

Gesellschaft für
Arzneimittelanwendungsforschung und
Arzneimittelepidemiologie

ABSTRACTBAND

33. Jahrestagung

29. bis 30. Oktober 2026

München

Gesellschaft für Arzneimittelanwendungsforschung
und Arzneimittelepidemiologie e. V.



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http://www.egms.de/de/meetings/gaa2026/

Sehr geehrte Damen und Herren,
liebe Kolleginnen und Kollegen,

im Namen des Vorstandes der GAA heiße ich Sie ganz herzlich bei unserer 33. Jahrestagung willkommen.

Wie in den vergangenen Jahren werden wir am Donnerstagvormittag vor der gewohnten Abfolge der Tagungssessions wieder mit einem Pre-Conference-Workshop starten. Der Fokus liegt auf komplexen Interventionen zur Verbesserung der Arzneimitteltherapie. Danach stehen verschiedene Sessions zu aktuellen Themen rund um unser Leitmotiv "Arzneimittelanwendungsforschung und Arzneimittelepidemiologie" auf dem Programm. Einzelheiten zu den Themenblöcken und dem Pre-Conference-Workshop entnehmen Sie bitte diesem Programmheft.

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 ausgezeichnet 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 30. Oktober 2026 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

Komplexe Interventionen zur Verbesserung der Arzneimitteltherapie am Beispiel des Deprescribing

Ort:
St. Vinzenz Haus, Nußbaumstraße 5, 80336 München
Treffpunkt: Friedrich von Gärtner Saal (EG, V0.20)

Anreise mit den U-Bahn-Linien U1, U2, U3 oder U6 (Ausgang F), Straßenbahn-Linien 16, 17, 18, 27 oder 28 bzw. Buslinien 52 oder 62; Haltestelle „Sendlinger Tor" aussteigen in Richtung Nußbaumstraße. Nach etwa 400 m links durch den Torbogen und der Beschilderung folgen.

Donnerstag, 29. Oktober 2026

10:00 – 12:00 **Pre-Conference-Workshop**

Komplexe Interventionen zur Verbesserung der Arzneimitteltherapie am Beispiel des Deprescribing

Die Verbesserung der Arzneimitteltherapie erfordert oft komplexe Interventionen, zum Beispiel bei Polypharmazie und potenziell unangemessener Medikation. Ihre Entwicklung und Evaluation stellt jedoch hohe methodische Anforderungen, da mehrere Akteure und Versorgungsebenen einzubinden und Verhaltensänderungen gefordert sind.

Ziel des Workshops ist, ein grundlegendes Verständnis komplexer Interventionsforschung sowie typischer methodischer Herausforderungen zu vermitteln. Der Workshop kombiniert kurze methodische Inputs mit interaktiven Arbeitsphasen. Am Beispiel des Deprescribing diskutieren die Teilnehmenden praxisnah u.a. die theoriegeleitete Entwicklung komplexer Interventionen, die Identifikation von Umsetzungsbarrieren, die Auswahl geeigneter Evaluationsdesigns sowie die Rolle von Prozessevaluation und Implementierungsaspekten.

Inhaltliches Konzept:
Prof. Dr. Tobias Dreischulte, Professor für Klinische Versorgungsforschung,
Institut für Allgemeinmedizin, LMU Klinikum München

Wissenschaftliches Programm der 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie e. V. (GAA)

Tagungsort:
St. Vinzenz Haus (LMU Klinikum München)
Nußbaumstraße 5, 80336 München

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

Donnerstag, 29. Oktober 2026	
Pre-Conference Workshop	
	Vorsitz: Dreischulte T, München
10:00 – 12:00	**Thema:** Komplexe Interventionen zur Verbesserung der Arzneimitteltherapie am Beispiel des Deprescribing
Jahrestagung – Hauptprogramm	
12:00 – 13:00	**Ankunft, Registrierung** und Mittagsimbiss
13:00 – 13:15	**Begrüßung und Einführung** in die Tagung (Gothe H, GAA)
13:15 – 13:30	**Grußwort** des Direktors des Instituts für Allgemeinmedizin des LMU Klinikums München (Gensichen J, München)
Themenschwerpunkt 1: Überversorgung mit Arzneimitteln	
	Vorsitz: Gothe H, GAA
13:30 – 14:05	**Key Note:** Arzneimitteltherapie im Alter – rational statt rationiert? (Kühlein T, Erlangen)
14:05 – 14:20	Überbehandlung bei Levothyroxin-Nutzenden anhand diagnostischer und prognostischer Thyreotropin (TSH)-Grenzwerte: Eine bevölkerungsbasierte Studie (Scholle O, Bremen)
14:20 – 14:35	Influenza-Impfquote bei ab 60-Jährigen und speziellen Risikogruppen (Lappe V, Köln)
14:35 – 15:00	**P a u s e**

Themenschwerpunkt 2: **Zwischen Verordnungsverhalten und Patientenpräferenzen**	
	Vorsitz: Schmiedl S, GAA
15:00 – 15:35	**Key Note:** Deprescribing in der Primärversorgung – Ergebnisse der PARTNER-Studie (Dreischulte T, München)
15:35 – 15:50	Eine Krankheit für jedes zugelassene Medikament? Veränderungen bei psychiatrischen Diagnosen und Verschreibungen bei Mädchen im Jugendalter (Hach I, Nürnberg)
15:50 – 16:05	Partizipative Entwicklung einer Intervention zur Prävention von Krankenhausaufenthalten aufgrund von Magen-Darm-Blutungen: Ein digitales Tool zur Verwendung in der allgemeinmedizinischen Praxis (Puzhko S, Bielefeld)
16:05 – 16:20	Der Einsatz von antiöstrogenen Medikamenten bei Mädchen und Frauen im gebärfähigen Alter sowie vor einer Schwangerschaft in Deutschland (Melcher N, Bremen)
16:20 – 16:35	Gesundheitsökonomische Modellierung bei begrenzten Ressourcen: Evidenzbasierte Entscheidungsunterstützung im Gesundheitswesen (Janke F, Jena)
16:35 – 17:00	**P a u s e**
Postersession 1	
17:00 – 18:00	**Vorsitz:** Jobski K, Lappe V, GAA
	1. Outpatient antidepressant drug use in children and adolescents between 2018 and 2022 – a large claims-based study (Dörks M, Oldenburg) 2. Off-Label-Einsatz von Arzneimitteln in der Pädiatrie: Was ist über die Häufigkeit und die Risiken bekannt? (Eberl S, Erlangen) 3. Mehr Männer als Frauen und mehr in Ost als West nutzen gewichtsreduzierende Medikamente? Analyse gewichtssenkender Arzneimittel in der privaten Krankenversicherung im Zeitverlauf 2019–2023 (Schneider N, Köln) 4. Data-driven identification of multiple medication use in the German National Cohort (NAKO) (Wicherski J, Bonn) 5. Socioeconomic Status and Type 2 Diabetes Mellitus – Identification of Potential Influencing Factors in the NAKO Cohort (Bößneck N, Frankfurt am Main) 6. Scale-Defined Anticholinergic Burden in Population-Based, Community, and Outpatient Settings: Preliminary Findings from an Ongoing Systematic Review (Könnecke J, Frankfurt am Main) 7. Stationsapotheker/in in der Zentralen Notaufnahme: Ein Pilotprojekt an einem deutschen nichtuniversitären Klinikum (Lindner S, von Ameln-Mayerhofer A, Sindelfingen) 8. Community Pharmacy-Based Care in Mental Health: Current Insights from the PharmBePsych Cluster-Randomized Trial (Springer L, Mainz) 9. Pharmakologische Ergebnisse der GESCO-Machbarkeitsstudie: Pilotierung einer geschlechts- und gendersensiblen Primärversorgungsintervention bei Patient:innen mit chronischen, nicht tumorbedingten Schmerzen unter langfristiger Opioidtherapie (Bencheva V, Witten)
	Ende des wissenschaftlichen Teils des ersten Tages
Ab 19:00	**Abendveranstaltung** Ab 19:00 Uhr erwartet uns die Gaststätte Löwenbräukeller, Nymphenburger Str. 2, 80335 München, https://loewenbraeukeller.com/de, Essen à la carte einschl. vegetarischer und veganer Optionen. Wir bitten um verbindliche Voranmeldung im Anmeldeformular zur Jahrestagung.

Freitag, 30. Oktober 2026	
Themenschwerpunkt 3: Evidenzsynthese und Causal Inference mit Arzneimitteldaten	
	Vorsitz: Meyer I, GAA
08:30 – 09:05	**Key Note:** Verwendung von Beobachtungsdaten in der Arzneimittelbewertung (Kühne F, Berlin)
09:05 – 09:40	**Key Note:** Von Arzneimitteldaten zu kausaler Inferenz: Theorie, Studiendesign und Fallstricke in der Versorgungsrealität (Demirer I, Bonn)
09:40 – 09:55	Patientenzahlen im Rahmen des AMNOG-Prozesses: Registerdaten vs. Routinedaten (Ehlert D, Abu Rajab-Conrads N, Köln)
09:55 – 10:10	Unterscheiden sich die Meldungen von Nebenwirkungen durch Verbraucher von denen durch Ärzte und Apotheker? (Dubrall D, Bonn)
10:10 – 10:30	**P a u s e**
Postersession 2	
10:30 – 11:30	**Vorsitz:** Jobski K, Lappe V, GAA
	10. Pharmacological stratification of Fall-Risk-Increasing Drugs for Prevention of Fall-related Injuries in Older Adults: A Population-Based Cohort Study (Schechner M, München) 11. Unerwünschte Ereignisse nach Arzneimittelgabe bei seltenen Erkrankungen – eine Analyse der EudraVigilance-Datenbank im Rahmen des CONTRIBUTE Projekts (Himmel J, Witten) 12. Measuring medication safety in primary care: a systematic review of the clinical content of 26 consensus based prescribing tools (Pohl S, München) 13. Medikationsfehler in Spontanberichten von unerwünschten Arzneimittelwirkungen: Ergebnisse des ALERT-Projekts mit besonderem Fokus auf medizinproduktassoziierten Kontrazeptiva (Weal J, Bonn) 14. Risk of Cancer among GLP-1 Receptor Agonist users: the impact of study design choices (Russek M, Bonn) 15. Nichtmedizinischer Gebrauch verschreibungspflichtiger Arzneimittel in der Berliner Club- und Partyszene (Rottenkolber D, Berlin) 16. Pflanzliche Arzneimittel bei gynäkologischen Beschwerden: Erkenntnisse aus der Real-World-Versorgung und Faktoren der Anwendung (Drebka A, Frankfurt am Main) 17. Verordnungsstatus und Anwendungsgewohnheiten von Ginkgo biloba L.-Blätterextrakt in der NAKO Gesundheitsstudie (Scholl A, Frankfurt am Main)
Themenschwerpunkt 4: Selbstmedikation	
	Vorsitz: Lappe V, GAA
11:30 – 12:05	**Key Note:** Selbstmedikation – was, wie oft, wie lange und wer weiß davon? (Seidling H, Heidelberg)
12:05 – 12:20	Schmerzmittelkonsum und subjektive Medikamentenüberzeugungen bei Personen mit und ohne Kopfschmerzen in Deutschland: Eine Analyse des Epidemiologischen Suchtsurveys (ESA 2021) (Moormann N, Oldenburg)

Themenschwerpunkt 5: **Aktuelle Herausforderungen der ePA**	
	Vorsitz: Bergner S, GAA
12:20 – 12:55	**Key Note:** Die elektronische Medikationsliste als Baustein der AMTS (Dartsch D, Hamburg)
12:55 – 13:15	**Prämierung der Poster, Abschluss und Verabschiedung** (Jobski K, Gothe H, GAA)
13:15 – 13:45	**M i t t a g s p a u s e**
13:45 – 15:00	**Mitgliederversammlung der GAA** Gäste sind willkommen.

Abstracts

01

Pharmakologische Ergebnisse der GESCO-Machbarkeitsstudie: Pilotierung einer geschlechts- und gendersensiblen Primärversorgungsintervention bei Patient:innen mit chronischen, nicht tumorbedingten Schmerzen unter langfristiger Opioidtherapie

Veronika Bencheva[1,2], Jordan Preuss[1], Alexandra Schmidt[3], Alexandra Kayser[3], Klaus Weckbecker[4], Neele Kufeld[4], Johannes Just[3], Birgitt Wiese[5], Christine Kersting[3], Achim Mortsiefer[3], Petra Thürmann[1,6]

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[6]Philipp Klee-Institute of Clinical Pharmacology, Helios University Hospital Wuppertal, Wuppertal, Deutschland

Hintergrund/Ziel: Chronische, nicht tumorbedingte Schmerzen (CNCP) werden sowohl durch das biologische Geschlecht (Sex) als auch das soziale Geschlecht (Gender) in ihrer Prävalenz, Symptomatik und Therapie beeinflusst. Darüber hinaus beeinflussen Geschlechterstereotype sowie dyadische Interaktionen die Arzt-Patienten-Kommunikation und damit potenziell die Versorgungsqualität. Trotz dieser Erkenntnisse werden geschlechts- und gendersensible Aspekte in den aktuellen Leitlinien zur Behandlung chronischer, nicht tumorbedingter Schmerzen (LTOT) bislang nur unzureichend berücksichtigt. Die GESCO-Studie (gefördert vom Bundesministerium für Gesundheit, 2522FSB14A/ 2522FSB14B) zielt darauf ab, vorhandenes Wissen zu bündeln und eine praxisnahe, geschlechts- und gendersensible Primärversorgungsintervention für Patient:innen mit CNCP, die LTOT erhalten, zu entwickeln.

Methoden: Die GESCO-Studie wurde gemäß dem MRC Framework for Developing and Evaluating Complex Interventions als Machbarkeitsstudie zur Entwicklung und Evaluation einer komplexen Intervention durchgeführt. Die Interventionsentwicklung basierte auf systematischen Literaturrecherchen, die Entwicklung einer Toolbox sowie ein pharmakologisches Handbuch unter Einbeziehung von Patient:innen und weiteren Stakeholdern. Mithilfe der Theory-of-Change-Methode wurde die Intervention entwickelt und anschließend in einer einarmigen Prä-Post-Pilotstudie mit acht Hausärzt:innen evaluiert, die insgesamt 38 Patient einschlossen. Die Intervention umfasste eine Schulung der Hausärzt:innen und zwei strukturierte, jeweils 30-minütige Arzt-Patient-Konsultationen. Datenerhebungen erfolgten zu Studienbeginn (T0), nach einem Monat (T1) und nach drei Monaten (T2). Der primäre Endpunkt war der Pain Disability Index (PDI). Pharmakologische Endpunkte umfassten die tägliche Opioiddosis (Morphinäquivalent), die Zufriedenheit mit der Arzneimittelinformation (SIMS) und den Pain Medication Questionnaire (PMQ).

Ergebnisse: Der Pain Disability Index (PDI) zeigte eine mittlere Reduktion von 3,38 Punkten zwischen T0 und T2, ohne statistische Signifikanz ($p = 0,078$) zu erreichen. Die Schmerzintensität (0–10) verringerte sich bei Männern von 5,7 auf 5,1 und bei Frauen von 6,1 auf 5,5. Frauen erhielten im Mittel etwa 30 % niedrigere Opioiddosen (Morphinäquivalente) als Männer. Die SIMS-Werte lagen bei Männern zu den Erhebungszeitpunkten höher als bei Frauen und zeigten einen Anstieg im Studienverlauf. Für den PMQ zeigte sich ebenfalls eine Verbesserung der Werte im Verlauf der Intervention, wobei Männer eine stärkere Verbesserung aufwiesen als Frauen; der Unterschied in den Veränderungswerten war jedoch nicht statistisch signifikant ($p = 0,23$, Mann-Whitney-U-Test).

Diskussion/Schlussfolgerung: Die GESCO-Studie wurde gemäß dem MRC Framework for Developing and Evaluating Complex Interventions als Machbarkeitsstudie zur Entwicklung und Evaluation einer komplexen Intervention durchgeführt. Die Interventionsentwicklung basierte auf systematischen Literaturrecherchen, die Entwicklung einer Toolbox sowie ein pharmakologisches Handbuch unter Einbeziehung von Patient:innen und weiteren Stakeholdern. Mithilfe der Theory-of-Change-Methode wurde die Intervention entwickelt und anschließend in einer einarmigen Prä-Post-Pilotstudie mit acht Hausärzt:innen evaluiert, die insgesamt 38 Patient einschlossen. Die Intervention umfasste eine Schulung der Hausärzt:innen und zwei strukturierte, jeweils 30-minütige Arzt-Patient-Konsultationen. Datenerhebungen erfolgten zu Studienbeginn (T0), nach einem Monat (T1) und nach drei Monaten (T2). Der primäre Endpunkt war der Pain Disability Index (PDI). Pharmakologische Endpunkte umfassten die tägliche Opioiddosis (Morphinäquivalent), die Zufriedenheit mit der Arzneimittelinformation (SIMS) und den Pain Medication Questionnaire (PMQ).

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Bitte zitieren als: Bencheva V, Preuss J, Schmidt A, Kayser A, Weckbecker K, Kufeld N, Just J, Wiese B, Kersting C, Mortsiefer A, Thürmann P. Pharmakologische Ergebnisse der GESCO-Machbarkeitsstudie: Pilotierung einer geschlechts- und gendersensiblen Primärversorgungsintervention bei Patient:innen mit chronischen, nicht tumorbedingten Schmerzen unter langfristiger Opioidtherapie. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa01.
DOI: 10.3205/26gaa01, URN: urn:nbn:de:0183-26gaa019
Dieser Artikel ist frei verfügbar unter http://www.egms.de/en/meetings/gaa2026/26gaa01.shtml

02

Participatory Development of an Intervention to Prevent Hospitalizations Due to Gastrointestinal Bleeding: A Digital Tool for Use in General Practice

Kerstin Bernartz[1], Svenja Claaßen[1], Leyla Polat[1], Stephanie Picker-Huchzermeyer[1], Kiran Chapidi[1], Prashamsa Chapidi[1], Tobias Dreischulte[2], Marjan van den Akker[1], Christiane Muth[1], Svetlana Puzhko[1]

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Background/Aim: Medication-related adverse events, including gastrointestinal bleeding, pose a significant risk of hospitalization in patients with polypharmacy. However, interventions to improve medication safety are often difficult to implement in general practice because they do not adequately address the practical needs of both general practitioners (GPs) and patients. The aim of this study is to develop a feasible intervention for the prevention of hospitalizations due to gastrointestinal bleeding, using a participatory approach that involves relevant stakeholders, to ensure its suitability for implementation in routine practice.

Methods: The intervention development was based on a participatory, multi-stage research design involving GPs, medical assistants (MAs), pharmacists, specialist physicians, and patients. The process began with a literature review and an initial interprofessional workshop, where evidence-based interventions proven effective were discussed with regard to their implementability and selected for further development. Subsequently, qualitative interviews were conducted with representatives of the stakeholders groups to identify facilitators and barriers to implementation. Building on this, focus groups in the form of deliberative consultations (DCs) [1] were conducted to reach an informed consensus on the implementability of the intervention components and ways to enhance it. The DC methodology is based on principles of democratic deliberation, whereby all perspectives are taken into account and group dynamics are balanced through a two-phase design: deliberations in homogeneous professional groups (phase 1), followed by deliberation in a mixed group comprising representatives of the homogeneous groups (phase 2), with the goal of reaching common working agreements. Rapid qualitative thematic analysis [2] of the transcripts from the workshops, interviews, and deliberations was performed to iteratively select and refine the intervention components to optimize their feasibility based on the findings.

Results: Participating stakeholders, including patients, actively engaged in the various steps of the intervention development and provided constructive feedback, reflected in the content and design of the intervention components. Based on stakeholders´ feedback, the digital TARGET-ADE platform was created, containing a digital tool, study materials, patient brochures, and links to additional resources. The core intervention component is the digital TARGET-ADE tool for GPs. It provides algorithms for risk screening and clinical decision support, including general and medication group-specific recommendations for managing identified risks, as well as conversation guides to support shared decision making with patients about deprescribing and alternative treatments. The patient brochures available on the digital platform are printable educational materials designed to strengthen patients' knowledge of the risks associated with medications that may cause gastrointestinal bleeding and relevant protective measures. Specific brochures address gastrointestinal bleeding, correct medication use, "sick day rules", and general recommendations for safe medication use. The combination of digital and printable materials was considered optimal by all stakeholder groups.

Discussion/Conclusion: Successful prevention of hospitalizations requires strategies that can be implemented in routine healthcare. The participatory intervention development process, involving relevant stakeholders, helped to develop an intervention that the involved stakeholders considered feasible for implementation in routine care. The actual feasibility and acceptability of the digital tool and individual intervention components will be evaluated in a pilot study starting in autumn 2026 in general practices in Ostwestfalen-Lippe.

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1. Rahimzadeh V, Longo C, Gagnon J, Fernandez C, Bartlett G. Assessing the quality of deliberative stakeholder consultations involving allied health profes-sionals in pediatric palliative care and hematology/oncology in Canada. BMC Palliat Care. 2021;20(1):189. DOI: 10.1186/s12904-021-00884-2
2. Mathieson A, Elvey R, Wilson P. Development and application of a qualitative rapid analysis framework in a hybrid trial within primary care. BMJ Open. 2024;14(7):e076792. DOI: 10.1136/bmjopen-2023-076792

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Please cite as: Bernartz K, Claaßen S, Polat L, Picker-Huchzermeyer S, Chapidi K, Chapidi P, Dreischulte T, van den Akker M, Muth C, Puzhko S. Participatory Development of an Intervention to Prevent Hospitalizations Due to Gastrointestinal Bleeding: A Digital Tool for Use in General Practice. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa02.
DOI: 10.3205/26gaa02, URN: urn:nbn:de:0183-26gaa022
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa02.shtml

03

Socioeconomic Status and Type 2 Diabetes Mellitus – Identification of Potential Influencing Factors in the NAKO Cohort

Nele L. Bößneck, Alexandra Drebka, Julie K. Könnecke, Annika J. Scholl, Alexander Hau, Beatrice E. Bachmeier
Goethe Universität, Frankfurt am Main, Germany

Background/Aim: Diabetes mellitus is one of Germany's major health policy challenges, with a prevalence in 2024 of 10.3% in the adult population (men 11.6%, women 9.0%) [1]. Type 2 diabetes (T2D) accounts for 90-95% of all diabetes cases. Prior evidence suggests that the risk of developing T2D is associated with low socioeconomic status [2]. The aim of this study is to comprehensively characterize socioeconomic factors (income, occupational status and education) of T2D in the German National Cohort (NAKO).

Methods: Descriptive statistics and binary logistic regression were used to identify potential influencing factors among individuals with and without T2D in a cross-sectional analysis. From the NAKO baseline cohort (n = 204,605) [3], participants with missing data on age or sex, missing or inconsistent drug utilization data, and those with type 1, gestational or unclear diabetes status were excluded. The final study cohort consisted of 10,096 individuals with T2D and 187,795 without diabetes. We analyzed socioeconomic exposure including monthly net equivalent income, occupational status (ISEI), and educational achievement (ISCED-11) and adjusted for smoking, alcohol consumption, and physical activity.

Results: The prevalence of T2D in our study cohort was 5.05%. Among persons with T2D the majority was male (61.22%) while sex was almost equally distributed among persons without diabetes (49.21% male). Individuals with T2D tended to be older on average (60.54 ± 7.70 years) than those without diabetes (49.29 ± 12.73 years). About one third of the Individuals with T2D were in the lowest income deciles D1 and D2, whereas participants without diabetes tended to belong to higher income deciles (one fifth in D9 and D10). Similar patterns were also evident in occupational status and education. Binary logistic regression showed a socioeconomic gradient in all three factors with low odds for higher socioeconomic levels and high odds in lower socioeconomic levels.

Discussion/Conclusion: T2D was consistently associated with higher odds in lower socioeconomic levels across all three factors examined (income, occupation and education), mostly pronounced for education. These associations persisted after adjustment for smoking, alcohol consumption, and physical activity, suggesting that factors beyond individual health behaviour contribute to the socioeconomic gradient. Our findings support the relevance of socioeconomic factors for comprehensive diabetes care and guideline development. Analyses of potential associations of psychosocial factors as well as patient- and medication-related factors with diabetes status are planned for the next future.

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Please cite as: Bößneck NL, Drebka A, Könnecke JK, Scholl AJ, Hau A, Bachmeier BE. Socioeconomic Status and Type 2 Diabetes Mellitus – Identification of Potential Influencing Factors in the NAKO Cohort. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa03. DOI: 10.3205/26gaa03, URN: urn:nbn:de:0183-26gaa033
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa03.shtml

04

Outpatient antidepressant drug use in children and adolescents between 2018 and 2022 – a large claims-based study

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Background/Aim: The use of antidepressants in children and adolescents has increased steadily, regardless of concerns about effectiveness and safety. The COVID-19 pandemic has led to increased psychological strain for both children and adolescents. Therefore, the aim of this study was to investigate whether antidepressant prescribing patterns changed during the pandemic.

Methods: Based on claims data from a large German statutory health insurance provider, we compared antidepressant prescribing patterns for the years 2018-2022 with a focus on 2019 (pre-pandemic) and 2021 (pandemic). The prescribing prevalence for children and adolescents <18 years was determined, stratified by age, sex, drug class and prescriber specialty.

Results: Overall, between 475,750 (2018) and 585,520 (2022) children and adolescents per year were included. The use of antidepressants increased from 2.2 in 2019 to 2.7 per 1,000 children and adolescents in 2021 (+22.7%). The highest prevalence as well as the highest absolute increase were found in females aged 15–17 years (15.0 in 2019 to 19.0 per 1,000 in 2021 (+26.7%)). The prevalence of selective serotonin reuptake inhibitor prescribing increased from 1.5 in 2019 to 2.1 per 1,000 children and adolescents in 2021. The share of prescriptions by child and adolescent psychiatrists increased from 49.5% in 2019 to 59.9% in 2021.

Discussion/Conclusion: We found a rise in overall ATD prescribing primarily due to an increase in selective serotonin reuptake inhibitor prescribing in adolescent females. Understanding the potential contribution of pandemic measures is important for evaluating the broader consequences of pandemic policies in future research.

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Please cite as: Dörks M, Jobski K, Fassmer A, Poustka L, Cornelisse S, Bachmann C, Stahmeyer J, Meißner I, Hoffmann F. Outpatient antidepressant drug use in children and adolescents between 2018 and 2022 – a large claims-based study. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa04.
DOI: 10.3205/26gaa04, URN: urn:nbn:de:0183-26gaa042
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa04.shtml

05

Pflanzliche Arzneimittel bei gynäkologischen Beschwerden: Erkenntnisse aus der Real-World-Versorgung und Faktoren der Anwendung

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Hintergrund/Ziel: Pflanzliche Arzneimittel (pAMs) stellen eine häufig genutzte Option bei unkomplizierten gynäkologischen Beschwerden dar. Dennoch ist wenig darüber bekannt, wie pflanzliche Gynäkologika im Versorgungsalltag eingesetzt werden, wie ihr therapeutischer Nutzen ist und welche Faktoren ihre Anwendung beeinflussen.

Methoden: Verschiedene Datenquellen wurden komplementär kontextualisiert: Abverkaufsdaten (Insight Health GmbH) für die Analyse von Bezugswegen [1], PhytoVIS-Daten (Kooperation Phytopharmaka) für die Bewertung des wahrgenommenen therapeutischen Nutzens [2] und Gesundheitsdaten der NAKO zur Identifikation von Faktoren, die mit der Anwendung pflanzlicher Gynäkologika assoziiert sind [3]. Die statistische Auswertung umfasste deskriptive und bivariate Analysen sowie logistische Regressionsmodelle, deren Robustheit durch verschiedene Sensitivitätsanalysen geprüft wurde.

Ergebnisse: Etwa 72% der ausgewerteten pflanzlichen Gynäkologika wurden ohne ärztliche Verordnung im Rahmen der Selbstmedikation bezogen, während 18% über private und 10% über gesetzliche Krankenversicherungen erstattet wurden. Insgesamt wurden in den westlichen Bundesländern tendenziell eher pAMs verwendet als in den Östlichen. Die Mehrheit der Anwenderinnen berichtete über eine moderate bis sehr gute Symptomlinderung, wobei der wahrgenommene Nutzen mit Anwendungsdauer und Darreichungsform assoziiert war. Weder Wirksamkeit noch Verträglichkeit waren mit der Nutzung von Begleitmedikation assoziiert. Relevante Faktoren für die pAM-Nutzung waren unter anderem Alter, Inanspruchnahme gynäkologischer Versorgung, Vorerkrankungen und Lebensstilfaktoren.

Diskussion/Schlussfolgerung: Pflanzliche Gynäkologika werden in Deutschland überwiegend rezeptfrei in der Selbstmedikation bezogen. Gleichzeitig zeigen unsere Auswertungen deren gute Verträglichkeit und Symptomlinderung. Dies unterstützt die Rolle der pAMs als ergänzende Therapieoption und unterstreicht einen von den Krankenkassen bislang nicht gedeckten Versorgungsbedarf. Darüber hinaus wurden personen- und versorgungsbezogene Faktoren wie Alter, Inanspruchnahme gynäkologischer Versorgung, Vorerkrankungen und Lebensstilfaktoren identifiziert, die mit der Anwendung von pAMs assoziiert waren. Diese Erkenntnisse können dazu beitragen, die Versorgung gynäkologischer Beschwerden durch die Integration pflanzlicher Therapieoptionen zukünftig zu optimieren.

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Bitte zitieren als: Drebka A, Scholl AJ, Könnecke JK, Bößneck NL, Bachmeier BE. Pflanzliche Arzneimittel bei gynäkologischen Beschwerden: Erkenntnisse aus der Real-World-Versorgung und Faktoren der Anwendung. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa05.
DOI: 10.3205/26gaa05, URN: urn:nbn:de:0183-26gaa055
Dieser Artikel ist frei verfügbar unter http://www.egms.de/en/meetings/gaa2026/26gaa05.shtml

06

Does consumer reporting of adverse drug reactions differ from physician and pharmacist reporting?

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Background/Aim: Previous studies from other countries [1] as well as from Germany [2] have shown that the reporting of adverse drug reactions (ADRs) from consumers differed from that of physicians or health care professionals in general. However, findings from studies conducted in other countries may not be generalizable to Germany due to differences in prescribing practices, genetic backgrounds of the ADRs, awareness of spontaneous reporting systems, and reporting behaviours. Additionally, due to the substantial increase in the number of non-serious consumer reports in recent years following the implementation of the new pharmacovigilance legislation [3], the findings from earlier studies may no longer be applicable. Thus, the aim of our study was to characterize consumer reporting of ADRs. Therefore, consumer reports were compared to reports from physicians and pharmacists.

Methods: Spontaneous ADR reports received between 2018 and 2024 were extracted from the European ADR database, EudraVigilance. ADR reports explicitly submitted by consumers (n= 180,114), physicians (n= 112,927), or pharmacists (n= 60,120) were identified to ensure that reporting patterns were clearly attributed to the respective reporter types. Report characteristics such as the number of reports per year, patient demographics, and the most frequently reported drugs and ADRs were analysed descriptively. Subsequently, reporting odds ratios (RORs) and corresponding 95% confidence intervals (CIs) were calculated to identify the drug classes, and ADRs more frequently reported in consumer reports.

Results: Although the number of consumer reports declined between 2020 (n= 35,797) and 2024 (n= 19,373) following the initial increase observed between 2018 (n= 25,657) and 2020 n= 35,797), the number remained higher than the number of reports from physicians (2024: 13,379) or pharmacists (2024: 5,815). Patients aged 20-45 years were more frequently included in consumer reports than in reports from physicians and pharmacists. ROR analysis revealed that the drug classes "systemic hormonal preparations" (e.g., thyroid preparations) and "genito-urinary system and sex hormones" (e.g., estrogens and progestogens) not only accounted for a large proportion of consumer reports but were also more frequently reported by consumers compared to physicians and pharmacists. Within the drug class "genito-urinary system and sex hormones", sexual desire disorders along with several terms describing psychiatric disorders (e.g., anxiety symptoms, depression, and mood alterations) were more often observed in reports from consumers. In reports related to "systemic hormonal preparations", anxiety symptoms along with disturbances in initiating and maintaining sleep were more frequently reported by consumers.

Discussion/Conclusion: The findings from our study underscore that consumer reporting differs from physician and pharmacist reporting. Consumer reporting may provide complementary information for the detection of subjective neuropsychiatric ADRs. The increased reporting of depression and mood alterations associated with sex hormones supports current recommendations for increased vigilance of patients receiving sex hormones.

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Please cite as: Dubrall D, Weal J, Schmid M, Sachs B. Does consumer reporting of adverse drug reactions differ from physician and pharmacist reporting?. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa06.
DOI: 10.3205/26gaa06, URN: urn:nbn:de:0183-26gaa062
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa06.shtml

07

Off-label drug use in paediatrics: What do we know about its prevalence and associated risks?

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Background/Aim: In paediatric clinical practice, paediatricians often need to prescribe medicines outside the terms of their marketing authorisation, as the authorised information may not cover a specific age group, indication, dose, or route of administration. Additionally, a suitable paediatric formulation may be unavailable. A recent analysis of Kinderformularium.DE, a database providing evidence-based information on paediatric medications, found that 37% of its age- and indication-specific dosing recommendations were classified as off-label [1].

This project aimed to synthesise evidence from reviews published over the past decade on the prevalence and risks of off-label and unlicensed drug use in paediatrics.

Methods: We conducted a narrative review, using a targeted PubMed search to identify relevant review articles from 2014 to 2025. Data were systematically extracted and compared with particular attention to definitions, study populations, settings, and outcome measures. Due to substantial methodological and clinical heterogeneity, prevalence estimates were not statistically pooled and should not be interpreted as directly comparable. Additionally, the primary studies cited in the included reviews were identified and examined for evidence concerning risk-related outcomes, which were not addressed consistently across the reviews.

Results: Of 1,534 citations screened, 10 reviews comprising 136 unique primary studies were included. Substantial heterogeneity regarding definitions, populations, settings, and outcome measures was detected. Reported off-label use ranged from 1.2% to 99.7%, and unlicensed use from 0% to 79.0%. Age- and setting-related patterns were evident but context-dependent, with the highest and most consistent rates of off-label use observed among neonatal and intensive-care populations. Evidence regarding risks was limited. The available observational evidence from 13 primary studies suggested that off-label or unlicensed medicines may be associated with adverse drug reactions in some settings. However, the magnitude – and possibly the presence – of this association, the causality and generalizability remain uncertain, due to variability in patient characteristics, treatment context, medicine burden and the type of off-label use.

Discussion/Conclusion: Overall, off-label drug use is common in paediatric practice, but substantial heterogeneity limits comparisons between studies and settings. Quantitative evidence on associated risks remains insufficient to reliably determine their magnitude, clinical significance, or causality. Robust general estimates will require harmonised definitions and study methodology. In clinical practice, accessible, evidence-based information should support individual treatment decisions and clearly indicate when evidence is limited or when additional safety monitoring may be warranted.

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Please cite as: Eberl S, Neubert A. Off-label drug use in paediatrics: What do we know about its prevalence and associated risks?. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa07.
DOI: 10.3205/26gaa07, URN: urn:nbn:de:0183-26gaa075
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa07.shtml

08

Patient numbers within the AMNOG process: registry data versus routine data

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Background: Based on the Act on the Reform of the Market for Medicinal Products (AMNOG), newly approved drugs containing new active substances are subject to an early benefit assessment after market entry according to §35a SGB V and pharmaceutical companies are required to submit a dossier in this context [1]. Module 3 of this dossier contains, amongst other things, information on the number of patients who are eligible for the medicinal product within the statutory health insurance (SHI), so called SHI target population. Since the AMNOG came into force, 44% (426/970) of all benefit assessments have been conducted in the field of oncology (data as of Q1/2026) [2]. Commonly used data sources for identifying the SHI target population in this therapeutic area include routine data of the SHI and cancer registry data. A particular challenge arises when both data sources are compared and produce different results.The aim is to compare incidence and prevalence estimates for selected indications for which analyses of routine data and cancer registry data were available.

Methods: Published AMNOG-Dossiers were screened regarding the use of routine data and cancer registry data for the purpose of calculating the size of the SHI target population. On this basis, prostate cancer (PCA) was selected as an example for determining prevalence and chronic myeloid leukaemia (CML) for determining incidence, and possible reasons for discrepancies were discussed [3].

Results: Depending on the specific data source used, differences in the number of patients can be observed. For example, a variation of up to six times in incidence was observed for CML, and a variation of up to approximately 25% in prevalence was observed for PCA. With regard to the analyzed indications and statistical disease frequencies, various factors within the data sources – such as the choice of the pre-observation period and the completeness of the data – can be identified as influencing the number of patients.

Conclusion: Routine data and registry data are significant data sources used to determine the size of the SHI target population in the context of benefit assessments. In this regard, the relevant aspects of the data sources and their methodology must be taken into account when interpreting the data.

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Please cite as: Ehlert D, Abu Rajab-Conrads N, Schwalm A. Patient numbers within the AMNOG process: registry data versus routine data. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa08.
DOI: 10.3205/26gaa08, URN: urn:nbn:de:0183-26gaa089
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa08.shtml

09

An ill for every approved pill? Changes in psychiatric diagnoses and prescriptions in adolescent girls between 2015-2023

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Background/Aim: Only a few psychotropic medications are approved for the treatment of mental disorders in children and adolescents. The appropriate use of a medication requires both a valid indication and the correct age. The aim of this study is to describe changes in the prevalence of psychiatric diagnoses and prescriptions among young girls in connection with the COVID-19 pandemic, and to attempt to place these within a broader historical context and identify underlying trends.

Methods: We analyzed prescription and validated diagnosis (ICD-10) data of 12–17-year-old adolescents (N= 3.352.291) from a large German statutory health insurance (AOK). To capture changes in connection with the pandemic, we defined three time periods (prepandemic, pandemic, postpandemic), determined prescription and diagnosis prevalence in the corresponding periods and compared them.

Results: Among young girls, a significant increase in depressive disorders (F32: +29.7%) and obsessive-compulsive disorders (F42: + 42.7%), – but above all, a significant increase in anxiety disorders (F40: +78%) – was observed during the study period. Diagnoses such as somatoform disorders, on the other hand, decreased (F45: -26.7%). The most commonly prescribed psychotropic medications in girls were antidepressants (primarily SSRIs), stimulants (primarily methylphenidate), and antipsychotics (primarily quetiapine).

Discussion/Conclusion: A significant increase in mood disorders and anxiety disorders among adolescents has been reported worldwide. In Germany, in 1998, somatoform disorders were the most commonly diagnosed condition on medical certificates among young women aged 18–24, accounting for about one-third of cases [1]. However, the prevalence of somatoform disorders has been declining for years [2]. This can be interpreted positively as an indication of more precise diagnosis. On the other hand, it is also striking that diagnoses are increasingly being made for conditions for which approved medications are available, at least by adulthood. The increase in ADHD diagnoses among girls is also worth noting here. In our study, we found only modest increases following the pandemic (+1.6%). However, a recently published study by the DAK in 2024 found a 21% increase in ADHD diagnoses among girls compared to 2023. The gender ratio for new cases in 2024 is thus 2:1 (in 2024, 22.4 boys and 11.3 girls per 1,000 children and adolescents received an ADHD diagnosis for the first time) [3]. In our data, ADHD is the psychiatric diagnosis most frequently associated with a prescription for psychopharmacological medication. In summarizing medication trends for young women over the past two or three decades in this area, we note that, in addition to antidepressant effects, the primary goal has been a sedative effect – an effect achieved in 1998 through benzodiazepines and tricyclic antidepressants, whereas today melatonin, quetiapine, and methylphenidate are the drugs of choice.

Overall, a higher prevalence of more precise diagnosed mental disorders can be assumed, which are treated on an indication-specific basis and increasingly with medication. The advantages and disadvantages of these changes are discussed. More specific diagnoses may have replaced earlier more or less provisional diagnoses. On the other hand, it is also conceivable that diagnoses are made based on the available range of approved medications.

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Please cite as: Hach I, Langner I, Selke G, Eichler U. An ill for every approved pill? Changes in psychiatric diagnoses and prescriptions in adolescent girls between 2015-2023. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa09. DOI: 10.3205/26gaa09, URN: urn:nbn:de:0183-26gaa093
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10

Adverse events after drug administration in rare diseases – an analysis of the EudraVigilance database within the CONTRIBUTE project

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Background/Aim: According to current estimates, approximately 5–8% of the population in Germany are diagnosed with an autoimmune disease, including various rare neurological and rheumatological disorders. In recent years, novel immunmodulatory drugs have been approved for some of these conditions. However, evidence on the effectiveness and safety of these drugs outside clinical trials remains limited. Therefore, within the CONTRIBUTE project, the real-world evidence is being investigated using various data sources reflecting usage of these compunds under real-life conditions.

This analysis aims to examine the adverse reaction profiles of novel drugs for selected neurological and rheumatological autoimmune diseases using the EudraVigilance database.

Methods: The analyses were conducted using the EudraVigilance database, which is maintained by the European Medicines Agency (EMA) and collects spontaneous reports of adverse drug reactions (ADRs). A retrospective, descriptive, indication-based analysis was conducted on spontaneous reports for all novel drugs approved between 2009 and 2023 for a rare neurological or rheumatological disease. For each disease, two case definitions (broad and narrow) were developed through a consensus process including clinical experts. Data were retrieved in June 2026. Reports not associated with one of the defined diseases were excluded from the analyses. Reactions that did not represent an explicit adverse reaction (e.g., the MedDRA preferred term 'Off-label use') were excluded. The analyses were conducted using Python (version 3.12.4) and Excel (version 2506).

Results: For belimumab used to treat systemic lupus erythematosus (SLE), 5,807 reports containing a total of 26,688 reactions were identified using the broad disease definition. Using the narrow disease definition, 5,777 reports containing 26,485 reactions were identified. For the broad SLE definition, 5,274 (90.8%) reports involved female patients, and 2,572 (44.3%) involved patients aged 18–64 years. The five most frequently reported reactions were 'Systemic lupus erythematosus', 'Pain', 'Fatigue', 'Arthralgia', and 'Pyrexia'. Of the reported reactions, 18,219 were classified as serious (68.3%) of which 732 (2.7%) were associated with death, and 7,227 (27.1%) involved hospital admission or prolonged hospital stay. The characteristics of the reports were comparable between the two disease definitions.

Discussion/Conclusion: The evaluation of spontaneous adverse drug reaction reports provides insights into the safety profiles of novel drugs, including those used to treat rare diseases. These data can contribute to the assessment of the safety of these medicines under real-world conditions. The findings provide a basis for further discussion of potential safety signals and may support the generation of hypotheses for future pharmacoepidemiological research.

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Please cite as: Himmel J, Rottenkolber M, Bast N, Hellwig K, Kiltz U, Schmiedl S. Adverse events after drug administration in rare diseases – an analysis of the EudraVigilance database within the CONTRIBUTE project. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa10.
DOI: 10.3205/26gaa10, URN: urn:nbn:de:0183-26gaa107
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa10.shtml

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Health Economic Modelling in an Era of Limited Resources: Supporting Evidence-Based Healthcare Decisions

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Background/Aim: The costs of new drugs, particularly in oncology, are rising steadily despite various political measures aimed at limiting spending. In Germany alone, spending on patent-protected drugs rose by 18% to around €2.54 billion in the period from February to April 2024 compared with the previous year, with oncology drugs dominating the list of the 40 drug groups with the highest costs. The treatment of cancer therefore represents a resource-intensive area within the healthcare context.

Given these limited financial resources, the question of how to use new and innovative, yet expensive, treatment efficiently is becoming increasingly urgent. This challenge is already recognized within the Germany healthcare context, where the AMNOG (Act of the Reform of the Market for Medicinal Products) mandates an early benefit assessment for newly approved drugs upon market entry. Therefore, cost-effectiveness analyses may serve as an instrument within the reimbursement process should pricing agreements between manufacturers and the statutory health insurance fail to be reached.

Although health economic evaluations are criticised as tools for rationing, we contend that this perspective overlooks the reality of healthcare decision-making under conditions of scarcity. Given that healthcare resources are limited, not only in Germany but worldwide, choices about how these resources are allocated cannot be avoided. Rather than replacing the broader societal and political processes involved in setting healthcare priorities, cost-effectiveness analyses can serve as a valuable source of evidence to inform these decisions, strengthen deliberative processes, and improve transparency of resource allocation.

Determining an appropriate reimbursement price remains a complex and contested process, and the present analysis underscores the value of continued health economic evaluation. As an example of health economic modelling, we therefore selected the addition of pembrolizumab to standard of care for the treatment of locally advanced cervical cancer as an innovative treatment approach, in order to evaluate its cost-effectiveness from the perspective of the German statutory health insurance.

Methods: We constructed a three-state transition model, comprising the health states stable, progressive, and dead. Furthermore, we calculated time-dependent transition probabilities based on published Kaplan-Meier survival data from the respective phase III trials [1].

Transitions were possible from the stable to the progressive state and from both the stable and the progressive state to the dead state. Patients could also remain in their current state. The dead state served as an absorbing state. However, as survival curves represent aggregated multicause data, we had to assume that possible transitions between states would not include a transition back from the progressive to the stable state.

Over a defined time horizon, the model then aggregated costs, life-years, and quality adjusted life-years for both the intervention arm and the standard therapy arm. Based on these, we could calculate the respective incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR).

To evaluate cost-effectiveness, we used a common approach within health economic evaluations, in which one times the GDP per capita in Germany is used as a willingness-to-pay threshold. The calculated ICER and ICUR values had to meet the respective threshold to be considered cost-effective.

Results: Within the baseline scenario, where no parameters were altered from their assumed or calculated values, the addition of pembrolizumab to standard therapy for the treatment of locally advanced cervical cancer could not be considered cost-

effective. This result is supported by the deterministic and probabilistic sensitivity analyses. The deterministic sensitivity analysis showed that the drug price had the greatest influence on the ICUR, and that a price reduction about 86.0% would be needed to achieve cost-effectiveness. The probabilistic sensitivity analysis showed a probability of only 0.6% of achieving cost-effectiveness against the assumed willingness-to-pay-threshold.

Discussion/Conclusion: Two other health economic evaluations assessed the treatment from an international perspective [2], [3]. One evaluation focused solely on the US healthcare system and concluded that the treatment was not cost-effective [2]. The second one assessed the US, Italian, and Chinese settings, concluding that the treatment was cost-effective in the US and Chinese setting but not in the Italian setting [3].

Two of the main differences were the applied time horizon and the utility values assigned to the different health states across the two intervention arms.

While all analyses concluded that drug costs are the most influential parameter with the respect to cost-effectiveness, in our view a substantial reduction in drugs costs would be necessary for the treatment to be considered cost-effective within the German healthcare context.

Based on the conflicting results from external studies and our own analyses, we conclude that further research is needed. This highlights the need for more transparent and standardized health economic evaluations across different healthcare settings to provide a more comprehensive evidence base and complete the current research perspective.

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Please cite as: Janke FF, Hartmann M, Pietschmann K, Römer M, Bauerschlag D, Farker K, Wurschi GW. Health Economic Modelling in an Era of Limited Resources: Supporting Evidence-Based Healthcare Decisions. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa11.
DOI: 10.3205/26gaa11, URN: urn:nbn:de:0183-26gaa117
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa11.shtml

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Scale-Defined Anticholinergic Burden in Population-Based, Community, and Outpatient Settings: Preliminary Findings from an Ongoing Systematic Review

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Background/Aim: The cumulative exposure to medications with anticholinergic properties is associated with various adverse health outcomes, including those affecting cognitive and functional health [1]. Research on anticholinergic burden (AB) largely focuses on older adults and clinically vulnerable populations, while less is known about its frequency and medication composition across broader age groups and measurement scales. This review aims to systematically synthesize evidence on the extent of scale-defined AB and the contributing medications in community, population-based, and outpatient settings.

Methods: This ongoing systematic review follows PRISMA 2020 reporting guidelines. PubMed, Embase, and Web of Science were searched for studies published from January 2000 onward. Eligible studies reported, or provided sufficient data to derive, the frequency of AB in community, population-based, or outpatient settings using AB scales evaluated in previous methodological reviews. We assessed the risk of bias using the Joanna Briggs Institute (JBI) critical appraisal tool for prevalence studies. Owing to substantial methodological heterogeneity, findings were synthesized descriptively.

Results: Preliminary findings indicate a geographically diverse evidence base that is nevertheless concentrated in higher-income settings and dominated by studies of older adults. The Anticholinergic Cognitive Burden Scale (ACB), Anticholinergic Drug Scale (ADS), and Anticholinergic Risk Scale (ARS) were the most frequently applied instruments. Reported exposure varied considerably by population, setting, scale, threshold, and exposure definition. Where age- and sex-specific data were reported, exposure was generally more frequent in older age groups and among women. Most exposed individuals were classified in lower burden categories. When comparing results within and across studies, frequency estimates based on the ACB and ADS tended to be at the higher end of the reported ranges, whereas estimates based on the ARS and Anticholinergic Activity Scale (AAS) were more often at the lower end. Cardiovascular, psychotropic, and antiallergic medications were common contributors to AB, although medication profiles varied substantially across studies and scales.

Discussion/Conclusion: Preliminary evidence suggests that AB is relevant beyond institutional and specialist-care settings and is not confined to geriatric populations. However, reported frequencies depend strongly on the scale, threshold, and exposure definition used, limiting direct comparisons between studies. These findings support examining AB across a broader adult age range in pharmacoepidemiological research. Clearer reporting of the rationale for scale choice and implementation, as well as more contemporary and transparent approaches to AB measurement, may improve comparability and interpretability across populations and settings.

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Please cite as: Könnecke JK, Bößneck NL, Drebka A, Scholl AJ, van den Akker M, Bachmeier BE. Scale-Defined Anticholinergic Burden in Population-Based, Community, and Outpatient Settings: Preliminary Findings from an Ongoing Systematic Review. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa12.
DOI: 10.3205/26gaa12, URN: urn:nbn:de:0183-26gaa124
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa12.shtml

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Influenza vaccination rates among people aged 60 and older and among specific at-risk groups

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Background/Aim: For the flu vaccine, the WHO and the EU have set a target vaccination rate of 75% for people aged 60 and older [1]. In 2025, the European Society of Cardiology declared vaccination to be the fourth pillar of cardiovascular prevention [2]. Older patients and those with multiple chronic conditions are at increased risk of dying from the disease. The aim of the study was to determine the influenza vaccination rate among people aged 60 and older (2017–2023) as well as among high-risk patients who had suffered a heart attack and those in long-term care (2023).

Methods: Study population: BARMER insurees aged 60 and older who were continuously insured throughout the observation year. Influenza vaccination: Fee schedule codes 89111, 89112, 89112 Y, specific codes of the Associations of Statutory Health Insurance Physicians, vaccinations provided as statutory benefits by the health insurance, pharmacy vaccinations (special codes). Nursing care: at least 14 days of inpatient nursing care, including day care, night care, and short-term care. Heart attack: 2021–2023 continuously insured individuals with an acute heart attack in 2022 (inpatient discharge diagnosis ICD-10 I21, I23) excluding those with a heart attack in 2021 (confirmed outpatient diagnosis, inpatient discharge and secondary diagnoses I21, I22, I23, I24.1, I25.2) [3].

Results: In 2023, 40.8% of insured individuals aged 60 and older were vaccinated against influenza. After peaking at 48.9% in the first year of the COVID-19 pandemic, vaccination rates fell almost back to the pre-pandemic level (38.6% in 2019). The highest vaccination rates were found in the eastern federal states (Saxony-Anhalt: 55.2%), and the lowest in the south (Bavaria: 30.0%, Baden-Württemberg: 29.7%). More than half of the patients at particularly high risk from influenza – those in inpatient care (vaccination rate: 48.9%) or those who had suffered a heart attack (43.3%) – were not vaccinated against influenza. In 2023, 0.6 percent of the vaccinations were administered in pharmacies and 99.4 percent by physicians. Family physicians administered 94.8% of all vaccinations.

Discussion/Conclusion: The WHO's target influenza vaccination rate is not even close to being met, not even among particularly vulnerable patient groups such as people who have had a heart attack or those receiving inpatient care. The option to get vaccinated at pharmacies, available since 2022 in Germany, has so far made only a minor contribution to the vaccination rate. Strategies are needed that enable primary care physicians – as key players – to significantly increase vaccination rates, particularly among at-risk patients. In addition, awareness of the importance of vaccinations must be raised among nursing staff and residential care facilities.

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Please cite as: Lappe V, Grandt D, Schubert I. Influenza vaccination rates among people aged 60 and older and among specific at-risk groups. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa13.
DOI: 10.3205/26gaa13, URN: urn:nbn:de:0183-26gaa132
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa13.shtml

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Clinical pharmacist in the emergency department: A pilot project at a German non-university hospital

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Background/Aim: Despite the introduction of the German nationwide standardized medication plan (Bundeseinheitlicher Medikationsplan, BMP) and increasing digitalization in hospitals, the prevalence of drug-related problems (DRPs) remains high. In particular, at the interface between outpatient and inpatient care, incomplete information and communication issues across different healthcare professions may increase the risk of DRPs. Clinical pharmacy interventions have been shown to reduce DRPs; however, in most hospitals, pharmaceutical services are primarily provided in the context of elective medication reconciliation. In Germany, structured pharmaceutical care for patients entering the hospital through the emergency department (ED) is still not widely established.

The aim of our project was to investigate and improve the medication process within the ED of our main hospital through the continuous presence of a clinical pharmacist, as well as to identify DRPs at an early stage and resolve them in collaboration with the medical staff.

Methods: Clinical pharmacy services were provided for eight hours per day, during five weekdays per week. For patients admitted to hospital through the ED (mean age 78.5 years), current medication, the quality of medication plans brought to the hospital, admission diagnosis, and estimated glomerular filtration rate (eGFR) were systematically recorded. In addition, structured medication reconciliation and medication review were performed directly with the patient, and necessary medication adjustments, including substitution according to the hospital formulary, were made. Identified DRPs were discussed directly with the medical staff and appropriate interventions were initiated.

Results: Between September 2025 and September 2026, 495 patients received clinical pharmacy review. In approximately 70% of patients, at least one intervention was performed due to at least one identified DRP. The most frequent interventions were pause or stop of a medication/substance and dose adjustment. More than 90% of the pharmacists' recommendations were accepted and implemented by physicians.

The analysis of the source documents for medication information revealed only 50% of patients had a BMP available on admission. Only approx. every second BMP document could be correctly implemented into software by means of a scanner (read of the BMP QR-code). Other information sources have been: medication plans, paper notes provided by patients or relatives, interviews (with and without sufficient knowledge about correct dosing), photographs and brown bag analysis.

In an additional evaluation survey, ER-physicians reported a substantial reduction in their workload, corresponding to an estimated average time saving of 25 minutes per patient, as well as a relevant contribution of the clinical pharmacy service to medication safety.

Discussion/Conclusion: Our findings demonstrate the added value of the integration of a clinical pharmacist into the ED medication processes, particularly with regard to a substantial improvement of medication safety and reduction of the physicians' workload. Based on these results, we plan to extend the operating hours of this clinical pharmacy service. Furthermore, the project may serve as a model for establishing clinical pharmacy services in the emergency departments of non-university hospitals.

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Please cite as: Lindner S, Löffler M, von Ameln-Mayerhofer A. Clinical pharmacist in the emergency department: A pilot project at a German non-university hospital. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa14.
DOI: 10.3205/26gaa14, URN: urn:nbn:de:0183-26gaa149
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa14.shtml

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Non-medical use of prescription-only medicines in Berlin's club and party scene

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Background/Aim: Research on substance use in nightlife environments has largely focused on illicit drugs, whereas the non-medical use of prescription-only medicines (POMs) has received comparatively little attention. Consequently, evidence on the prevalence, patterns of use, and sources of supply associated with non-medical POM use in Berlin's club and party scene remains limited. The objective of the present study was to assess the 12-month prevalence of non-medical POM use (defined as use

without a valid medical prescription) among adults in Berlin's club and party scene. It also examined polysubstance use, negative experiences associated with non-medical POM use, and sources of supply.

Methods: An anonymous, internet-based cross-sectional survey was conducted among 515 adults between November and December 2025 who self-identified as part of Berlin's club and party scene. Participants were recruited through social media, messaging groups, and flyers distributed near selected nightlife venues. A pre-tested study-specific questionnaire assessed non-medical use of predefined POM categories, polysubstance use, negative experiences, and sources of supply. Descriptive analyses were performed.

Results: Overall, 272 respondents reported non-medical use of POMs during the previous 12 months. The substances most frequently used in connection with club or party attendance were anesthetics/analgesics (86.4%), sedatives/hypnotics (43.0%), and medications for treatment of erectile dysfunction (23.2%). Polysubstance use across POM categories was common, with 58.9% of users reporting non-medical use from at least two medicine categories. Negative experiences attributed to suspected poor quality or incorrect dosage were reported by 39.0% of users. The most frequently reported sources of supply were friends or acquaintances (48.2%), messaging services (32.4%), and dealers (8.5%).

Discussion/Conclusion: The observed patterns of non-medical POM use, particularly involving anesthetics/analgesics and sedatives/hypnotics, broadly aligns with previous findings documenting substantial ketamine, benzodiazepine, and opioid use in German and international nightlife settings. The prominence of friends or acquaintances and messaging services as reported sources of supply highlights the relevance of informal and digitally mediated supply networks. The results support the need for low-threshold, scene-specific, and targeted medication-safety interventions.

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Please cite as: Ludwig L, Rottenkolber D. Non-medical use of prescription-only medicines in Berlin's club and party scene. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa15.
DOI: 10.3205/26gaa15, URN: urn:nbn:de:0183-26gaa151
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa15.shtml

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The utilization of anti-estrogenic drugs in girls and women of childbearing age and before pregnancy in Germany

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Background/Aim: The median age at childbirth has risen over the past decades. Since the prevalence of chronic diseases also increases with age, drug exposure in women who have not yet completed family planning is an increasingly important topic. This includes potential exposure to anti-estrogenic drugs, which, among others, are used in breast cancer treatment and, in part, should not be taken in the nine months prior to pregnancy. Given the lack of drug utilization studies in this field, we aimed to systematically describe the prevalence of anti-estrogenic drug use in women of childbearing age and to characterize pregnancies occurring in women using these drugs.

Methods: We used German claims data covering ~20% of the German population and the years 2004–2023. For each year, we determined the age-specific and age-standardized prescription prevalence of anti-estrogenic drugs (tamoxifen, fulvestrant, letrozole, anastrozole, and exemestane) among females aged 13–49 years based on cross-sectional analyses. Further we identified all pregnancies occurring in women within one year after anti-estrogenic drug use and described the time between the last prescription and pregnancy onset.

Results: In age group 41–45 years, the prescription prevalences were 3 to 11 times higher compared to age group 31–35 years in 2023. For example, for tamoxifen, it was 3.67 per 1,000 in age group 41–45 vs. 0.55 per 1,000 in age group 31–35 years. The age-standardized prescription prevalence for any anti-estrogenic drug increased by 53% between 2004 (1.48 per 1,000) and 2023 (2.26 per 1,000). Overall, we identified 1,069 pregnancies occurring in women within one year after anti-estrogenic drug use. For tamoxifen (423 pregnancies), there was a prescription within nine months before pregnancy onset in 322 pregnancies (76.1%) and within three months in 116 pregnancies (27.4%).

Discussion/Conclusion: The age-standardized prescription prevalence of anti-estrogenic drug use has increased since 2004 in Germany. Given the parallel trend toward later motherhood, this means there will be an increasing number of pregnancies occurring in mothers after anti-estrogenic therapy. In view of the long half-life of these drugs due to their accumulation in adipose tissue, it will be important to monitor their use and the compliance with recommendations.

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Please cite as: Melcher N, Haug U. The utilization of anti-estrogenic drugs in girls and women of childbearing age and before pregnancy in Germany. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa16.
DOI: 10.3205/26gaa16, URN: urn:nbn:de:0183-26gaa167
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa16.shtml

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Analgesic use and medication beliefs in persons with and without headache: An analysis of the Epidemiological Survey of Substance abuse in Germany (ESA 2021)

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Background/Aim: Headache disorders, such as tension type headache or migraine, belong to the most prevalent diseases worldwide and have a high disease burden. Treatment usually consists of acute medication like non-opioid analgesics which are often available as over-the-counter medication (OTC). To date, there are few data on how German headache patients consume analgesics and none regarding medication beliefs, which can be important for treatment because compliance and addiction partly depend on how patients feel about medication. While problematic medication use can be assessed by a German short questionnaire for medication use ("Kurzfragebogen für Medikamentengebrauch"; KFM), medication beliefs can be displayed by the Beliefs about Medicines Questionnaire (BMQ).

Therefore, the aim of this study was examining how analgesic use differs among respondents with headache compared with those without headache, and whether medication-related thinking differs between the two groups.

Methods: This retrospective descriptive study utilizes data from the 2021 Epidemiological Survey of Substance Abuse, a German cross-sectional population-based study. Respondents with and without headache were compared in terms of demographic variables and medication use, prescriptions and OTC use in two different time intervals. We compared beliefs about medication and problematic medication use, considering a 12-month time frame, determined by the BMQ and the KFM.

Results: Out of 9,046 respondents, 1,049 respondents reported suffering from headache (11.9%). In all age groups, women were more often affected than men (17.8% of female respondents vs. 6.0% of male respondents). Respondents with headache significantly more often reported analgesic use than respondents without headache (93.5% vs. 69% in a 12-month interval). Most respondents with headache and respondents without headache used at least one OTC (71.2% vs. 52.2%), many of them used only OTC drugs (37.3% vs. 36.2%). A larger proportion of respondents with headache tended to see benefits of medication rather than risks (37.8% vs. 22.8%). However, they significantly more often showed problematic medication use, measured by the KFM, compared to those without headache (26% vs. 5.2%).

Discussion/Conclusion: Most headache patients consumed analgesics, and they perceived a higher need for these. OTC use is common, which means accessibility for medication, but also less surveillance of side effects and the number of analgesics consumed. Our results indicate that further treatment and prophylactic options are needed and that knowledge about these should be spread. Further studies are needed to explore if effects are based on comorbidities or headache itself.

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Please cite as: Moormann N, Hoffmann F, Bantel C, Jobski K. Analgesic use and medication beliefs in persons with and without headache: An analysis of the Epidemiological Survey of Substance abuse in Germany (ESA 2021). In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa17.
DOI: 10.3205/26gaa17, URN: urn:nbn:de:0183-26gaa170
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa17.shtml

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Data-driven identification of multiple medication use in the German National Cohort (NAKO)

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Background/Aim: Polypharmacy is commonly characterised by the number of medications, leaving clinically relevant information such as distinct medication patterns insufficiently understood. Therefore, the objective of this analysis was to identify medication patterns using an unsupervised clustering approach.

Methods: Latent Dirichlet Allocation (LDA) was applied to baseline assessment data from the German National Cohort (NAKO). In the NAKO all medications reported to be taken regularly during the preceding 7 days are included. For the main analysis, corresponding ATC codes were aggregated at level 4. The analysis was restricted to ATC codes reported by ≥ 1.0% of participants and participants taking ≥ 2 medications regularly with complete information on ATC codes and frequency of use. Tuning metrics, model stability, and clinical interpretability were used to determine the number of the clustering topics. For visualisation at topic level, Hellinger-based Multidimensional Scaling plots were used. At participant level, Uniform Manifold Approximation and Projection (UMAP) projection was applied.

Results: 55,052 participants (mean age 57 years, 55% female) fulfilled the eligibility criteria. Highest clinically interpretability was achieved by a 6-topic model which comprised a gynaecological-endocrine hormone pattern, a cardiovascular secondary prevention pattern, a diabetic-cardiorenal pattern, a respiratory/allergy pattern, a male-dominated cardiovascular-urological pattern, and a pattern of chronic pain with psychotropic and neurological co-medication. At the topic level, clinically related cardiometabolic patterns showed a sufficient separation despite their close relationship. At the participant level, compact clusters with dominant topic membership and overlapping regions were visible, aligning with the mixed-membership structure of LDA.

Discussion/Conclusion: In this cohort study, the LDA approach appears appropriate for identifying clinically plausible medication patterns. Based on the main analysis, a 6-topic model is indicated. Sensitivity analyses, profiling of topic-dominant participants, and regression analyses of associated features will follow.

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Please cite as: Peltner J, Wicherski J, Degen M, Ebert N, Haug U, Heier M, Linseisen J, Keil T, Haenisch B. Data-driven identification of multiple medication use in the German National Cohort (NAKO). In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa18.
DOI: 10.3205/26gaa18, URN: urn:nbn:de:0183-26gaa183
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa18.shtml

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Measuring medication safety in primary care: a systematic review of the clinical content of 26 consensus based prescribing tools

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Background/Aim: Consensus-based prescribing tools are widely used in drug utilisation research and quality measurement to identify drug therapy problems in primary care. Yet, little is known about how consistently these tools define and operationalise medication safety risks.

Our aim is to characterise how contemporary consensus-based prescribing tools define and operationalise drug therapy problems (DTPs), and to assess the implications of tool selection for pharmacoepidemiologic measurement of prescribing quality and drug-related risk at population level.

Methods: We conducted a systematic review of consensus-based prescribing tools applicable to primary care. MEDLINE and Embase were searched for publications from 1 January 2010 to 31 July 2026, with additional reference and citation screening. Eligible studies reported the development of tools comprising explicit prescribing criteria addressing one or more drug therapy problem (DTP) domains (drug-drug, drug-disease, drug-age interactions, overprescribing, underprescribing). Paediatric, single-drug, or highly context-specific instruments were excluded. Prescribing criteria were standardised into consolidated DTP themes defined by risk context, focus drug, and clinical outcome. Themes were assigned to DTP domains and mapped to standardised clinical outcome categories. A binary theme-by-tool matrix was constructed to quantify thematic scope, convergence, and outcome coverage across tools using descriptive distributional analyses.

Results: Data analysis has not been completed. Results will be available by the beginning of the symposium.

Discussion/Conclusion: First results imply that consensus-based prescribing tools might vary markedly in their operationalisation of drug therapy problems and associated clinical outcomes. For applications in drug utilisation studies, quality measurement, and audit – the choice of tool determines which prescribing risks are measurable and which remain unobserved. An outcome-oriented, theme-based framework could enable explicit comparison of measurement scope across tools and support more transparent selection, adaptation, and interpretation in population-level research.

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Please cite as: Pohl S, Dreischulte T. Measuring medication safety in primary care: a systematic review of the clinical content of 26 consensus based prescribing tools. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa19.
DOI: 10.3205/26gaa19, URN: urn:nbn:de:0183-26gaa190
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa19.shtml

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Risk of cancer among GLP-1 receptor agonist users: the impact of study design choices

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Background/Aim: Glucagon-like peptide-1 receptor agonists (GLP-1RAs) have been linked to changes in the risk of multiple cancers through observational studies with varying design choices. These changes have ranged from protective to harmful effects even for the same cancer type, with sometimes unexpectedly large and early effects. In this study, using current pharmacoepidemiological standards, we estimate the risk of four obesity- and hormone-related cancers following GLP-1RA initiation and evaluate how study design choices influence risk estimates.

Methods: Emulation of the design of a previous randomised controlled trial comparing the GLP-1RA liraglutide to placebo, using dipeptidyl peptidase-4 inhibitors (DPP4i) as placebo proxy. Based on U.S. claims data, the rate of new endometrial, pancreatic, prostate, and thyroid cancer diagnoses is estimated for liraglutide alone and all GLP-1RAs, using propensity-score matching for confounding adjustment. Cancer-specific subdistribution hazard ratios (sHRs) were estimated using Fine-Gray models. Sensitivity analyses evaluated the influence of comparator choice, implementation of a latency window, specificity of the outcome definition, confounding assessment window, eligibility criteria, and intercurrent event handling.

Results: GLP-1RA initiation was not associated with increased risks of endometrial, pancreatic, or prostate cancer. A modest increase in thyroid cancer risk was observed, with a stronger association for liraglutide than for all GLP-1RAs, corresponding to small absolute risk increases. Sensitivity analyses demonstrated substantial variations in effect size depending on design choices, particularly implementation of a latency window.

Discussion/Conclusion: GLP-1RA initiation was not associated with meaningful increases in the risks of endometrial, pancreatic, or prostate cancer and was associated with a small increase in thyroid cancer risk although confidence intervals were wide. Study design choices substantially influence effect sizes and may explain discrepancies across previous studies.

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Please cite as: Russek M, Haenisch B, Krüger N, Wang SV, Schneeweiss S. Risk of cancer among GLP-1 receptor agonist users: the impact of study design choices. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa20.
DOI: 10.3205/26gaa20, URN: urn:nbn:de:0183-26gaa204
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa20.shtml

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Pharmacological Stratification of Fall-Risk-Increasing Drugs for Prevention of Fall-related Injuries in Older Adults: A Population-Based Cohort Study

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Background/Aim: Falls are a major cause of morbidity among older adults. While deprescribing fall-risk-increasing drugs (FRIDs) is recommended for secondary prevention, their high prevalence limits efficient targeting in primary prevention. Stratification by pharmacological FRID subclasses or drugs with fall-risk-increasing adverse reactions (FRIAR-drugs) may improve identification of high-risk patients, yet their added value in routine care is uncertain.

Therefore, the aim of this study is to compare pharmacological FRID classifications with a FRIAR-based framework for predicting fall-related hospitalisations and to identify drug subgroups that differentiate fall-risk among exposed older adults in a primary prevention context.

Methods: We conducted a retrospective cohort study including 120,867 adults aged ≥65 years prescribed at least one FRID or FRIAR-drug at baseline. Fall-related hospitalisations in 2019 were identified using ICD-10 codes. Multivariate logistic regression evaluated pharmacological FRID (sub)groups and FRIAR-drug classifications, adjusted for established general predictors. Model performance was assessed using internal validation and sensitivity analyses.

Results: During follow-up, 2,788 individuals (2.3%) experienced a fall-related hospitalisation. Pharmacological subgroups associated with higher risk included serotonin re-uptake inhibitors, older antiepileptics, and drugs with moderate anticholinergic properties. In contrast, the FRIAR-drug framework added little prognostic information beyond established FRID classifications. The final model demonstrated moderate discrimination (AUC 0.73) with stable predictive performance on internal validation.

Discussion/Conclusion: Pharmacological stratification of FRIDs allows clinically useful differentiation of fall-risk among exposed older adults, whereas FRIAR-based classification adds limited prognostic value. These findings support more selective prioritisation of medication review in primary-preventive fall strategies, although external validation and evaluation of decision-relevant risk stratification are required.

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Please cite as: Schechner M, Rottenkolber M, Oehler P, Guthrie B, Grill E, Hoffmann S, Piller J, Bender A, Dreischulte T. Pharmacological Stratification of Fall-Risk-Increasing Drugs for Prevention of Fall-related Injuries in Older Adults: A Population-Based Cohort Study. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa21.
DOI: 10.3205/26gaa21, URN: urn:nbn:de:0183-26gaa216
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa21.shtml

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Mehr Männer als Frauen und mehr in Ost als West nutzen gewichtsreduzierende Medikamente? Analyse gewichtssenkender Arzneimittel in der privaten Krankenversicherung im Zeitverlauf 2019–2023

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Hintergrund/Ziel: Adipositas wird von der WHO als eigenständige Erkrankung eingeordnet. Die Zahl adipöser Menschen in Deutschland steigt, und mit ihr die metabolische Krankheitslast. Parallel gewinnen Arzneimittel mit gewichtssenkender Wirkung an Bedeutung, insbesondere GLP-1-Rezeptor-Agonisten. In der privaten Krankenversicherung (PKV) gelten im Vergleich zur gesetzlichen Krankenversicherung (GKV) andere Rechtsquellen, aber mit ähnlichen Folgen für die Leistungsbeurteilung. Erstattet wird nur, was im Einzelfall medizinisch notwendig und vertraglich eingeschlossen ist. In der GKV sind reine gewichtssenkende Arzneimittel pauschal ausgeschlossen (SGB V § 34). Vor diesem Hintergrund verfolgt diese Arbeit das Ziel, das reale Versorgungsgeschehen von gewichtssenkenden Arzneimitteln in der PKV abzubilden.

Methoden: Als Basis dienten die pseudonymisierte Arzneimittelrechnungsdaten von 17 PKVen, die sich auf den Zeitraum 2019 bis 2023 bezogen. Von den ca. 300 Mio. Datensätzen wurden die Arzneimittel derjenigen Personen eingeschlossen, die mindestens eine Substanz von einer breiten Liste von gewichtsreduzierenden Wirkstoffen. In die Auswertungen gingen insbesondere die GLP-1-Agonisten. Die Sekundärdaten lagen als Individualdaten vor und erlaubten die Schätzung von

Behandlungsprävalenz, Verordnungsvolumen (DDD) sowie Alters-, Geschlechts- und Regionaleffekte auf Ebene der Bundesländer, deskriptiv und mittels logistischer Regression.

Ergebnisse: Die Behandlungsprävalenz der Versicherten mindestens eines gewichtssenkenden Arzneimittels (DDD) stieg im Betrachtungszeitraum an. Die Prävalenz der GLP-1-Agonisten verdreifachte sich nahezu. In beiden Geschlechtern konzentriert sich die Inanspruchnahme auf das mittlere und höhere Lebensalter, unter 40 Jahren blieb sie gering. Männer stellen rund drei Viertel der Personen mit mindestens einer Verordnung, auch altersadjustiert bleibt ihre höhere Verordnungswahrscheinlichkeit bestehen (OR = 1,67, 95-%-KI 1,66–1,69). Zwischen Ost- und Westdeutschland zeigt sich dabei ein deutliches Gefälle. In den ostdeutschen Bundesländern werden gewichtssenkende Arzneimittel häufiger in Anspruch genommen als in den westdeutschen.

Diskussion/Schlussfolgerung: Der medizinische Bedarf und die Versorgung mit GLP-1 Agonisten wächst in ganz Deutschland, nicht nur für die Privatversicherten. Eine Unterscheidung zwischen Indikationen (Adipositas, Diabetes mellitus Typ 2) kann infolge der fehlenden Diagnosen in den PKV-Daten nicht vorgenommen werden. Eine Erstattung für Adipositas erfolgt im Rahmen der Kulanz und gelegentlich nach Fallprüfung, obwohl der § 34 SGB V für die PKV nicht gilt. Nach Vorliegen einer gesicherten DM2-Diagnose gelten die gleichen Erstattungsregeln wie in der GKV. Die PKV-Prävalenzen, v.a. die Geschlechterverhältnisse, sind aufgrund struktureller Unterschiede nicht auf die GKV übertragbar. Sekundärdaten aus der GKV beziehen sich nur auf DM2-Patienten, nicht aber auf adipöse Patienten. Es fehlen die Daten der Selbstzahler beider Kostenträgerarten. Aus Sicht der Versorgung eint die PKV und GKV außerdem eine fehlende systematische und zielgerichtete frühe Adipositasprävention. Erforderlich ist ein multimodales und stufenweises Konzept über alle Lebens- und Versorgungsbereiche, das auch moderne Medikamente einschließen kann – aber nicht muss.

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Please cite as: Schneider N, Jacke C. Mehr Männer als Frauen und mehr in Ost als West nutzen gewichtsreduzierende Medikamente? Analyse gewichtssenkender Arzneimittel in der privaten Krankenversicherung im Zeitverlauf 2019–2023. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa22.
DOI: 10.3205/26gaa22, URN: urn:nbn:de:0183-26gaa226
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa22.shtml

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Prescription Status of Ginkgo biloba L. Leaf Extract and Treatment Habits in the German National Cohort

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Background/Aim: Dementia and cognitive impairment are highly prevalent, and even mild stages are associated with a notable loss in health-related quality of life. Pharmacological treatment options include Ginkgo biloba L. leaf extracts (GBE), which have been assessed by the Committee on Herbal Medicinal Products (HMPC/EMA) as effective and safe based on evidence from clinical studies [1], [2].

So far, little is known about how GBE is used in routine care in the German population. GBE is available over the counter or can be prescribed by physicians. However, it remains unclear which factors are associated with physician involvement and whether this is related to treatment habits.

This may be clinically relevant, as physician involvement through prescription and/or recommendation could be associated with more appropriate drug utilization (e.g. adherence, trust in therapy) and thereby with effectiveness and safety.

Methods: We conducted a cross-sectional pharmacoepidemiological analysis of the German National Cohort (NAKO) baseline dataset (n=204,610). After data cleaning, the final sample comprised 199,813 participants. All persons who reported using GBE were included in our study (n=1,108; ATC codes N06DP01/N06DX02).

We analysed prescription status, age, sex, mode of intake, and duration of intake, as well as associations between these variables using binary and ordinal logistic regression models. Adjusted odds ratios (aORs) with 95% confidence intervals (CIs) and p values were reported as appropriate.

Results: GBE users were predominantly female (60.1%, n=666), and their mean age was 58.5 years (SD 9.5). About half used GBE without a physician's prescription or recommendation (51.3%, n=568), while roughly a third (29.8%; n=330) reported a physician's recommendation. Only 18.6% (n=206) received a formal physician's prescription.

Female GBE users were significantly less likely to receive a recommendation or formal physician's prescription compared with male users (aOR=0.79, 95% CI 0.63–0.99; p=0.04). Greater physician involvement in GBE use tended to be more common among older users, although this association was not statistically significant.

Almost all GBE users took it regularly (91.5%; n=1,014), and the majority (65.4%; n=725) used it for more than three months. Prescription status was not significantly associated with intake mode. However, GBE utilization upon recommendation of a physician was significantly associated with longer intake duration compared with GBE use without physician involvement (aOR=1.35, 95% CI 1.05–1.75; p=0.02).

Discussion/Conclusion: Age did not appear to be a key factor in physician involvement in GBE use, whereas GBE was less likely to be recommended or prescribed by a physician among female than male users.

Notably, recommendation of GBE by a physician was associated with longer treatment duration, suggesting that medical guidance may support more consistent intake. Since formal prescriptions were relatively uncommon (<20%), adequate counselling in pharmacies and sufficient health literacy may be particularly important to support safe and effective self-medication.

In order to explore if there are factors that might influence whether GBE is formally prescribed, further studies are required investigating prescribing patterns in relation to potential determinants, such as symptom severity, socioeconomic factors, or insurance status.

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Please cite as: Scholl AJ, Drebka A, Könnecke JK, Bößneck NL, Bachmeier BE. Prescription Status of Ginkgo biloba L. Leaf Extract and Treatment Habits in the German National Cohort. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa23.
DOI: 10.3205/26gaa23, URN: urn:nbn:de:0183-26gaa232
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa23.shtml

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Overtreatment among levothyroxine users defined by diagnostic and prognostic thyrotropin (TSH) cut-offs: a population-based study

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Background/Aim: Many levothyroxine users have thyrotropin (thyroid-stimulating hormone, TSH) levels below the diagnostic reference range (“diagnostic” cut-offs), and are therefore considered overtreated. Evidence from predominantly untreated cohorts has led to a definition of TSH cut-offs based on cardiovascular and all-cause mortality risk (“prognostic” cut-offs). It is unclear how often overtreatment according to prognostic cut-offs occurs. We estimated the prevalence of overtreatment among levothyroxine users based on both cut-offs and identified subgroups with a higher prevalence of overtreatment.

Methods: In the baseline assessment of the German National Cohort (NAKO), a population-based prospective multi-center cohort study, TSH levels were available from 109,997 participants aged 19–74 years. We used study-specific TSH cut-offs to assess the prevalence of overtreatment among levothyroxine users.

Results: Among 13,095 levothyroxine users, 19.3% (95% confidence interval [CI] 18.6–20.0) were overtreated using the diagnostic TSH cut-off (<0.45 mIU/L) and 42.5% (95% CI 41.6–43.3) were overtreated according to the prognostic cut-off (≤0.87 mIU/L). A higher prevalence of levothyroxine overtreatment based on the prognostic TSH cut-off was particularly observed in older age groups (e.g., ≥60 years vs. 20–39 years: adjusted prevalence ratio [aPR] 1.32, 95% CI 1.21–1.44), in users with a long time since first thyroid diagnosis (e.g., ≥10 years vs. ≤1 year: aPR 1.88, 95% CI 1.39–2.54), and in those with higher levothyroxine doses (e.g., >1–1.5 µg/kg/day: aPR 1.58, 95% CI 1.47–1.70; >1.5 µg/kg/day: aPR 2.12, 95% CI 1.96–2.29; each compared with ≤0.67 µg/kg/day).

Discussion/Conclusion: One in five levothyroxine users was overtreated according to the diagnostic TSH cut-off; this prevalence was twice as high when applying the prognostic TSH cut-off. The identification of subgroups with a higher prevalence of overtreatment in this study may help prioritize patients for potential dose reduction or deprescribing of levothyroxine.

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Please cite as: Scholle OHF, Ittermann T, Völzke H, Pohlabeln H, Feldkamp J, Günther K, Friedrich N, Nauck M, Krist L, Leitzmann MF, Li Y, Lieb W, Mikolajczyk R, Moreno Velásquez I, Obi N, Pischon T, Schmidt B, Schultheiss UT, Stopsack KH, Brandes B. Overtreatment among levothyroxine users defined by diagnostic and prognostic thyrotropin (TSH) cut-offs: a population-based study. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa24.
DOI: 10.3205/26gaa24, URN: urn:nbn:de:0183-26gaa247

This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa24.shtml

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Community Pharmacy-Based Care in Mental Health: Current Insights from the PharmBePsych Cluster-Randomized Trial

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Background/Aim: Non-adherence to long-term maintenance pharmacotherapy remains a major challenge in mental disorders and is associated with increased risks of relapse and disease progression. Complex medication regimens and medication-related problems may further compromise the safe and effective use of psychotropic drugs. Community pharmacies provide low-threshold access to patients and can complement outpatient mental healthcare through continuous pharmaceutical support. PharmBePsych aims to improve medication adherence while promoting safe and effective long-term medication use through community pharmacy-based care.

Methods: PharmBePsych is a multicenter, cluster-randomized controlled trial with single blinding conducted in community pharmacies in Rhineland-Palatinate and Hesse, Germany. Participating pharmacies recruited adults with selected mental disorders receiving disorder-specific pharmacotherapy and continue to deliver the intervention. The intervention group receives a structured 12-month pharmaceutical care program combining psychopharmacotherapy education with continuous medication management. Following an initial in-person consultation, the hybrid model allows flexible follow-up via telepharmacy or in person. The control group receives standardized pharmaceutical care. Medication adherence is assessed as the primary outcome (15-STARS); medication-related problems and other patient-reported measures are secondary outcomes.

Results: Recruitment was conducted from July 2025 to July 2026 and has been completed, with 94 patients currently enrolled in the trial (intervention: n = 50; control: n = 44), against a prespecified target of 290. A total of 22 community pharmacies enrolled at least one patient. Practical challenges occurred at different levels: engaging patients in a program requiring 12 months of continued participation; integrating the additional workload of recruitment and continuous care into routine pharmacy practice; and addressing procedural and technical challenges, including diagnosis confirmation and the implementation of telepharmacy. Follow-up is ongoing, with study completion in August 2027.

Discussion/Conclusion: PharmBePsych highlights both the opportunities and practical challenges of establishing continuous pharmaceutical care for patients with mental disorders in community pharmacy practice. Experiences from recruitment and care delivery provide valuable insights for implementing such longitudinal care. Ongoing evaluation will determine whether this complementary approach improves medication adherence and supports medication safety in long-term pharmacotherapy.

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Please cite as: Springer L, Kaupp M, Lietz C, Schlenk M, Lieb K, Wiegand H, Friedland K. Community Pharmacy-Based Care in Mental Health: Current Insights from the PharmBePsych Cluster-Randomized Trial. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa25.
DOI: 10.3205/26gaa25, URN: urn:nbn:de:0183-26gaa257
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa25.shtml

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Medication errors in spontaneous adverse drug reaction reports: Findings from the ALERT project with a focus on device-associated contraceptives

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Background/Aim: Medication errors (MEs) are unintended failures in the drug treatment process that may lead to patient harm and are considered preventable [1]. They represent a substantial burden for patients and healthcare systems and are a key focus of the WHO Global Patient Safety Challenge “Medication Without Harm” [2].

Hormonal contraceptives are available as oral formulations as well as device-associated products such as vaginal rings, subcutaneous implants, and intrauterine systems. While these methods offer benefits such as long-acting contraceptive effects and reduced user burden, their use involves specific administration and handling procedures that may create distinct medication safety challenges.

Evidence-based data on the occurrence and associated factors of MEs in day-to-day practice are needed for their prevention but remain limited. We investigated spontaneous adverse drug reaction (ADR) reports involving MEs among German adults, using the European ADR database EudraVigilance as part of the ongoing ALERT-Project [3].

Methods: In this study, spontaneous ADR reports from EudraVigilance received between 2012 and 2023 were extracted. Subsequently, the dataset was divided into ME reports by using the Standardized MedDRA query "medication error (narrow)" and ADR reports. A disproportionality analysis was performed by calculating reporting odds ratios (ROR) with corresponding 95% confidence intervals comparing the ME reports with the ADR reports. Within this analysis contraceptives (ATC code: G02B, G03A) were among the drug classes more frequently associated with MEs. Contraceptives were then stratified by route of administration and device-associated route administrations were further analysed regarding their most frequently reported MEs and ADRs.

Results: We identified 8,969 ME reports and 271,326 ADR reports. Out of the most frequently reported drugs (14 with >= 100 ME reports), four belonged to the contraceptive drug class and accounted for 718 reports in total. Furthermore, disproportionality analysis showed increased RORs of being reported with an ME for several contraceptive drugs (e.g. "Etonogestrel" OR 10.3 [95% CI 8.6-12.5]; "Ethinylestradiol, etonogestrel" OR 3.9 [95% CI 3.3-4.5]. Stratification by route of administration revealed that, besides of oral contraceptives (36.8%), vaginal (24.7%), subcutaneous (19.3%), and intrauterine (15.6%) contraceptives were frequently reported with MEs. These non-oral routes are associated with device-based contraceptive products and account for about 60% of all contraceptive reports. Consistent with this observation, device-related terms such as "Complication associated with device" and "Device expulsion" were among the most frequently reported ADRs for device-based contraceptives. The most commonly reported MEs within this group were "Incorrect product administration duration" and "Inappropriate schedule of product administration", followed by device-associated terms such as "Device use error".

Discussion/Conclusion: Hormonal contraceptives, particularly device-associated formulations such as vaginal rings, subcutaneous implants and intrauterine systems, were frequent in ME reports and showed disproportionate ME reporting, suggesting challenges in their safe use. Device-related issues constituted a substantial proportion of reported MEs, indicating that device use and handling are important contributors to the observed errors. Therefore, further individual case assessments are needed to identify the underlying causes of the reported MEs associated with contraceptive devices and support strategies for improving their drug therapy safety.

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Please cite as: Weal J, Sachs B, Kayser C, Dubrall D. Medication errors in spontaneous adverse drug reaction reports: Findings from the ALERT project with a focus on device-associated contraceptives. In: 33. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie. München, 29.-30.11.2026. Düsseldorf: German Medical Science GMS Publishing House; 2026. Doc26gaa26. DOI: 10.3205/26gaa26, URN: urn:nbn:de:0183-26gaa263
This article is freely available from http://www.egms.de/en/meetings/gaa2026/26gaa26.shtml

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