) and postherpetic neuralgia (G03.0) observed in the period 2022–2023 in persons with continuous insurance coverage: inpatient main diagnosis and/or outpatient diagnosis marked as “confirmed,” without any of these diagnoses (including inpatient secondary diagnosis) having been present in the previous year (standardized to the population of Germany (December 31, 2023)). The herpes zoster vaccination was studied in a cohort that was continuously insured from 2019 to 2023. Outpatient billing codes (89128, 89129) and special codes from the Association of Statutory Health Insurance Physicians (KV) were taken into account, as were vaccinations billed as voluntary benefits. Two vaccinations at least one month apart or at least three vaccinations were considered complete vaccination. Vaccination activity in general practices was determined for practices that were active as general practices from 2019 to 2023 and treated at least 50 BARMER-insured patients aged 60 and older who were

treated at only one general practice. Insured persons who were vaccinated in non-general practitioner practices or for whom no information on the vaccinating practice was available were excluded.

Results: The incidence of herpes zoster increased by 3.4% among 18- to 59-year-olds between 2018 and 2023, while it decreased by 11.2% among those over 60 (zoster ophthalmicus 0.0% vs. -7.0%, PHN 25.0% vs. 0.0%). 3.9% of all adult insured persons with herpes zoster were admitted to hospital for herpes zoster (ICD-10 code B02/G03.0) (main diagnosis), compared with 4.8% of those aged 60 and over. People aged 60 and older who were fully vaccinated by the end of 2022 had a 64% lower risk of developing herpes zoster (B02) in 2023 than unvaccinated individuals.

21.3% of people aged 60 and older were fully vaccinated between 2019 and 2023, including 19.4% of men and 22.4% of women. In the 5-year age groups 65–69 to 80–84, the full vaccination rate was around 25 percent, while only 14.9 percent of 60- to 64-year-olds, 17.8 percent of 85- to 89-year-olds, and 9.7 percent of those over 90 were fully vaccinated. The vaccination rate varied between the different federal states, ranging from 15.2% in Baden-Württemberg to 29.3% in Saxony-Anhalt. Vaccination rates were lowest in southern Germany and highest in the eastern federal states. After receiving their first vaccination, 20% of those over 60 did not receive a second vaccination within six months, and 13.7% did not receive a second vaccination within a year.

Around 96% of herpes zoster vaccinations were administered by general practitioners. Vaccination activity varied greatly between GP practices: the lowest 10% vaccinated only up to 7% of patients aged 60 and older, while the top 10% vaccinated 41% or more.

Conclusion: Herpes zoster is a painful condition with potentially serious complications that, according to studies, can increase the risk of stroke [3] or the development of dementia [4]. Against this backdrop, a vaccination rate of 21.3% is completely inadequate. Significant differences in vaccination rates between general practitioners' practices have been identified, indicating that strategies focused on medical practices (e.g., vaccination management systems, training on vaccination counselling and management) could increase vaccination rates. These should be supplemented by patient-focused strategies (e.g., electronic vaccination records) and the introduction of a preventive care appointment at age 60 to assess vaccination status and provide advice on recommended vaccinations. The opportunity to avoid herpes zoster and its complications and consequences should therefore be made more accessible to patients.

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12

Medication use in headaches in children and adolescents: the patients' and parents' perspectives

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Background: Headaches in children and adolescents are common and can significantly affect their and their families' daily lives. However, little is known about how the children's headaches are managed at home.

Materials and Methods: We invited children and adolescents and their parents who visited the neuropediatric department of a university hospital due to headache to participate in the study. We interviewed the pediatric patients and asked the accompanying parents to complete a questionnaire.

Results: We included 98 pediatric patients and their parents who reported on current medication use for the child's headache. The affected patients were 13.9 (median; Q25/Q75 10.8/15.5; min/max 6.1/17.9) years old, 51% of them

were female. 38% of patients and 42% of parents reported that headache medication was “always” or “often” used. On the question who decides if medication is taken, 32% of patients and 7% of parents stated that the child decided while 33% of patients and 65% of parents said that they shared decision making. Of patients, 53% reported to have free access to the medication while 41% of parents stated that their child had free access. 61% of parents stated that the medications had been recommended by a physician, 7% by a pharmacist, and 2% by both healthcare professionals. Of parents, 27% did not report on a physician’s or pharmacist’s recommendation, and 3% did not answer the question.

Conclusion: Children and adolescents with headaches report greater autonomy in managing medication than their parents perceive. Guidance on headache medication use from healthcare professionals seems to be lacking in about one-third of families. Therefore, healthcare professionals should proactively offer support to families. In particular, pharmacists should be aware when analgesics are purchased for children and adolescents and advise medical consultation when appropriate.

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13

Analysis of medication used for abortion in the outpatient setting – results of a nationwide online survey among physicians

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Background: In 2023, more than 100.000 abortions were performed in Germany. A relevant proportion of abortions are conducted as outpatient visits using self-administered abortion drugs. According to the guidelines, antiemetics and analgesics are recommended as concomitant medication but details are lacking. Up to now, there is only few data which medication is given to women in the outpatient setting.

Materials and Methods: A nationwide online survey among physicians was conducted using LimeSurvey. Physicians were asked to participate if they offer medical abortion according to information provided by the German Medical Association and the association Doctors for Choice Germany e.V. A descriptive statistical analysis was conducted using SPSS.

Results: Out of all the invitations sent out (n=282), n=75 responses were received (response rate 26.6%). Finally, n=55 responses met the predefined inclusion criterion (at least one reported medication regimen) and were included in our analysis .

The majority of physicians were female (80%), practice in a metropolis (61,8%), and had a specialization in gynecology and obstetrics (90.9%). 54.5% had more than ten years of professional experience, 54.5% offered only medical abortion while 45.5% also perform surgical abortion.

Almost all physicians reported a combination of mifepristone (usually 200mg or 600mg orally) and misoprostol (200–800µg in varying dosages and forms of administration) as abortion medication. In most cases, standard dosing regimens are used but patient-related individual adjustments (e.g. due to gestational age) are often made. Analgesic medication is predominantly based on ibuprofen, often supplemented by other analgesics such as paracetamol or codeine. Some physicians reported also the use of butylscopolamine. Dimenhydrinate was the most frequently used antiemetic usually administered on an as needed base.

Conclusion: This survey highlights for the first time a considerable heterogeneity in the practical implementation of medical abortion in Germany. In particular, there are not only discrepancies regarding the drugs used for inducing abortion but also regarding concomitant analgesic and antiemetic medication.

The results of this survey underline the need for observational studies and clinical trials in this setting as well as the development of specific guidelines ensuring an optimum treatment of this vulnerable population.

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Exploring Pharmacotherapy in Parkinson's Disease Psychosis: a Mixed-Methods Study

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Background: Psychosis is a common and debilitating non-motor complication in Parkinson's disease (PD) that significantly impairs quality of life for patients and caregivers. Clozapine has demonstrated efficacy in treating Parkinson's disease psychosis (PDP), effectively reducing hallucinations and delusions without worsening motor symptoms. However, its use is limited by the need for regular hematological monitoring due to the risk of agranulocytosis. Contrastingly, quetiapine is widely prescribed as a more convenient alternative, despite inconsistent and limited evidence for its efficacy in PDP. This divergence raises questions about real-world treatment experiences and prescribing practices.

Materials and Methods: This mixed-methods study integrated semi-structured interviews with patients hospitalized for PDP at a university center and a structured survey of neurologists and geriatricians involved in their care. Patient interviews explored perceptions of treatment effectiveness, adverse effects, quality of life, and autonomy. Physician surveys assessed prescribing preferences, attitudes towards clozapine monitoring burden, and perceptions of treatment challenges. The data were analyzed thematically and quantitatively to compare patient experiences with clinical practice.

Results: Eleven patients (mean age 81 years; 9 on quetiapine, 2 on clozapine) reported markedly different treatment experiences. Most patients treated with quetiapine described persistent hallucinations, sedation, dizziness, increased fall risk, and reduced independence. In contrast, clozapine-treated patients experienced significant symptom resolution and functional improvement. Fourteen physicians completed the survey, with a strong majority preferring quetiapine due to perceived ease of use and difficulties associated with clozapine blood monitoring. While acknowledging quetiapine's limited effectiveness, physicians prioritized safety, feasibility, and logistical considerations over optimal symptom control.

Conclusion: The study reveals a critical misalignment between patient-reported outcomes and physician prescribing practices in PDP management. Patients prioritize symptom control and restoration of autonomy, whereas physicians often emphasize treatment feasibility and patient safety. These findings underscore the need for structural reforms to facilitate integration of clozapine monitoring into outpatient care and for systematic inclusion of patient-reported outcomes into routine clinical decision-making. Addressing these gaps is essential to achieve truly patient-centered pharmacotherapy for Parkinson's disease psychosis.

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Predicting potassium trajectories for risk monitoring in outpatients with heart failure, diabetes mellitus, or chronic kidney disease

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Background: Hypo- and hyperkalemia can have serious consequences, especially in patients with heart failure (HF), chronic kidney disease (CKD), and diabetes mellitus (DM). As general monitoring recommendations for ambulatory care may be too loose to catch individual risk situations in outpatients, prediction models could assist by revealing individual trends that may require close clinical action (e.g., adjustments in monitoring intervals or medication regimens). We aimed to develop a dynamic prediction model for potassium concentration in the outpatient sector for patients with HF, CKD, and/or DM.

Materials and Methods: We used administrative claims data from Scotland collected at the Tayside Health Informatics Centre and selected patients between January 1st and June 30th, 2020 and underlying conditions of HF, CKD, and/or DM. The follow-up time of each patient was divided into assessment periods to predict a patient’s maximum potassium value within the next four weeks (prediction periods). Three linear mixed-effect models were fitted and model performance was assessed using root-mean-squared-error (RMSE), mean absolute error (MAE), and mean squared error (MSE).

Results: Among 5,918 patients with a mean age of 76.2 years, a median of 17.0 potassium concentrations were measured per patient corresponding with 1.71 measurements per assessment period. In total, we predicted 5,478 maximum potassium values. The final model performed with a RMSE of 0.52, MAE of 0.39, MSE of 0.27, and with no apparent trends in the residuals over time. Prediction was more accurate within the potassium reference range, and tended to underestimate extremely high and overestimate low observations. Among the strongest predictors were newly acquired acute kidney injury, last measured potassium, and use of low ceiling and high ceiling diuretics.

Conclusion: We propose a blueprint of a decision support tool which predicts potassium concentration longitudinally by updating the predictions based on accumulating data. Our findings demonstrate that dynamically reassessing predictors can aid in estimating potassium levels over multiple months with reasonable accuracy in the outpatient setting.

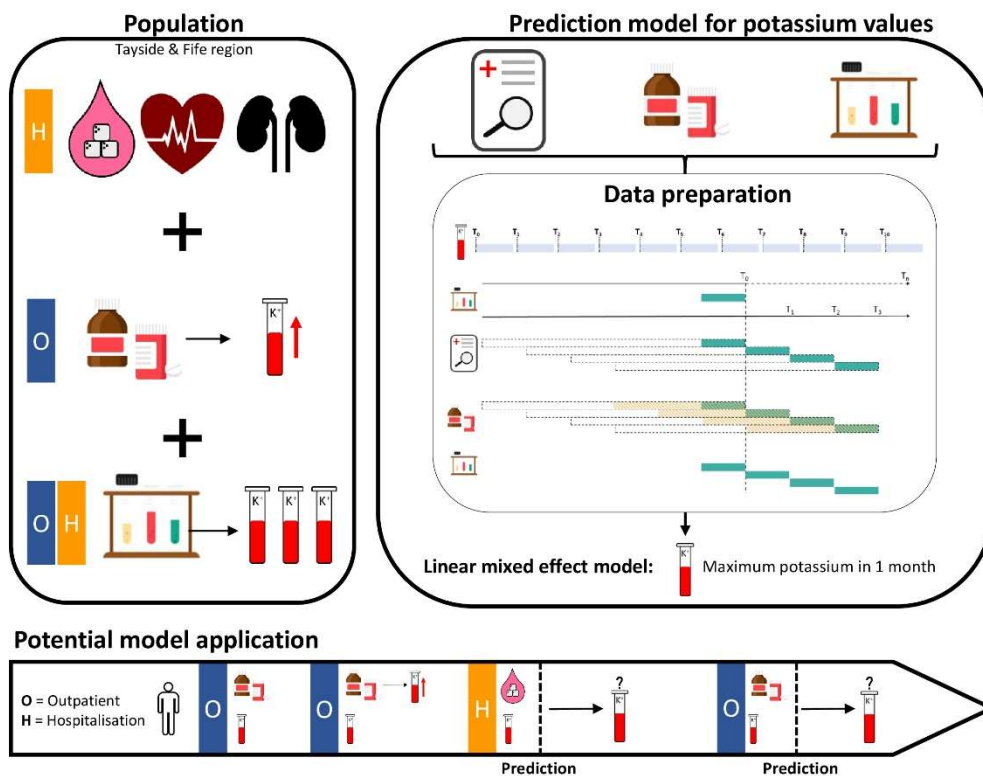


Figure 1

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16

Ginkgo biloba L. for Cognitive Impairment in the Context of Polypharmacy and Anticholinergic Burden – Real-World Evidence from Everyday Practice

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Background: Anticholinergic drugs as well as polypharmacy are frequently associated with a decline in cognitive function [1] and other adverse effects. The potential to evoke undesired anticholinergic drug effects can be assessed using the German ACB (Anti-Cholinergic Burden) score and a value of >2 should be avoided [2]. In cases where the utilization of anticholinergic drugs cannot be circumvented and deprescribing is difficult, alternative medication strategies are necessary to prevent adverse effects like cognitive impairment.

The utilization of monographed Ginkgo biloba L. leaf extracts (GBE) is conceivable because of their recognized effectiveness and good tolerability [3]. Moreover, preclinical animal studies have already shown that GBE antagonizes cognitive deficits induced by anticholinergic drugs [4].

Our study aimed to investigate the role of GBE in the context of polypharmacy by examining the prevalence of concomitant medication and the potential ACB arising from them. In addition, we assessed the perceived effectiveness and tolerability of GBE in relation to the number of co-medications and the presence of critical ACB scores (>2).

Materials and Methods: We retrospectively analyzed real-world outcomes reported by patients using GBE to treat cognitive impairment. The sample was taken from the pharmacoepidemiologic database PhytoVIS, in which personal therapy experiences with herbal medicinal products were collected alongside with information on drug utilization patterns, comorbidities and comedication [5]. For all cases with concomitant medication, we determined the number of co-medications (categorized as +1, +2, or ≥3) and the cumulative anticholinergic burden using the German ACB score [2]. Descriptive statistics and non-parametric bivariate statistical tests (Spearman correlation) were applied to assess associations between variables.

Results: Out of 191 patients, two third took GBE alongside with concomitant medication (64.9%; n=124), whereby about half (48.4 %, n=60) took one additional drug, nearly a third (31.5 %, n=39) took two, and a fifth (20.2 %, n=25) three or more; the number of concomitant drugs increased with advancing age (Spearman $\rho=0.44$, $p<0.001^{***}$).

Perceived effectiveness of GBE was high: 90,6 % (n=173) reported a therapeutic benefit, regardless of any concomitant medication. Tolerability was similarly favorable: 89 % (n=170) experienced no adverse events. There was no correlation between the perceived effectiveness and tolerability and the number of co-medications (Spearman $\rho_{\text{Eff}}=0.05$, $p=0.478$; $\rho_{\text{Tot}}=0.06$, $p=0.452$).

Regarding the ACB, almost three quarters (71.8 %, n=89) took exclusively non-anticholinergic drugs; among those taking at least one anticholinergic agent (28.2 %, n=35), cumulative ACB scores were generally low (ACB=1 in 23.4 % (n=29), ACB=2 in 1.6 % (n=2), and a critical ACB >2 in 3.2 % (n=4)). The four patients with a ACB >2 were all older than 50 years with multiple comorbidities and co-medications. In all four cases GBE was rated as therapeutically effective and without any adverse events.

Conclusion: Our results demonstrate that GBE is an effective and well tolerated option for the treatment of cognitive impairment, even in combination with multiple co-medications. Despite limited number of cases with critical ACB >2 (n=4), our study exhibited excellent outcomes. Retrospective longitudinal studies with larger samples including population based health and outcome studies would help to further clarify the potential of GBE in managing cognitive impairment related to polypharmacy and anticholinergic therapies.

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17

Real-world use of pembrolizumab in Germany: patient characteristics and survival

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Background: Pembrolizumab was the drug that incurred the highest costs for statutory health insurance in Germany in 2023. Using real-world data, we aimed to characterize patients treated with pembrolizumab in Germany and describe their overall survival.

Materials and Methods: Using claims data, we included patients treated with pembrolizumab between 2015 and 2022. We characterized them regarding age, sex, and type of cancer and described their overall survival after the first administration of pembrolizumab.

Results: Among 9,937 included pembrolizumab users, the majority had lung cancer (58%), followed by melanoma (11%), and urothelial cancer (7%). Median age was 69 years; 26% of female and 30% of male patients were >75 years. Overall, 26% of patients died within 4 months after first administration of pembrolizumab. Among lung cancer patients, 26% of females and 31% of males died within four months. In melanoma patients, this proportion was 12% in both sexes.

Conclusion: One quarter of pembrolizumab users died within a short period of time after the first administration. These findings underscore the need to improve the identification of patients who are less likely to benefit from pembrolizumab in order to minimize the treatment burden in the terminal phase and improve resource allocation in the healthcare system.

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18

Effect of a pharmaceutical intervention on the completeness of medication histories upon elective hospital admission in elderly patients

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Background: Transitions of care pose special challenges for everyone involved in the healthcare system. The interface between outpatient and inpatient care is particularly prone to errors. This can be seen from the fact that, according to a systematic review, up to 67% of patients have at least one unintended medication discrepancy (UMD) in their medication history upon hospital admission [1]. Older patients in particular are at risk due to their comorbidities and the resulting drug therapy.

Materials and Methods: A two-part study investigated the frequency and severity of UMDs in a German hospital. As part of a prospective cohort study, 100 participants over the age of 65 who regularly took at least three medications were included, and the frequency of UMD in medication history during elective hospital admission to the urology department at Helios Klinikum Krefeld was examined. After the medical recording of premedication was completed, the best possible medication history (BPMH) was collected by a pharmacist and the information concerning UMD was compared.

In the following prospective, randomized controlled intervention study, the influence of a pharmaceutical intervention on the occurrence of UMD was investigated. Forty-three participants received the standard procedure (comparable to the prospective cohort study). In the intervention group ($n = 43$), the best possible medication history was recorded in the electronic patient file. The medical staff checked, supplemented, and, if necessary, changed the inpatient medication after appropriate review.

Results: 72% of medication histories in urology showed at least one unintended discrepancy. 60% of participants had errors in prescription medication that was taken on a long-term basis. In the intervention group the proportion of patients with at least one UMD was reduced from 60.5% to 14.0% ($p < 0.001$; odds ratio 9.431, CI 95% 3.277–27.148). Compared to usual medication use in the outpatient sector, medications were particularly often accidentally forgotten, added, or dosages changed. In both studies, more than half of the UMDs were of potential clinical relevance if the discrepancy had reached the patient (NCC MERP category D–I).

Conclusion: When taking a medication history upon admission to hospital, unintended discrepancies occur regularly, leading to errors in the continuation of medication. The comprehensive deployment of pharmaceutical staff can significantly reduce unintended errors. The impact on patient-relevant factors such as mortality and readmissions should be subject of future work [2].

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19

Correlations and Partial Correlations in a 10-Year Trend Between Age, Polypharmacy, and the Number of Patients per Morbidity Related Group in Schleswig-Holstein, With Consideration of the Impact of the COVID-19 Pandemic

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Background: Age and polypharmacy, as well as the primary pharmacological treatment at the center of an individual patient's care, are crucial both for patient-related treatment outcomes and for the economic background of healthcare. For patients, the cooperation of all physicians involved in treatment and the necessary communication processes are essential. The medication plan and the electronic health record could provide far better support than is currently the case. The General Data Protection Regulation (GDPR) restricts patient-related communication between treating physicians, whereas no such limitations exist for anonymized epidemiological analyses. A 10-year analysis allows the identification of trends in healthcare provision that describe multiple aspects of success-oriented cooperation in the historical use of existing drugs, their benefits and limitations – including restricted availability and drug–drug interaction issues – arising from medical prescriptions.

Materials and Methods: All prescriptions issued by physicians in Schleswig-Holstein for patients with statutory health insurance in Germany between 2014 and 2023 were analyzed. The evaluation was conducted across physicians on a per-patient basis. Patient data were pseudonymized. Medications were identified via a pharmaceutical central number, from which the international ATC code with German specification was derived from the corresponding database. For each patient and year, drug costs could be aggregated at the ATC four-character level (third level). The ATC-4 code with the highest cost determined the Morbidity Related Group (MRG). The number of ATC-4 codes per patient served as a cross-physician measure of polypharmacy. For each MRG and year, averages for age and polypharmacy across all patients were calculated, along with the number of affected patients. For each MRG, linear trends in age, polypharmacy, and patient numbers were determined over the observation period. Correlations and partial correlations of these three variables were then calculated as a function of the MRG. In addition to linear trends, changes between specific years were examined. Pairwise comparisons of 2019, 2021, and 2023 enabled analysis of the parameters and their correlations/partial correlations before, during, and after the COVID-19 pandemic. The modulus value derived from correlations indicates whether all partial correlations are numerically greater or smaller than the corresponding

correlations. Correlations and partial correlations can be translated into relationships in spherical trigonometry and Jacobian elliptic functions.

Results: There are MRGs in which the variables age and polypharmacy display essentially linear increasing or decreasing trends; a threshold of absolute deviations from the linear trend can be used to identify such cases. Of further interest are MRGs in which a trend reversal occurs within the 10-year period.

Across all MRGs with at least 100 patients, correlations between patient numbers, mean age, and mean polypharmacy were found to be 0.216, 0.663, and 0.405, respectively, with a modulus value of 1.044. Corresponding partial correlations were -0.073, 0.644, and 0.356.

Due to the modulus value of 1.044 being slightly above 1, all partial correlations were smaller than the correlations, with a sign reversal in one case. The modulus value was close to the critical threshold of 1.

To assess the impact of the COVID-19 pandemic on the number of patients with prescriptions, correlations were analyzed between 2019–2021, 2019–2023, and 2021–2023, representing changes before, during, and after the pandemic. The resulting values were 0.985, 0.988, and 0.978. Here, a comparatively high modulus value of 21.999 was obtained, with partial correlations of 0.581, 0.675, and 0.195.

In this case, the modulus value of about 22 is substantially larger than the critical threshold of 1, and no sign reversal of partial correlations occurred. The correlations for COVID-related changes were close to 1. Excluding one of the three variables in each case led to a markedly reduced partial correlation between the remaining two variables.

Conclusion: There are MRGs in which the variables age and polypharmacy display essentially linear increasing or decreasing trends; a threshold of absolute deviations from the linear trend can be used to identify such cases. Of further interest are MRGs in which a trend reversal occurs within the 10-year period.

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Error Management in CIRS-NRW

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Background: CIRS-NRW is a regional and interprofessional implementation of a Critical Incident Reporting System used in healthcare settings across North Rhine-Westphalia, Germany. Its primary goal is to enhance patient safety by systematically collecting, analyzing, and learning from critical incidents, near misses, and errors in clinical practice. Since 2019, the Chambers of Pharmacists of North Rhine and Westphalia-Lippe have been official partners in CIRS-NRW. Medication errors represent one of the most critical areas in the field of patient safety. Critical Incident Reporting Systems have been transformative in high-risk industries, especially in civil aviation.

Materials and Methods: In CIRS-NRW, the process begins when healthcare professionals access and fill out electronic incident report forms. These forms are submitted to a central office, where they are reviewed and anonymized to protect the identity of the individuals and institutions involved. Reports submitted by pharmacists or concerning incidents in pharmacies – such as medication errors – are specifically handled by staff members of the Pharmacists Chambers of North Rhine and Westphalia-Lippe. These experts review and publish the reports.

Results: CIRS-NRW has led to a range of impactful initiatives aimed at improving patient safety and reducing medication errors, particularly in pharmacy practice: Regular seminars are held on medication safety, helping healthcare professionals enhance their situational awareness and discuss measures for safer practices. Both Pharmacists' Chambers of North Rhine and Westphalia-Lippe have integrated a Room of Horrors pharmacy simulation into their preregistration training courses. In collaboration with Federal Association of Health IT (bvitg), CIRS-NRW published a position paper addressing risks in Methotrexate dosing, recommending improvements to electronic medication plans and alert systems. Medication errors reported through CIRS-NRW not only contribute to a recurring article series in the *Deutsche Apotheker Zeitung*, where real-world cases and practical insights are shared, but also serve as a valuable foundation for health services research. One first project focused on the imprinting of tablets and capsules and its potential to cause dosing errors.

Conclusion: CIRS-NRW represents a promising approach to strengthening patient safety through collaboration among various self-administration organizations. Its structured reporting and analysis of medication errors not only support professional education and healthcare research but also foster a culture of transparency and continuous improvement. Looking ahead, stronger cooperation with other organizations that collect medication error data – such as the Drug Commission of German Pharmacists could further enhance the system's impact and contribute to a more comprehensive understanding of medication safety.

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Trends in antidepressant use in 11 European regions 2018–2022: an interrupted time series analysis of the impact of the COVID-19 pandemic

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Background: The COVID-19 pandemic (March 2020 to May 2023) has placed immense strain on people's health and well-being. In addition to the direct effects of the disease on physical health, the uncertainty regarding the disease and its long-term effects on health, well-being and the private economy also had detrimental effects on mental health; moreover, many countries implemented restrictions on social distancing and limited movements of people, which may have exacerbated this further, with differing influences on different demographic groups. The increasing prevalence of mental health conditions as a topic of concern predates the COVID-19 pandemic but has gained further attention since. Nevertheless, evidence on the specific effect of the COVID-19 pandemic on depression incidence and prevalence trends remains inconclusive, as research findings differ widely depending on study design, country, and time period studied. Our study aimed to explore the effects of the pandemic on dispensed volumes of antidepressants in outpatient settings in different regions of Europe and to assess potential age- and sex-related differences of its impact on incidence of antidepressant dispensing, applying consistent methodology to comparable data. - This presentation is based on a paper by Selke Krulichová et al.

Materials and Methods: We conducted a retrospective, observational, cross-national comparative study in eleven European countries/regions of different geographic locations, health systems, and administrative responses to the

pandemic. The participating countries and regions were Croatia, Czechia, Finland, Germany, Lombardy (Italy), Slovenia, Sweden, Northern Ireland, England, Scotland, and Wales. For each country/region, we used monthly pharmacy dispensing data measured in DDD from January 2018 to December 2022. The data included all dispensed prescription antidepressants (ATC code N06A). For Croatia, Finland, Germany, Lombardy, Slovenia, Sweden, the data were stratified into five age groups (0–17, 18–44, 45–64, 65–74 and 75 years and over) and by sex. In addition, for these six countries/regions, monthly data on counts of incident recipients of antidepressants were used. We performed a descriptive analysis and an interrupted time series analysis using ARIMA methods. We introduced two types of external regressors: To capture the short-term changes in the first three months of the pandemic, we introduced a regressor that reflected the presumed stockpiling behaviour between March 2020 and May 2020. To assess the longer-term effect of the pandemic, we explored changes in trend. For this purpose, we used a ramp regressor with onset immediately subsequent to the short-term regressor, i.e., in June 2020, and finishing at the end of the observation period. For six regions, we analysed volume and incident use stratified by age and sex.

Results: During the pandemic, the pre-existing long-term trend in unstratified dispensed volumes significantly increased only in Slovenia and Germany and weakened in Scotland and Wales (estimated changes in slope +0.16, +0.10, –0.23, and –0.68 defined daily doses per thousand inhabitants per day, respectively, for each month). In all regions except Slovenia there was a significant stock-piling effect in March 2020, followed by decreases in April and May. Remarkably, in Slovenia, the opposite occurred. The stratified quarterly analysis revealed the greatest relative increase in females aged 0–17 (+64% in Sweden to +167% in Croatia in the last quarter of 2022 compared with the last quarter of 2019). Both rate of change and difference between sexes were lower in higher age groups. Incidence increased most steeply in females aged 0–17, where the estimated pandemic-related increase explained 11% (Sweden) to 55% (Lombardy) of new patients receiving antidepressants.

Conclusion: The trends observed during the pandemic did not always significantly differ from the trends already established before the pandemic. However, there are substantial country-, age-, and sex-specific developments. The most marked changes in incidence during the later stages of the pandemic were observed in the youngest age group, especially in Lombardy, which belonged to the regions most affected by the COVID-19 pandemic and subsequent restrictive measures. However, an increase attributable to the pandemic, at least in the period until the end of 2021, also occurred in all other countries/regions in this age group, predominantly in females. In 2022, the incidence among the youngest stabilized except for Lombardy, where it continued to grow, and Slovenia, where it started to decrease again. The moderation of dynamics observed in most countries/regions may be a consequence of the easing of anti-COVID-19 measures or of growing resilience. Overall, we found a substantial set of common developments in these regions, most notably, a marked increase in antidepressant dispensing in female adolescents. Contrary to our initial expectations, older age groups, including the elderly, were substantially less affected. Also, in higher age groups, COVID-19-associated changes differed much less between males and females. Regions with high antidepressant use already before the pandemic showed no increase in the overall trend of dispensed volume. Further research is needed to investigate the effects of various restrictive measures on population subgroups and to find effective measures for increasing resilience and mitigating the impact of potential future public health crises on mental health, especially in young people. Such analysis may require development of a theoretical framework for assessing strategic, pandemic-scale interventions and also detailed patient-level data.

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From manufacturing to patient: Ensuring stability and integrity of frozen faecal microbiota capsules during storage and shipping in the setting of the FRESCO trial

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Background: The ongoing FRESCO trial [1] is designed to assess the efficacy and safety of long-term (12 weeks) oral administration of frozen encapsulated faecal microbiota (FM) and a sterile microbiota filtrate (FMF) compared to placebo (PL) in patients with mild to moderate active ulcerative colitis (UC).

A key challenge in the supply of frozen FM or FMF capsules is ensuring the integrity and stability of the frozen investigational medicinal product (IMP) throughout the entire supply chain – from manufacturing to administration to the patient – in order to preserve therapeutic potential and safety. After manufacture, the capsules should be stored at temperatures of ≤ -65 °C and remain frozen at ≤ -10 °C during transport and storage at the patient's home.

Materials and Methods: Storage conditions of FM and FMF capsules have been tested for integrity and stability at ≤ -65 °C over a period of 12 months and at -15 °C \pm 5 °C over a period of 3 months.

The composition of FM in the produced and stored bulk material should remain above 75 % similarity compared to the initial reference stool sample and should not drop below an acceptable 70 % similarity threshold predefined for the trial after 12 months of storage, as determined by 16S rRNA gene sequencing of the V1V2 variable regions of the 16S rRNA gene and Bray-Curtis similarity analysis.

The stability of FMF was proved by photometric analysis of bile acids, total protein, aspartate aminotransferase (ASAT) and glutamate dehydrogenase (GLDH) from 1 day up to 12 months after storage at ≤ -65 °C. The analytes must remain stable over this time as assessed using the Wilcoxon rank signed test.

The shipping process was validated by measuring the temperature in the transport boxes used (va-Q-med 7 premium, Va-Q-tec®) at various time points up to 30 hours.

For the checking of IMP temperature during the transport, a temperature measurement strip was enclosed to the box, controlled and documented on an inspection sheet at the clinical trial centres to ensure temperature monitoring and storage conditions.

To assure the storage temperature at the patient's deep freezer, a thermometer is included with the delivery, allowing the patient to monitor the daily temperature of the IMP.

Results: When testing the microbiota stability of FM capsules the similarity of the bacterial community between the reference stool sample and the capsules stored at different temperatures (≤ -65 °C, -15 °C \pm 5 °C) for different storage periods up to 12 month was > 78 % for all batches tested and thus above the accepted threshold.

Studies of FMF showed no negative impact of storage at ≤ -65 °C on the stability of the analytes (bile acids, total protein, ASAT, GLDH) in the FMF capsules over a period up to 12 months. Furthermore, an increased temperature of -15 °C \pm 5 °C over 3 months also revealed no significant effect on stability of the analytes compared to storage at ≤ -65 °C.

The process validation for shipping the IMP was successfully completed. The shipping process with IMP was simulated and the temperature curve was monitored. After 24 hours, the temperature in the box was at least below -18.2 °C, and after 30 hours below -17 °C. The clinical trial centers confirmed the specified temperature of the IMP delivery and the storage conditions on the inspection sheet. All results met the specified acceptance criteria. The procedure and documentation of the shipping process were validated, justified, and approved for the FRESCO study.

The storage temperature of the IMP at the patient's deep freezer is daily documented in the patient diary and proved by the study monitor.

Conclusion: Validated processes for storage and shipping of frozen IMPs within the FRESCO trial were established maintaining the integrity and stability of the IMPs throughout the entire supply chain. Based on the stability data collected, the Federal Institute for Drugs and Medical Devices (BfArM) approved an extension of the shelf life of the frozen capsules from 6 to 12 months. The processes were successfully carried out over a period of 180 IMP shipments, without any deviation in temperature.

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Manufacturing frozen double encapsulated faecal microbiota as innovative therapy option for FRESCO-study (long-term transfer of FROzen Encapsulated, multi-donor-Stool for active ulcerative Colitis)

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Background: Developing innovative therapeutic strategies to restore gut microbiota has gained significant interest across various conditions, including gastrointestinal, metabolic, neurologic, hematological, inflammatory, neoplastic and infectious diseases. The approach of faecal microbiota transplantation (FMT) has emerged as a promising method to rebalance the intestinal microbial diversity and functionality by transferring a complex collection of microorganisms from healthy donors to patients. Dysbiosis in gut microbiota is increasingly recognized as one key contributor in the pathogenesis and activity of ulcerative colitis. Meta-analyses have shown, that FMT significantly improves remission rates in ulcerative colitis patients [1], [2]. However, colonoscopic delivery of FM cannot provide continuous, long-term administration and is associated with safety concerns for patients, limiting its widespread use.

Materials and Methods: Faecal microbiota (FM), faecal microbiota filtrates (< 0.2 µm, FMF) or placebo (0.9 % NaCl, PL) are double encapsulated in enteric-coated hypromellose capsules (Vcaps entericTM, Lonza). Donors undergo extensive screenings to exclude potential pathogens, in accordance with safety requirements from the Federal Institute for Drugs and Medical Devices (BfArM). To increase the transferred microbial diversity, a multi-donor strategy is used by pooling capsules from different donors. The frozen capsules are orally administered in patients enrolled in the FRESCO study [3] – a randomized, double-blind, placebo-controlled, three-arm, multicentre trial in patients with mild to moderate active ulcerative colitis.

Results: The investigational medicinal products (IMP) – double-encapsulated faecal microbiota (FM), faecal microbiota filtrates (FMF), and placebo (PL) – are classified as medicinal products that require a manufacturing licence. Therefore, a quality management system has been implemented covering all manufacturing and quality control processes in accordance with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) including comprehensive qualification and validation of the equipment used and the processes. In the setting of the FRESCO trial, each patient receives 600 capsules (FM, FMF or PL) over a period of 12 weeks by two successive supplies. More than 150 IMPs, corresponding to more than 90.000 capsules, have been released since the start of the study in 2023.

Conclusion: The encapsulation of fecal microbiota represents an innovative development in microbiome therapies, offering a convenient and effective method of treatment that simplifies application, improves patient safety, and may enhance compliance in comparison to colonoscopic application. Here, we present the qualified process of manufacturing frozen capsules according to GMP requirements and certified by inspections of the State Authority of Thuringia (TLV). The FRESCO study contributes to assess long-term clinical efficacy and safety of frozen multi-donor FMT in active ulcerative colitis.

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Introduction of Biopharmaceuticals in Europe: Early Diffusion Patterns and Data Availability

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Background: Many therapeutic innovations are biopharmaceuticals, also referred to as biologics. Their applications include a diverse set of therapeutic areas incorporating oncology, rheumatology, endocrinology, dermatology, infectious diseases, and immunology. Biopharmaceuticals offer a number of advantages over synthetic drugs. Complexity in their development and production as well as in their handling are reasons stated for their high prices compared to traditional medicines. Hence, health systems in Europe face clinical and economic challenges with introducing them. As drug expenditure is rising rapidly, outpacing other healthcare expenses, biopharmaceuticals account for a significant portion of this increase. In view of this, payers and health technology assessment agencies are compelled to prioritize and make tough decisions regarding which medicines genuinely offer value for patient care and deliver favourable cost effectiveness, and which do not, to more effectively target scarce resources. Joint efforts across Europe are therefore essential to ensure their sustainable and equitable use. However, to date few cross-national comparative studies have assessed their introduction. Our study aimed to assess the availability of health authority data and variation in the early diffusion of biopharmaceuticals across Europe. – This presentation is based on a paper by Veszelei et al. [1].

Materials and Methods: A cross-sectional design was used to assess the availability of health authority data across Europe and to assess the utilization of biopharmaceuticals introduced between 2015 and 2019, in both hospital and out-of-hospital care. For our study, we selected 17 biopharmaceuticals across 7 distinct ATC groups (level 4), reflecting a wide range of therapeutic areas. 17 European countries and 2 regions were able to provide data on biologicals administered in-hospital, dispensed out-of-hospital and/or provided by wholesalers for the period 2015 to 2022. A scoring system was implemented to provide a rank for the whole study population regarding their overall biopharmaceutical diffusion for these therapies. Each country was assigned a score that ranged from 1 to 19, reflecting its relative accumulated diffusion across each therapeutic area. The country with the highest diffusion in each graph received the lowest score, while the country with the lowest diffusion received the highest. If two or more countries/regions had identical values, they were given equal scores. The overall rank was determined by summing their scores across all seven therapeutic areas, where a lower total score indicated higher biopharmaceutical diffusion.

Results: Germany and Austria exhibited the highest overall diffusion rates and were ranked 1 and 2, respectively. Norway, Sweden, Iceland, and Denmark similarly demonstrated high diffusion rates, with Norway leading this group. Finland, the last remaining Northern country, positioned itself in the middle of the rankings. Belgium closely followed the rank of the first four Nordic countries. A small gap separates Belgium from Italy, which ranks eighth with higher diffusion than the average study population. In contrast, Catalonia was ranked in the middle, while Scotland was ranked 13th with lower diffusion rates. Croatia was ranked among the five countries with the lowest diffusion. All central and Eastern European countries, with the exception of Slovenia, displayed low diffusion rates and were consequently ranked below the average rank. The lowest rankings were observed in Slovakia, Lithuania, Romania, and Latvia. When differentiating according to therapeutic group, the Southern European countries and regions Italy and Catalonia, along with Scotland and Croatia, showed varied diffusion rates in the respective therapeutic groups. In contrast, three Western European countries, Austria, Belgium, and Germany, displayed high or medium diffusion rates across all therapy groups, apart from the fixed dose combination of insulin glargine and lixisenatide, as well as follitropin delta. Notable is that in these categories, comparable European countries, by their respective ranking, exhibited inconsistent diffusion patterns. In examining the early diffusion of specific therapies, tildrakizumab demonstrated the lowest level of diffusion, with 12 countries or regions showing no uptake. Follitropin delta had nine countries/regions without any diffusion during the studied period. In contrast, secukinumab and erenumab exhibited the highest diffusion rates, with all countries showing an uptake. For the remaining therapies, the diffusion was widespread, with only one or two countries or regions lacking diffusion on average.

Conclusion: This study is, to the best of our knowledge, the first to investigate the market diffusion of a large number of different premium-priced biopharmaceuticals across Europe using health authority data. By incorporating real-world drug utilization data from 17 European countries and two regions, it reveals variability in the early diffusion of biopharmaceuticals across these nations and regions. The differences are likely attributable to several interlinking and interacting reasons. Among the determinants are market size, strength of economy, price regulation mechanisms, differences in early access, clinical traditions, and prevalence rates. Additionally, the study highlighted substantial challenges in acquiring data from health authorities and considerable differences in the data that were provided for monitoring drug utilization across the included countries/regions. The findings highlight the importance of strengthened collaboration between European countries to support the sustainable, cost-effective, and equitable introduction of biopharmaceuticals, particularly in settings with constrained resources. They also underscore the need for more harmonized data collection and reporting to better understand the disparities in biopharmaceutical diffusion across Europe.

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Interprofessional Collaboration in the Medication Process: An Analysis of the AMTS Action Plans since 2007

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Background: Medication safety (Arzneimitteltherapiesicherheit, AMTS) centers on ensuring the integrity of the entire medication process – from prescribing by physicians to dispensing in pharmacies, and ultimately to correct administration by patients, caregivers, or other involved parties. The goal is to align each step of the process to minimize risks and enhance therapeutic safety. Achieving AMTS requires interprofessional collaboration across all sectors, particularly in light of increasing digitalization in healthcare. The “Action Plan of the Federal Ministry of Health to Improve Medication Safety in Germany” (AMTS Action Plan) has, since its inception, aimed to strengthen interprofessional cooperation to improve patient safety in medication use. This analysis focuses on related activities within the AMTS Action Plan since 2007 and examines their development and implementation.

Materials and Methods: The analysis is based on AMTS Action Plans published by the Federal Ministry of Health between 2007 and 2021. A systematic document analysis was conducted to identify all measures related to interprofessional collaboration, extract thematic priorities, and examine additional parameters such as implementation strategies. Furthermore, the study investigates which solution approaches were developed, discussed, and – where applicable – implemented by stakeholders over time.

Results: Initial evaluations of the documented measures show that improving interprofessional collaboration within the medication process is a recurring theme. Between 2007 and 2021, a total of five AMTS Action Plans were published (n=5), comprising 231 documented measures (n=231). Of these, 3% (n=7) directly and approximately 12% (n=27) indirectly relate to interprofessional collaboration. Key thematic areas include medication safety checks, the medication process itself, and cross-sectoral care. A more detailed analysis of these developments will be presented in the poster session.

Conclusion: Preliminary findings indicate that interprofessional collaboration has been consistently addressed in the AMTS Action Plans. However, most proposed solutions remain at a conceptual level and have yet to be translated into binding structures. A systematic and practice-oriented design of interprofessional collaboration remains a central challenge for the implementation of AMTS. Final assessments will be presented following completion of the full analysis.

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ALERT – analysis of adverse drug reactions and medication errors in adults in Germany

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Background: 30-60% of all adverse drug reactions (ADRs) are estimated to be avoidable [1]. To reduce ADRs, further knowledge about their occurrence, types and associated factors, is necessary. Medication errors (MEs) are defined as unintended failures in the drug treatment process that lead to, or have the potential to lead to, harm to the patient. They are considered to be avoidable in all cases [2].

Funded by the Innovation fund of the Federal Joint Committee, ALERT aims to characterize ADRs and MEs in adults in Germany with a particular focus set on polymedicated patients, older patients and severe ADRs by generating quantifying data regarding frequency, severity and associated factors. In conjunction with an in-depth analysis of the subgroups of particular interest these analyses should allow for conclusions on the causes of ADRs and MEs and the establishing of key facts as a basis for recommendations to reduce ADRs and MEs.

Materials and Methods: In ALERT we conduct a retrospective, non-interventional pharmacoepidemiological study using five complementary real-world data sources referring to inpatients and outpatients. These include:

1. spontaneous ADR reports with and without MEs from EudraVigilance;
2. ME reports without ADRs from the German Federal Institute for Drugs and Medical Devices (BfArM) drug therapy safety database;
3. systematically collected ADR/ME cases, which led to a presentation in emergency departments, from the ADRED study;
4. electronic health records from the University Hospital Bonn (UKB), comprising diagnoses, drug therapies, and inpatient clinical records; and
5. nationwide outpatient routine data according to § 300 (2) SGB V and § 295 SGB V from the Associations of Statutory Health Insurance Physicians provided by the Central Research Institute for Ambulatory Health Care (Zi), covering drug prescriptions and diagnostic codes across all statutory health insurers.

Notably, each dataset carries inherent limitations. Hence, our methodological approach was to perform a complementary analysis of all data sources with a view to compensate for some of these individual limitations.

Results: About 280,000 spontaneous reports of ADRs were found in the EudraVigilance database with over 43,000 cases regarding polymedicated patients, over 103,000 regarding older patients (≥ 65 years) and over 120,000 reports with serious ADRs. Of these, almost 9,000 involved MEs, and another about 3,000 ME-reports were found in the drug therapy safety database of the BfArM. Results from the reports will be linked to outpatient routine data from the Zi (drug prescriptions and diagnoses of approximately 47,4 million adult patients per year) to allow quantification of drug use frequency and estimation of ADR reporting rates. For further analysis of the inpatient sector, around 115,000 cases regarding 79,000 patients from the electronic health records of the university hospital Bonn (UKB) as well as around 8,000 cases from the ADRED cohort including in- and outpatient data are available for further in-depth analyses.

Conclusion: The data sources mentioned above are in general suitable for further in-depth analyses of ADRs and MEs in both, inpatient and outpatient care. These analyses will target factors being associated with ADRs and MEs such as polymedication and age.

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(AI-Supported) Use of Observational Data in Regulatory Research

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Background: Evidence derived from real-world data (“real-world evidence”, RWE) is increasingly being considered in regulatory decision-making processes at national and international levels. Observational data have become an established source of knowledge, particularly for the assessment of drug safety. The possible use of this data throughout the entire life cycle of a drug are as diverse as the data sources themselves.

The objective is to provide an overview of the current use of RWE into regulatory decision-making and to provide insights from two research projects conducted at the German Federal Institute for Drugs and Medical Devices (BfArM): FQrisk and Real4Reg.

Materials and Methods: FQrisk is a cohort study based on nationwide claims data from the German statutory health insurance AOK examining the safety of fluoroquinolone antibiotics using current good pharmacoepidemiological practice. Real4Reg is an EU-funded multi-stakeholder project that leverages various observational data sources from Denmark, Finland, Portugal, and Germany. It focuses on the heterogeneity of observational data and the possibilities for optimising the current standard of analysis using AI-driven approaches such as super learners, large language models and neural networks for propensity scores, conditional average treatment effects or the identification of confounding factors.

Conclusion: The role of RWE in regulatory research and decision-making is contextualised by the presentation of the two research projects, while potential challenges, solutions and use cases for the application of observational data in regulatory research are discussed.

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Use of targeted therapy in non-small-cell lung cancer patients in rural and urban areas of Saxony-Anhalt (2010–2023)

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Background: Over the past two decades, numerous targeted therapies (TT) have been integrated into routine non-small-cell lung cancer (NSCLC) treatment in Germany. This study aims to assess regional disparities in the utilization of TT for NSCLC in Saxony-Anhalt using cancer registry data.

Materials and Methods: Cancer registry in Saxony-Anhalt collects data on all curative and palliative systemic treatments. TT were identified according to the ENCR recommendations on recording treatment data [1] and classified according to the Anatomical Therapeutic Chemical Classification System levels [2]. Rural areas were defined as counties with a low urbanity index of the Central Research Institute of Ambulatory Health Care (ZI) [3].

Results: This study included 13,379 NSCLC patients from rural areas and 4,504 from urban areas, diagnosed between 2010 and 2023. From 2010 to 2014, epidermal growth factor receptor tyrosine kinase inhibitors (N=192, 35%) and vascular endothelial growth factor inhibitors (N=179, 33%) were the most commonly used TT. Programmed cell death protein 1/death ligand 1 inhibitors were the most commonly used TT group from 2015 to 2019 (N=1,625, 62%), and this increase continued from 2020 to 2023 (N=2,253, 81%). Overall, the utilization of TT increased over time, with an increase observed both for patients residing in rural areas (2010-2014: 10%, 2015-2019: 41%, 2020-2023: 50%) and in urban areas (2010-2014: 9%, 2015-2019: 38%, 2020-2023: 41%). Similar disparities were observed in both early-stage (UICC I-III: urban: 17% vs. rural: 23%) and advanced NSCLC (UICC IV: urban: 45% vs. rural: 53%).

Conclusion: Despite concerns regarding healthcare access in rural areas, the utilization TT for NSCLC in Saxony-Anhalt has increased over time, in both rural and urban areas. The present study demonstrates that cancer registry data is a valuable resource for conducting drug utilization studies in Germany. Future research should examine referral patterns between regions and clinical centers and treatment timeliness to better understand TT utilization trends.

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Individual Pharmacotherapy Management (IPM) also identifies risks to drug therapy and patient safety arising from guideline recommendations

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Background: The Individual Pharmacotherapy Management (IPM) systematically identifies and rectifies drug-related risks, including those arising from guideline-based recommendations, to enhance patient safety [1], [2], [3], [4], [5], [6]. Although clinical practice guidelines lack legal force, they are evidence-based, consensus-driven standards that shape diagnostic and therapeutic decision-making in routine care. Given the importance of drug therapy safety, it is long overdue that the issue of reconciling guideline adherence with patient-centred risk evaluation is addressed.

Materials and Methods: The defining feature of the IPM, conceptualised by the author based on her internal medicine and clinical pharmacology background, is the adaptation of medication scores to patient scores (Figure 1). Drawing on her experience of conducting over 68,500 IPM analyses, the author has also approved the use of AI-assisted IPM with simulated models. In patient care, anonymised, AI-supported IPM requires informed patient consent. The IPM aims to review the medication list as accurately as possible in reference to the individual patient's condition. This uncovers real-world pathophysiological abnormalities and risk factors, particularly in the context of polypharmacy. The resulting personalised evaluation, aligned with guideline recommendations, supports the comprehensive detection of clinically relevant medication risks in the individual patient.

Results: IPM also detected risks to drug therapy and patient safety that resulted from guideline-based recommendations. The major categories of risks identified include adverse drug reactions, which can manifest acutely, in the long term or cumulatively. Additional risks arise from over-prescription and drug-disease interactions. It is imperative that these risks are recognised, documented and communicated to the attending physician. While monitoring can reduce certain risks, contraindicated therapies must be strictly avoided in cases of drug-disease interaction. Examples of various contextual IPM-detected cases are presented [7].

Conclusion: In terms of guideline recommendations, it is imperative to eliminate any additional risks to patients that may arise from the recommended drug therapy. Due to the specialization of medical disciplines, comprehensive pharmacological oversight, especially in cases of polypharmacy, is often lacking. Implementing established pharmacological expertise or AI-supported tools such as IPM can serve as effective preventive measures to ensure drug and patient safety in guideline-recommended therapy. Reconciling guideline adherence with patient-centered risk evaluation, IPM offers the unique structured approach to safeguard pharmacotherapy, prevent avoidable harm, and maintain clinical effectiveness.

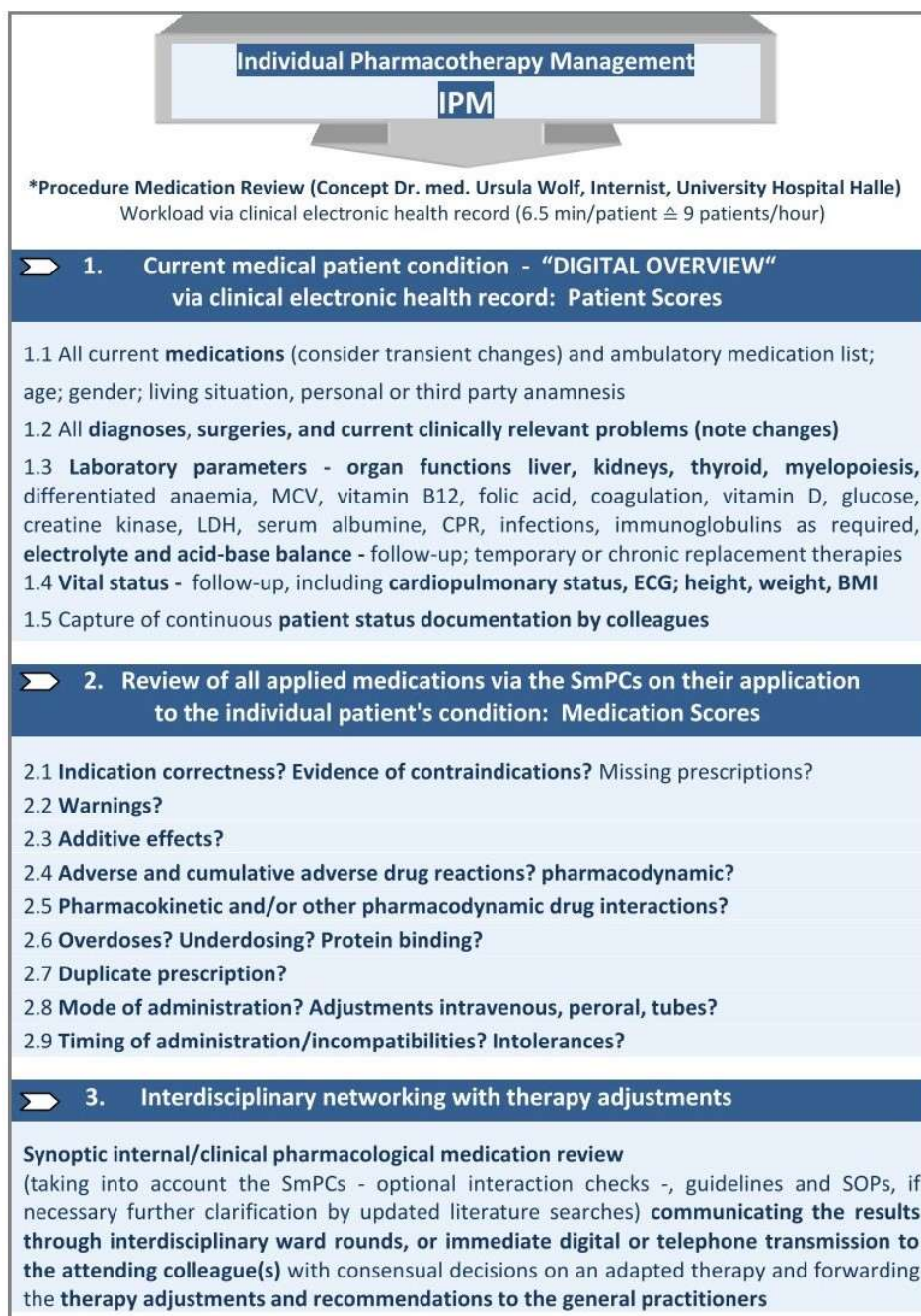


Figure 1: Comprehensive, reproducible Individual Pharmacotherapy Management to identify and counteract individual pathophysiological patient conditions which may be iatrogenically induced by drugs.

* IPM (applied Patient and Medication Scores) based on the inpatient Electronic Health Record (EHR) and Summaries of Product Characteristics (SmPCs), defined, conceptualised, implemented and practised by Ursula Wolf, MD, Head of Pharmacotherapy Management Department, Specialist in Internal Medicine with expertise in Clinical Pharmacology, performed >65,800 individual medication reviews for polypharmacy in elderly trauma, dementia, transplant and intensive care patients. The IPM physician applies the SmPCs by matching their evidence-based defined risks to the digitally captured individual Patient Scores which provide the necessary 'comprehensive patient overview'.

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Individual Pharmacotherapy Management (IPM) with defined electronic patient and medication scores prevents far-reaching multidimensional polypharmacy risks and is universally applicable with AI support

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Background: In multimorbidity and severe acute critical illness, polypharmacy [1] is mostly unavoidable. There is no prevention tool that considers the full range of risks [2] associated with adverse drug reactions (ADRs), intensified by drug-drug interactions (DDIs), drug-disease interactions (DDSIs), incorrect dosing and contraindications for the individual patient condition. An AI-based version would provide high future impact and is urgently needed. This study addressed these ongoing high-risk, high-consequence challenges for vulnerable patient groups in geriatric traumatology, intensive care, and transplantation medicine [3], [4] at University Medicine Halle (UMH) to provide and evaluate an evidence-based digital drug therapy and patient safety concept.

Materials and Methods: Real-world challenges in the half-daily routine reviewing of 25 to 52 high-risk polypharmacy medications, meanwhile 68,500 self-conducted medication reviews, necessitated a standardised, personalised bottom-up design to prevent any drug-related risks in polypharmacy. The Individual Pharmacotherapy Management (IPM) approach was conceptualised by applying defined patient scores based on individual patient conditions from his/her electronic health records, including diagnoses, laboratory data on organ functions and vital parameters and referring to the SmPCs for each individual medication adaptation (Figure 1). The associated effectiveness of IPM was assessed using retrospective pre/post studies in geriatric traumatology [5] on the primary outcomes of delirium, in-hospital falls, and renal impairment, with multivariable regression analyses. Furthermore, IPM efficiency was analysed based on comparative internal hospital quality control data in interdisciplinary intensive care units (ICU).

Results: The resulting IPM medication adaptations primarily related to identified pathophysiological abnormalities from cumulative ADRs, frequently pharmacodynamic DDIs, overdoses, pharmacokinetic DDIs, DDSIs, contraindications, anticholinergic burden, high-risk psychotropic drugs, benzodiazepines, serotonergic opioids, and missing prescriptions. The resulting targeted, personalised IPM interventions were associated with multidimensional, significant reductions of delirium (90 rel%), in-hospital falls (83 rel%) and any progression of renal impairment (100 rel%), identifying associated risk factors. The average length of stay for the most severely ill ICU patients decreased from 29.1 to 23.2 days within four years from onset of the IPM implementation. This provided a higher capacity for patients to be treated, by 32.7% in the ICUs, where critically ill patients are often mechanically ventilated and dialysed. Despite higher patient numbers, medication costs in the two interdisciplinary ICUs reduced by €451.597 (28%) during the first four IPM-years already [5], [6], [7], [8]. Drawing on her experience of conducting over 68,500 IPM analyses, the author has also approved the applicability of AI-assisted IPM with simulated models. This is achieved by continuously improving Perplexity-AI, among others, which enables the extended, easy and universal use of IPM. This application is accessible not only to healthcare providers, but to everyone, and supports patient empowerment, co-responsibility and health literacy. In patient care, anonymised, AI-supported IPM requires informed consent from the patient. Only the attending physician is authorised to implement IPM therapy recommendations.

Conclusion: According to the IPM real-world evidenced multidimensional preventive associations, the use of IPM scores ensures effective reproducibility and interoperability, even in multiprofessional teams and AI-supported applications. This structured, methodical strength and robustness positions the IPM as an internationally applicable model for improving drug therapy and patient safety in polypharmacy and caring for vulnerable patient groups, contributing to the running WHO-coordinated UN Decade of Healthy Ageing (2021-2030) [9].

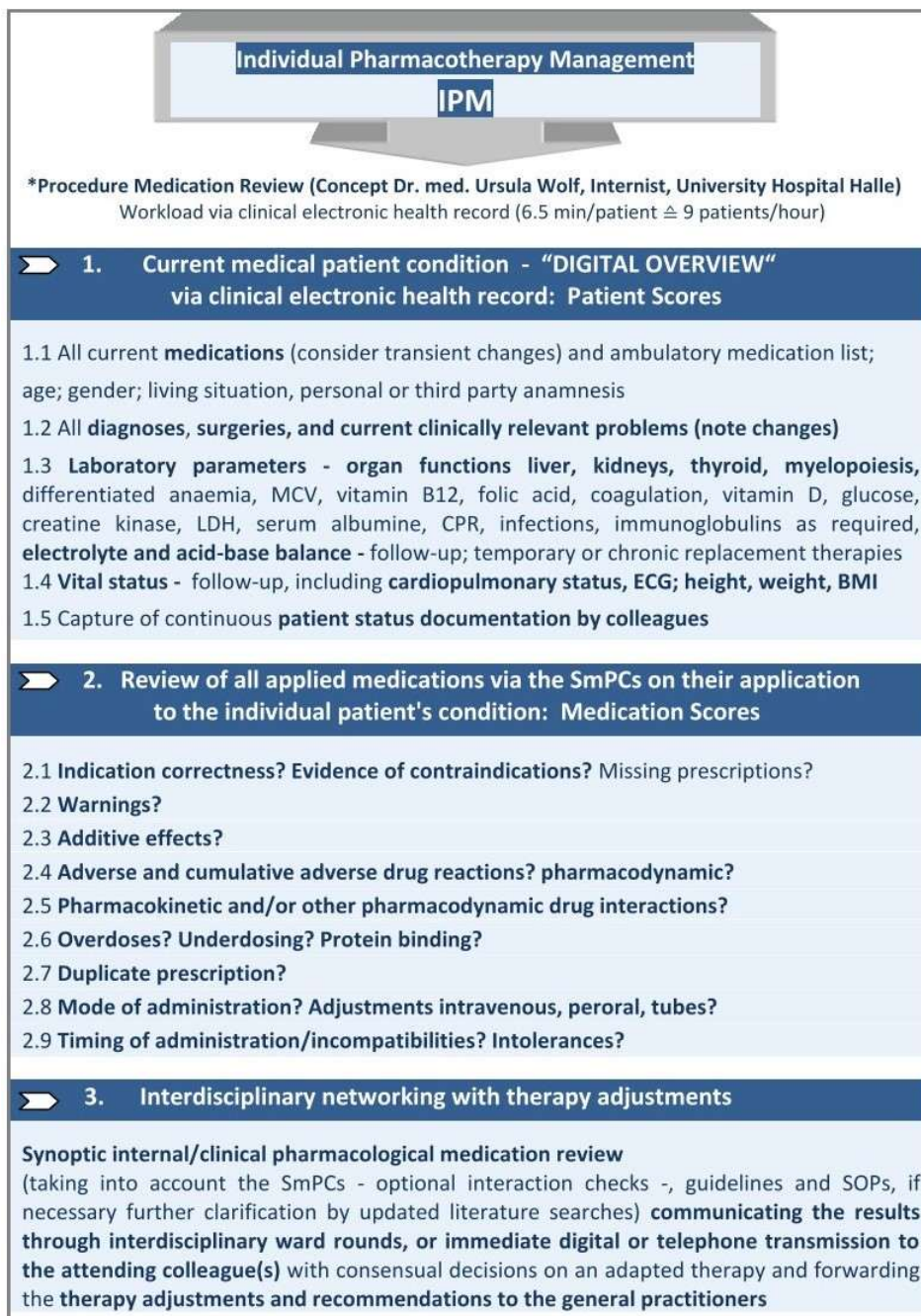


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