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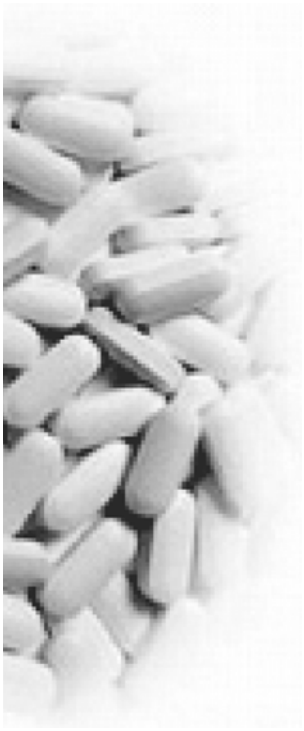

PROGRAMM UND ABSTRACT - BAND

16. Jahrestagung
19. bis 20. November 2009

Berlin
Auditorium Friedrichstrasse

Gesellschaft für Arzneimittelanwendungsforschung
und Arzneimittelepidemiologie (GAA) e. V.

16. Jahrestagung der GAA

Sehr geehrte Damen und Herren,
liebe Kolleginnen und Kollegen,
im Namen des Vorstandes möchten wir Sie ganz herzlich zu unserem Jahreskongress am 19. und 20. November 2009 nach Berlin einladen. Die Vorträgen und Poster greifen auch diesmal wieder ein breites Spektrum an Themen aus der Arzneimittelanwendungsforschung auf. Wir freuen uns, dass sich die Produktivität und Relevanz unseres Fachgebietes in zahlreichen für die Tagung eingereichten Forschungsergebnissen widerspiegelt. Wir hoffen, Ihnen auch für unsere 16. Jahrestagung ein attraktives Programm zusammengestellt zu haben.
An zwei Tagen werden Übersichtsvorträge und Forschungsergebnisse aus mehreren Themenschwerpunkten sowie eine Postersession präsentiert.
Unter dem Thema **Sekundärdatenanalysen** werden aktuelle Ergebnisse aus der Routinedatenforschung präsentiert. Weitere Forschungsergebnisse aus diesem Bereich werden bei der anschließenden Posterpräsentation vorgestellt.
Die **Zukunft der Arzneimittelversorgung** ist der zweite Themenschwerpunkt der Tagung, in dem unter Anderem auf die Möglichkeiten der sog. „personalisierten Medizin“ im Versorgungsalltag eingegangen wird.
Der Themenbereich **Arzneimitteltherapiesicherheit** fasst dieses Mal Beiträge zusammen, die auf vermeidbare unerwünschte Arzneimittelwirkungen fokussieren und den Einsatz von Interventionsinstrumenten und Informationssystemen untersuchen. Eine weitere Reihe von Vorträgen beschäftigt sich mit der Rolle der Apotheken bzw. pharmazeutischer Beratung bei Arzneimittelproblemen.

Einladen möchten wir außerdem alle Mitglieder und Interessenten zur Mitgliederversammlung am **20.11.2009**.

Der Vorstand der der GAA

Sebastian Harder Jutta Krappweis Holger Gothe Marion Hippus Gerd Glaeske

Die Veranstaltung wird von der Landesärztekammer und der Landesapothekerkammer Berlin zertifiziert.

Wissenschaftliches Programm der 16. Jahrestagung der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie e. V. (GAA)

Donnerstag, 19.11.09

13.30 – 14.00 Begrüßung und Einführung in die Tagung (S. Harder, Frankfurt am Main, und H. Gothe, Hall in Tirol)

14.00 – 14.30 Einführungsreferat B. Häussler (Berlin): „Wirkung und Nutzen: Ménage à trois“

Themenschwerpunkt I: Sekundärdatenanalysen

Vorsitz: I. Schubert (Köln)

14.30 – 14.45 Antibiotikaverschreibungen bei Kindern im Alter von 2 - 17 Jahren: Ein Vergleich zwischen Pädiatern und Hausärzten (S. Abbas, Köln)

14.45 – 15.00 Diabetes mellitus: Persistenz zur basalunterstützten oralen Therapie - Vergleich von Insulin glargin mit NPH-Insulin (R. Quinzler, Eschborn und Heidelberg)

15.00 – 15.15 Politikfolgenforschung mit Arzneimittelroutinedaten am Beispiel von Rabattverträgen und der aut-idem-Regelung (F. Hoffmann, Bremen)

15.15 – 16.45 **Kaffeepause und Posterdiskussion**

Themenschwerpunkt II: Zukunft der Arzneimittelversorgung

Vorsitz: H. Gothe (Hall in Tirol)

16.45 – 17.15 Das Gutachten des Sachverständigenrates 2009: Ausblick auf die Zukunft der Arzneimittelversorgung (G. Glaeske, Bremen)

17.15 – 17.45 Pharmakogenetik und Personalized Medicine (U. Fuhr, Köln)

17.45 – 18.15 GANI_MED - Greifswald Approach to Individualized Medicine (H. Völzke, Greifswald)

18.15 – 18.45 Einbettung der Arzneimitteltherapie in ein zukunftsweisendes Gesamtversorgungskonzept (C. Gries, Hamburg)

Ende der Veranstaltung: ca. 18.45

Ab ca. 19.00 Get Together mit Fingerfood, Getränken und Musik

Freitag, 20.11.09

Themenschwerpunkt III: Arzneimitteltherapiesicherheit (AMTS)

Vorsitz: K. Janhsen (Osnabrück)

9.00 – 9.30 Übersichtsreferat: AMTS im Krankenhaus: vermeidbare UAEs (P. Thürmann, Wuppertal)

9.30 – 9.45 Entwicklung einer deutschen Liste potentiell unangemessener Medikamente bei älteren Patienten (S. Holt, Wuppertal)

9:45 - 10:00 Arzneimittelsicherheit im Alter: Prävalenschätzung für potentiell problematische Arzneistoffe und Risikosituationen auf der Basis von Routinedaten (I. Schubert, Köln)

10.00 – 10.15 Gebrauch von Antiepileptika und das Risiko von Selbstschädigung und Selbsttötung (F. Andersohn, Berlin)

10.15 – 10.30 Die Metamizol -induzierte akute Agranulozytose – wie selten ist sie wirklich? Zwischenergebnisse vom Nationalen Pharmakovigilanz-Zentrum Berlin (PVZ-FAKOS) (E. Bronder, Berlin)

10.30 – 11.00 **Kaffeepause**

Vorsitz: J. Krappweis (Bonn)

11.00 – 11.30 Übersichtsreferat: Rolle von Arzneimittelinformationssystemen zur Förderung der Arzneimitteltherapiesicherheit (W. Haefeli, Heidelberg)

11.30 – 11.45 Dosierung nierenkritischer Medikamente auf internistischen Stationen vor und nach Implementierung von Dosisempfehlungen (S. Baum und S. Harder, Frankfurt am Main)

11.45 – 12.00 Optimierung der Pharmakotherapie von geriatrischen Alten- und Pflegeheimbewohnern durch Pharmazeutische Betreuung (J. Kruse, Münster und I. Waltering, Nottuln)

12.00 – 13.45 Mittagsimbiss und Posterdiskussion

12.30 – 13.30 Mitgliederversammlung der GAA e.V.

Themenschwerpunkt IV: Fortsetzung AMTS und freie Themen

Vorsitz: S. Harder (Frankfurt am Main)

13.45 – 14.00 Arzneimittelmissbrauch und – abhängigkeit in der Selbstmedikation – die Rolle der Öffentlichen Apotheken (S. Neuhaus, Bielefeld)

14.00 – 14.15 Bundesweiter Apotheken–Survey zu arzneimittelbezogenen Problemen in der Selbstmedikation (C. Eickhoff, Berlin)

14.15 – 14.30 Spiegeln Verordnungsmuster für Kinder und Jugendliche mit entzündlich-rheumatischen Erkrankungen die Therapieempfehlungen wider? (K. Janhsen, Osnabrück)

14.30 – 14.45 Stimmt die Behandlung der Ostearthritis mit Therapierichtlinien überein? Daten aus dem HERAS Survey (K. Janhsen, Osnabrück)

14.45 – 15.00 Der Einsatz von RFID (Radio Frequency Identification) zur Erhöhung der Arzneimitteltherapiesicherheit (M. Hartmann, Jena)

15.00 – 15.15 **Ausblick:** Ausrichtung des Deutschen Kongresses für Versorgungsforschung (DKVF) 2011 durch das DNVF und der GAA e.V.

Ende der Veranstaltung: ca. 15.30

Poster

Die Diskussionszeiten am Poster sind am Donnerstag, 19.11. von 15.45 - 16.45, und am Freitag, 20.11. von 12.00 - 13.45. Die Autoren werden gebeten, während dieser Termine zur Diskussion am Poster zur Verfügung zu stehen.

Posterformat: A0 hoch (100 cm Breite maximal)

1. Reporting of safety issues in clinical trials, SUSAR and DSUR (M. Kosa und J. Siegert, Dresden)
2. Vermeidbarkeit von Krankenhausaufnahme-bedingenden UAWs – eine Untersuchung zur Inter-rater-Variabilität innerhalb des Netzwerkes der regionalen Pharmakovigilanzzentren (S. Schmiedl, Wuppertal)
3. Development and application of an electronic tool for the collection of medication data in pharmacoepidemiological studies (R. Quinzler, Heidelberg)
4. Medication review of patients community-dwelling seniors using high-level home-care service (M. Ermer, Frankfurt am Main)
5. How asthma types are coded in the out-patient sector? – Analysis of claims data from 2004-2007 (R. Windt, Bremen)
6. Is there a correlation between hormone therapy and the prescription of antidepressants? (C. Gerdau-Heitmann, Bremen)
7. Prescription patterns of drugs inhibiting the renin-angiotensin-aldosterone-system (RAAS) in the Federal State of Saxony - an analysis of the AOK health insurance service database in the years 2003 and 2004 (M. Kosa, Dresden)
8. Prescription of antidepressants and comorbidity of depression (C. Schicktanz, Bremen)
9. Private prescriptions of zolpidem and zopiclone: What medication claims data won't tell us (F. Hoffmann, Bremen)
10. Insulin glargin stellt eine kostengünstige Alternative im Vergleich zu NPH-Insulin bei der Behandlung insulinpflichtiger Diabetiker dar: Ergebnisse einer Verordnungsdatenanalyse (F.W. Dippel, Berlin)
11. Resource utilization and treatment costs in type 2 diabetes on intensified insulin therapy with insulin glargine compared to insulin detemir under real world conditions in Germany (J. Knollmeyer, Frankfurt am Main)
12. Consumption of intranasal corticosteroid-containing sprays (INS) for the treatment of allergic rhinitis – a comparison of „real life" prescription data of treatment with budesonide and mometasone in Germany (O. Schöffski und B.Becker, München)
13. ATC-based determination of the specialization of Statutory Health Insurance Accredited Physicians (R. Schuster, Lübeck)
14. Informationsbedarf von Patienten: Auswertung der Anfragen an einen unabhängigen Arzneimittelberatungsdienst (L. Goltz und M. Kosa, Dresden)
15. Prävalenzschätzung und Outcome-Analyse für potentiell problematische Arzneimittelkombinationen im Alter auf der Basis von Routinedaten am Beispiel der Hyperkäliämie nach Gabe von ACE-Hemmern und Spironolacton. (Heymans L, Köster I, Lauterberg J, Schubert I, Köln und Bonn)

Abstracts der Beiträge

I. Analysis of medication claims data

01

Antibiotic prescription in children between 2 and 17 years: a comparison between pediatrists and general practitioners

Sascha Abbas, Peter Ihle, Lothar Heymans, Ingrid Schubert

PMV forschungsgruppe, Child and Adolescents Psychiatry, University of Cologne, Germany

Background and aim: Antibiotics are widely used for the treatment of infections in children and the best choice when treating acute bacterial infections. However, due to emerging resistance of bacteria against certain antibiotics a careful consideration of prescription is necessary, in particular, when the cause of infection is unclear. Antibiotic prescription may differ between physician groups. We therefore compared the prescription of antibacterials for systemic use in children between paediatricians and general practitioners.

Material and method: We used the statutory health insurance sample AOK Hesse/KV Hesse, comprising 20% of the whole AOK insurants in Hesse. Overall, 47,033 continuously insured children in 2006 between 2 and 17 years of age were included in the analysis. Prevalences of antibiotic use (at least one prescription) in children by age group and gender as well as antibiotic prescriptions by physician groups were calculated. In an analytic approach, odds ratios for antibiotic prescription were calculated by means of logistic regression adjusted for potential confounder, i.e. age, sex, number of contacts, diagnosis quarter in the year, further diagnoses, comparing general practitioners and paediatricians. In doing so, diagnosis specific models were run. Antibiotic use was defined as at least one prescription in a diagnosis quarter in the respective physician group when a certain diagnosis was given. Diagnoses were identified by ICD-10 code including respiratory (J00–06, J20–22) and urinary tract infections (N30, N39.0), pneumonia (J13–16, J18), otitis media (H65–66) and scarlet fever (A38). Systemic antibiotics were classified according to ATC code J01.

Results: Prevalence of systemic antibiotic use was 44.3% in girls and 41.2% in boys. Gender difference in prevalence was most prominent in the age groups 15–17 with 40.8% and 34.5% in girls and boys, respectively. Betalactams and penicillins (J01C) were the most frequently prescribed antibiotics followed by the group of macrolides, lincosamides and streptogramins (J01F). Mean number of prescriptions were 2 per year in both boys and girls. General practitioners and paediatricians prescribed 82.2% of all antibiotic prescriptions with 43.5% and 38.7%, respectively. In 12.2% of all practice contacts with general practitioners antibiotics were prescribed, in contrast to paediatricians with only 8.5% of all contacts. Significantly decreased odds ratios for antibiotic prescription were observed for paediatricians as compared to general practitioners with OR (95% CI) of 0.46 (0.43–0.50) for respiratory tract infections, 0.42 (0.32–0.56) for urinary tract infections and 0.38 (0.28–0.50) for nonsuppurative otitis media. No significant associations were observed when assessing scarlet fever, pneumonia and suppurative and unspecified otitis media.

Conclusions: In this retrospective analysis of a statutory health insurance sample, paediatricians were associated with a lower odds ratio of prescribing antibiotics in a diagnosis-specific analysis as compared to general practitioners when assessing diagnoses where discretion for antibiotic therapy is given. However, in diagnoses where antibiotic therapy is clearly indicated, i.e. scarlet fever, pneumonia and suppurative otitis media, no differences in prescription by physician group were observed. Reasons for antibiotic prescription differences are speculative and may be due to characteristics of the physician group itself or their patients. We tried to address differences in risk profiles between children treated by paediatricians and general practitioners by adjusting for potential confounders available in routine data. However, residual confounding, e.g. severity of disease, cannot be excluded. Further studies are warranted to verify the present findings and to gain more insight into potentially different treatment strategies between physician groups.

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Freely available from:
http://www.egms.de/en/meetings/gaa2009/09gaa01.shtml

02

Persistence with basal supported oral therapy – comparison of insulin glargine versus NPH insulin

Renate Quinzler[1], Miriam Ude[2], Alexandra Franzmann[1], Sandra Feldt[1], Katrin Schüssel[1], Kristina Leuner[2], Walter E. Mueller[2], F. W. Dippel[3], Martin Schulz[4]

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[2]Department of Pharmacology, Goethe-University, Frankfurt, Germany
[3]Sanofi-Aventis Germany, Berlin, Germany
[4]ABDA – Federal Union of German Associations of Pharmacists, Berlin, Germany

Background and aim: To assess the persistence of type 2 diabetic patients treated with basal supported oral therapy with insulin glargine (GLA) compared to NPH insulin (NPH).

Material and method: We performed a retrospective cohort study using claims data for ambulatory prescriptions within the German statutory health-insurance scheme (GKV), based on a representative sample of more than 80% of German community pharmacies. Insulin-naive patients treated with oral antidiabetic drugs (OAD) who were additionally initiating therapy with GLA or NPH between

01/2003 and 12/2006 were included and followed up until 12/2007. Persistence was defined as the duration of time from initiation of GLA or NPH until switching to intensified conventional insulin therapy (ICT). A switch to ICT was assumed whenever a short-acting insulin was prescribed for the first time followed by at least one prescription of a long-acting insulin within six months. Univariate and multivariate proportional hazards models were used to compare both cohorts.

Results: In total, 97,998 patients (61,070 GLA and 36,928 NPH) were included. Within the observation period, 23.5% of GLA patients and 28.0% of NPH patients switched to ICT. On average, these patients stayed 388 days on GLA and 313 days on NPH, respectively (p<0.001, log-rank test). The risk of switching to ICT was significantly higher for NPH patients compared to GLA patients (unadjusted hazard ratio [HR] 1.34 (99% CI: 1.29–1.38)). After adjustment for predefined covariables i.e., type of physician (general practitioner vs. specialist), region, insurance status (member, family member, retired), health insurance company, comedication, number of OAD, dose of basal insulin, the risk for NPH patients remained significantly higher (adjusted HR: 1.22 (99% CI: 1.18–1.27)).

Conclusions: Type 2 diabetic patients under basal supported oral therapy treated with GLA stay significantly longer on initial therapy until they switch to ICT when compared to NPH.

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03

Studying the impact of policy interventions with medication claims data: the case of rebate contracts and 'aut idem'

F. Hoffmann, G. Glaeske

Universität Bremen ZeS, Abteilung Gesundheitsökonomie, Gesundheitspolitik und Versorgungsforschung, Bremen, Germany

Background and aim: Since April 1st, 2007 pharmacies are obligated to substitute medications within the statutory health insurance system preferably to products for which rebate contracts were made. Physicians are able to exclude such a substitution when crossing ‚aut idem'. This regulation existed already since 2002. We aimed to investigate if the use of ‚aut idem' has changed after the introduction of rebate contracts.

Material and method: We used claims data of the Gmünder ErsatzKasse (GEK) and drew 3 independent random samples of 0.5% of the insured adult population in October 2006, 2007 and 2008 (n=6,195; n=6,300; n=6,845). After that, all relevant original prescriptions were screened.

Results: Between October in 2006, 2007 and 2008, we observed an increase of prescriptions in which ‚aut idem' was used (14.4%; 18.4%; 19.0%; p for trend<0.0001). We found considerable differences between the local regional associations of statutory health insurance physicians. In about a quarter of all prescriptions of October 2007 and 2008 (25.1% resp. 25.7%) in which substitution was excluded, a medication included in a rebate agreement was prescribed.

Conclusions: This study gives insight into the use of ‚aut idem' before and after the introduction of rebate contracts to the statutory health insurance system. Generally, evaluation of the impact of health policy interventions are clearly needed in Germany. Analysis using claims data can provide useful information for an evidence-based debate on the (positive and negative) impacts of policy interventions.

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III. Safety of drug therapy

04

Development of a German list of potentially inappropriate medication in the elderly

S. Holt[1,2], S. Schmiedl[1,2], P. A. Thürmann[1,2]

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[2]Department of Clinical Pharmacology, University Witten/Herdecke, Germany

Background and aim: Certain drugs are classified as potentially inappropriate medication (PIM) for elderly patients due to their increased risk for causing adverse drug reactions [Laroche ML et al. 2009]. Since published international PIM lists may not be suitable for Germany, we are developing a German PIM list (http://www.priscus.net/, SP3).

Material and method: After an extensive literature search a preliminary German PIM list has been created including more than 130 different drugs of 20 drug classes. A web-based, modified two round Delphi survey [RAND Corporation 1969] with a German speaking expert panel (25 experts of 7 different specialties) has been performed using a 5-point Likert scale. For certain drugs, experts differentiated between high and low doses and immediate vs. extended release preparations, respectively. This resulted in additional medicines to be evaluated in the second round.

Results: 82 of the drugs stated in the preliminary list were rated as PIM for elderly patients, e.g. indomethacin and

thioridazine. In contrast 26 drugs were rated as suitable for elderly patients, e.g. tramadol and risperidone. In 47 drugs, experts' rating failed to make a clear decision after the second round. In case the prescription cannot be avoided due to lack of alternatives, the final PIM-list includes recommendations with regard to e.g. monitoring parameters and frequency of monitoring. Furthermore, for some drugs alternatives were suggested by the experts, like melperone as an alternative for thioridazine.

Conclusions: A considerable number of drugs were unanimously considered to be potentially inappropriate for elderly people. However, due to the complex clinical therapeutic needs of elderly people, a "yes-or-no" scheme may oversimplify drugs' assessment in many instances. The final PIM list will be validated evaluating the relationship between usage of PIM and the occurrence of clinically relevant adverse effects in several cohorts of elderly German patients.

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05

Use of antiepileptic drugs and the risk of self harm or suicidal behaviour

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[2]McGill Pharmacoepidemiology Research Unit, McGill University, Montreal, Canada
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[4]Bremer Institut für Präventionsforschung und Sozialmedizin (BIPS), Universität Bremen, Germany

Background and aim: A recent meta-analysis of the US Food and Drug Administration (FDA) revealed that patients treated with antiepileptic drugs (AEDs) in randomized trials had a nearly doubled risk of suicidal thoughts and behaviour as compared with placebo. If all classes of AEDs increase the risk of suicidality remains, however, uncertain. Aim of our study was to investigate the risk of self harm or suicidal behaviour associated with the use of different classes of AEDs in patients with epilepsy.

Material and method: We performed a nested case-control study in a cohort of 44.300 patients with epilepsy who were treated with AEDs. Data were derived from the UK General Practice Research Database (GPRD). Patients with self harm or suicidal behaviour were identified by predefined codes. We included 453 cases and 8962 age- and sex-matched controls. AEDs were classified into 4 groups: barbiturates; conventional AEDs; newer AEDs with low (lamotrigine, gabapentin, pregabalin, oxcarbazepine) and with high (levetiracetam, tiagabine, topiramate, vigabatrin) potential of causing depression. Odds ratios (OR) were calculated using conditional logistic regression.

Results: Current use of newer AEDs with a high potential of causing depression was associated with a threefold increased risk of self harm/suicidal behaviour (OR=3.03; 95% CI 1.22–7.54) as compared with no use of AEDs during the last year. Use of barbiturates (OR=0.65; 95% CI 0.25–1.68), conventional AEDs (OR=0.73; 95% CI 0.54–0.97), or low risk newer AEDs (OR= 0.85; 95% CI 0.47–1.53) was not associated with an increased risk. Levetiracetam was the only individual AED associated with a significantly increased risk of self harm or suicidal behaviour.

Conclusions: Newer AEDs with a rather high frequency of depressive symptoms in clinical trials may also increase the risk of self harm or suicidal behaviour in clinical practice. For the most commonly used other AED classes, no increase in risk was observed.

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06

Metamizole (Dipyrone) Induced Acute Agranulocytosis – How rare is it really? Preliminary results from the National Pharmacovigilance-Center Berlin (PVZ-FAKOS)

E. Bronder[1], A. Klimpel[1], F. Andersohn[1], E. Garbe[1,2]

[1]Charité-Universitymedicine Berlin, Berlin, Germany
[2]Bremen Institute for Prevention Research and Social Medicine, University Bremen, Bremen, Germany

Background and aim: Despite the well-known risk of acute agranulocytosis, ambulatory prescriptions of metamizole raised from 32.2 Mio. Defined Daily Doses (DDD) in 2000 to 85.8 Mio. DDD in 2007 (+166%). The total number of German adult patients with metamizole induced agranulocytosis leading to hospitalisation or occurring in the hospital has not been estimated so far.

Material and method: Within PVZ-FAKOS, a German National Pharmacovigilance Center in Berlin, hospitalised patients with acute agranulocytosis in Berlin were identified. WHO causality assessment was used to identify cases caused by metamizole. We estimated the total number of patients with metamizole induced agranulocytosis in Germany under the assumption of 100% case ascertainment and similar metamizole prescription habits as in whole Germany.

Results: 92 patients with a validated diagnosis of AGR were included from Oct 2000 to June 2009 with 27 of them (29.3%) attributed to metamizole. The total numbers of adults with metamizole induced agranulocytosis in

Germany were estimated as approx. N=633 during the total study period (95% confidence interval [CI] 417–921) or N=72 per year (95% CI 48–105).

Conclusions: Even with the conservative assumption of complete case ascertainment in Berlin, a substantial number of patients were affected by metamizole induced agranulocytosis during the last years in Germany. Given the potential fatal consequences of agranulocytosis, these estimates support concerns about the increasing ambulatory use of metamizole in Germany.

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07

Appropriate dosing of drugs necessitating adjustment in patients with impaired renal function before and after an implementation of dose guidelines and an face-to-face educational intervention

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Background and aim: Whereas in larger hospitals individualized dose adjustment in renal insufficiency can be provided by expert systems and pharmacists, these options are often not available in smaller hospitals. We evaluated whether one short educational session for the medical staff of internal wards of a community hospital, focusing on creatinine clearance and dosing in renal insufficiency, and providing a list of frequently used drugs and their dosing schedule does reduce the rate of patients with unadjusted doses.

Material and method: In patients with a creatinine clearance <60ml/min, dosing schedules for 92 drugs were determined. After a 6-month observation period (cohort 1), an educational intervention and the abovementioned list were delivered to the medical staff. This intervention was followed by a further 6-months observation period (cohort 2).

Results: In cohort 1, 55/85 patients (median age 79y) had at least one initially inappropriately adjusted medication, and 47/85 remained so at discharge, whereas in cohort 2 (median age 77y), 28/85 patients had at least one initially inappropriately adjusted medication (p=0.014 compared to cohort 1) and 27/85 remained so at discharge (p=0.05). The total number of prescriptions in cohort 1 from the list of scrutiny (92 drugs most frequently used on the wards) was 319 (day 2 after admittance) and 341 (at discharge), in cohort 2, these numbers were 314 and 328, respectively. In cohort 1, 54.5% of all initial prescriptions of a drug for which adjustment is advised (N=202) followed an unadjusted dosage, this rate was 45.9% (from 220 prescriptions) at discharge. After the intervention (cohort 2), 26.8% of all initial prescriptions with a drug for which adjustment is advised (N=164) followed an unadjusted dosage (p<0.001 compared to cohort 1), this rate was 25.6% (from 176 prescriptions) at discharge (p<0.001 compared to cohort 1). No trend of fading of the interventions success was seen within the 6 months observation period after the intervention.

Conclusions: This intervention was on a „low key"-level, and no further support e.g. academic detailing was effected. Despite this, we found a considerable reduction in the use of critical drugs and the number of inappropriate doses in patients with impaired renal function.

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08

Potentials to optimize the pharmacotherapy of geriatric residents in nursing homes by pharmaceutical care

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Background and aim: During the last years pharmaceutical care has become more important to optimize pharmacotherapy. Especially geriatric patients due to polypharmacy and age-related changes in metabolism are at an increased risk for drug-drug-interactions, drug-disease-interactions and unwanted side-effects.

The aim of the project is to reduce medication associated problems of nursing home residents, improve their quality of life and reduce health care costs by lowering the number of hospital admissions or other effects.

Material and method: In 16 nursing homes from four different counties approximately 550 residents were recruited and complete patient data were affiliated over a period of six months. Inclusion criteria were: age=65 years, =3 medications and no progressive course of illness. Residents gave their informed consent to this appraisal.

To evaluate the basal health state of the residents a questionnaire based on the "Aktivitäten und existenzielle Erfahrungen des Lebens" (AEDL) of Krohwinkel was developed and conducted by nursing staff.

The following 18 months medication reviews are conducted and assessed with the Medication appropriateness index (MAI) of Hanlon JT et al. 1992 as well with START- and STOPP-criteria (Gallager P et al. 2007, Barry PJ et al. 2008). Interactions are checked with the ABDA-Database and potential drug-related problems are classified. Improvement of pharmacotherapy should be achieved by discussing medication-related problems with an interdisciplinary team including practitioner, nursing staff and pharmacist. Further on nursing staff should be teached on special aspects of applying drugs. Based on the experience community pharmacies should be trained to offer this service regularly.

Results: At the time of the abstract-deadline the project is standing at the end of the first 6-month period. Only limited data are available so further work-up needs to be done to present results.

Conclusions: With medication management, improved communication between practitioner and pharmacist and cooperation with the pharmacies an optimized pharmacotherapy of the geriatric residents should be achieved. Especially the importance of pharmaceutical care conducted by pharmacists to secure medication therapy should be emphasized.

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IV. Safety of drug therapy and free topics

09

Abuse of and dependence on non-prescription medications – the role of pharmacies

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Background and aim: The inappropriate use of medications often results in social, psychological and physical problems and is a serious public health concern. The abuse liability and dependence potential of non-prescription medications have been very rarely investigated although self-medication is widely spread in the population.

Material and method: Qualitative analysis of semi structured interviews with 5 pharmacists and 5 pharmaceutical technical assistants (PTAs) in pharmacies in 3 cities in Lower Saxony.

Results: The staff in pharmacies very often notices an inappropriate use of non-prescription medicaments in practice therefore it has the responsibility to prevent abuse of and dependence on medications. It has solid potentials and is highly motivated to manage this task, nevertheless it has to face some challenges. For example it is difficult to distinguish an appropriate use from a misuse or abuse, to communicate with the people concerned and to change their situation for the better. The staff in pharmacies attests a lack of adequate practicable strategies, concepts, materials and cooperation with other healthcare professionals.

Conclusions: It is safe to assume that the abuse of and the dependence on non-prescription medicaments will increase and entail numerous public health problems. The staff in pharmacies offers a promising potential to work against this development, but it needs more support to manage their task and to cope with the challenges. It is important to acquire practicable strategies, concepts and materials in cooperation with scientists and experts from various disciplines.

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10

Frequency of drug-related problems in self-medication in German community pharmacies

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Background and aim: In German community pharmacies prevalence of drug-related problems (DRPs) in OTC use is not known yet. Therefore, we initiated a study to quantify DRPs in self-medication. Further, we assessed factors having an impact on safe OTC use.

Material and method: Community pharmacists (CPs) were asked to document 100 consecutive customers presenting symptoms or requesting OTC (pharmacy-only) drugs by means of a standardized documentation form. A number of 10,000 encounters seemed reasonable in order to evaluate the set objectives. For each encounter, data like age, gender, first or repeated request, availability of a patient file including drug history and indication were documented. Additionally, identified DRPs, problem descriptions, and solutions were documented. Data were transcribed electronically, coded if necessary, checked for validity, and analyzed.

Results: In total, 109 CPs documented 12,567 OTC requests in 11,069 patients identifying DRPs in 17.6% (n=2206) of all cases.

In more than 75% of all cases patients requested a specific product. About 80% of all DRPs were documented in these cases. More than 70% of all DRPs were detected in four indications: pain, respiratory tract, gastrointestinal tract, and skin disorders. Four DRPs were responsible for almost 75% of all DRPs identified: self-medication inappropriate (29.7%), requested product inappropriate (20.5%), intended duration of drug use too long including drug abuse (17.1%), and wrong dosage (6.8%). If a drug history was available in the pharmacy, significantly more cases with wrong dosage ($p<0.05$) and drug-drug interactions ($p<0.001$) were detected, whereas wrong use of drugs was less frequent ($p<0.05$). In all cases, patients with identified DRPs were counselled accordingly. Furthermore, most frequent interventions were referral to a physician (39.5%), and switching patients to a more appropriate drug product (28.1%).

Overall, more than 90% of all DRPs were partly or completely solved in the pharmacy (45.3% and 44.9%, respectively).

Conclusions: In almost one out of five encounters, direct pharmacist-patient interaction in self-medication revealed relevant DRPs in German community pharmacies. About 80% of all DRPs were observed in cases where patients requested a product. Therefore, special attention has to be given to these patients especially since they often do not ask for advice. Having access to the patient file including data on both prescription-only and OTC products seem to increase patient safety.

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11

Are prescription patterns reflecting guideline recommendations for rheumatoid arthritis in children and adolescents?

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Background and aim: Rheumatoid arthritis (RA) in children and adolescents (CaA) is similar to adult forms but often progress and consequences are less severe in CaA. Therefore treatment optimization requires differentiation between mild and severe forms.

Drug treatment guidelines for juvenile idiopathic arthritis (JIA) consider these facts and recommend symptomatic treatment (NSAIDs, corticosteroids) and – in severe cases – DMARDs (disease modifying antirheumatic drugs) with methotrexate as first choice. Other DMARDs are not relevant in JIA except for specific cases. But prescriptions for these drugs increased over the last years remarkably. Aim of this analysis was to characterize drug treatment of CaA with RA with focus on DMARDs.

Material and method: Data analysis is based on prescribing data of the statutory health-insurance company GEK (around 375,000–380,000 enrolees aged 0–19 y per year) for the calendar years 2005–2007. RA patients were identified by reimbursement diagnoses (ICD10: M05-M09 and/or M13). Age- and sex-related disease and treatment prevalences including 95% confidence intervals (CI) were calculated.

Results: RA prevalence among 0–19 year old CaA does not relevantly change between 2005 and 2007 (2007:0,58%, 95%CI: 0,56–0,61%). Females are slightly more frequently concerned than males. Among both sexes prevalences increase with age. Only 56% of all CaA with RA receive at least one RA prescription per year with lower proportions in higher agegroups.

Females receive more frequently DMARDs than males. But DMARD treatment is with 8% of less importance among CaA. Methotrexate is the most frequently prescribed DMARD but still relevant proportions receive second and third line DMARDs.

Conclusions: For most of the CaA with RA our results are not contradictory to guidelines regarding drug treatment except for the age group 15–19 years where a deficit in DMARD therapy can be assumed. Although DMARDs are rarely prescribed the proportions of second and third line DMARDs are quite high. Most of them are not approved for children and/or for RA. Drug treatment patterns should be monitored. Further investigations should also focus non-pharmaceutical treatment options.

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12

Are clinical practice guidelines adequately considered in drug treatment of osteoarthritis patients? Results from the HERAS survey

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Background and aim: Guidelines for osteoarthritis patients (OAP) focus on drug treatment of pain and inflammation.

As there is a high risk for side-effects and interactions – especially in the vulnerable population of the elderly – evidence based recommendations for first choice drugs and co-medication are given.

Aim of the analysis was to investigate drug utilization in patients with clinically relevant osteoarthritis with regard to national treatment guidelines.

Material and method: 2,221 persons out of a registration office sample of 7828 citizens of the city of Herne (North Rhine-Westphalia) aged 40 years or older filled in a postal questionnaire in the year 2005 and gave information about symptoms, pain localisation and intensity, comorbidity and drug utilization. Information about drug utilization comprised prescribed drugs, self medication and aspects of patient compliance. Mentioned drug brands were identified regarding their active ingredient(s) and classified by the Anatomical Therapeutic Chemical Classification System (ATC-System). Survey participants who marked „Gelenk-Verschleiß (Arthrose)“ as the known cause of their joint pain where identified as OAP.

Results: 860 out of 2221 survey participants were identified as OAP (38.7%; 95%CI: 36.7–40.7%). 65.5% of the OAP (95%CI: 62.3–68.7%) were analgetic drug users in the last 12 months to reduce their pain complaints – but only 42.1% (95%CI: 38.8–45.4%) of the OAP had a guideline adequate treatment of symptoms with analgetic/anti-inflammatory drugs (Paracetamol, NSAIDs or COX 2 inhibitors) in their present medication. Among 333 OAP treated with an NSAID 56.2% (95%CI: 50.8–61.5%) received at least one additional active ingredient resulting in an increased risk for interactions. At least 41% of the OAP had an increased risk for gastrointestinal bleeding (GIT-risk: age>70 years, anamnestic ulcer or gastric bleeding, corticosteroid or anticoagulant treatment). A proportion of nearly 34% (33.9%, 95%CI: 29.0–38.8%) of this high-risk group was treated with NSAIDs. But only every fifth patient of the high-risk group with NSAID utilization (19.8%, 95%CI: 12.6–27.0%) received the recommended gastric protection (Proton Pump Inhibitor or Misoprostol).

Conclusions: Relevant deficits in the drug treatment of OAP can be assumed from these results. Both symptom therapy and co-medication and consideration of potential interactions are concerned.

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13

Using RFID for reducing medication errors

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Background and aim: Medication errors are one of the largest categories of adverse events in healthcare; Reported incidents range from 1.3 to 7.8% (Kanjanarat, 2003) with a median prevalence of 4.3% (Winterstein, 2002). Little reliable data exists on the frequency of medication errors in European countries. Nevertheless, available studies carried out in Europe reveal that medication errors have a clinical and economic impact of similar magnitude as it does in the USA and other countries. Studies carried out by ISMP-Spain have indicated that 1.4% of hospitalised patients in Spain suffer one or more preventable adverse drug events during their hospital stays with mean cost of € 3000 per event (Otero López MJ, 2001).

Material and method: Jena University Hospital has extended its deployment of SAP NetWeaver to identify, track and match medication accurately and in real-time from the hospital's pharmacy until they are administered to patients in the critical care department. In order to ensure that end-to-end process from the pharmacy to the patient, all unit doses of patient medication, transport boxes of the pharmacy and steel containers of the automatic, internal transport system had to be equipped with Radio Frequency Identification (RFID) tags.

Results: By using passive RFID tags, medication can be tracked in real-time from the hospital's pharmacy to intensive care and individual patients. Medication can be matched digitally to the individual patient by checking the reference codes on an RFID bracelet worn by the patient. Using handheld scanners, the nursing staff can read these codes, link them to the patient data on file in the hospital's IT system and gain instant access to detailed information on the patient.

Conclusions: By gaining the ability to track and match medication with RFID tags throughout the hospital in real-time, it is possible to reduce the risk of any dispensing errors.

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Poster

14

Reporting of safety issues in clinical trials, SUSAR and DSUR

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Background and aim: In clinical trials as well as in pharmacovigilance safety issues have to be reported to the pharmaceutical manufacturer and competent authorities. In clinical trials furthermore reports have to be sent to the competent ethics committees. The adherence to the Guidelines for reporting safety issues in clinical trials is analyzed from the routine work point of view.

Material and method: The usefulness of safety reports SUSAR (suspected unexpected serious adverse reactions) reports and DSUR (developmental safety update reports) and the adherence to the corresponding guidelines was analyzed on the basis of the daily workload due to incoming safety reports in an ethics committee (Ethics committee of the Medical Faculty of the Technische Universität Dresden).

Results: SUSAR reports not in adherence with the guidelines are the majority of all SUSAR reports received. In many cases even simple formal requirements are violated (reporting of events occurring in conjunction with blinded trial medication without decoding, double and triple reporting of single events, reporting of events well established in SMPC or investigators brochure (e.g. bleeding in patients treated with a combination of Clopidogrel, ASA, Heparin and factor Xa), update reports sent in conjunction with initial reports, etc.). Additionally data quality is in many cases so poor (unknown indication, unknown concomitant medication, cases that the reporting physician has not treated, unknown age and sex, male patients treated for ovarian cancer, etc.) that no evaluation is possible. Furthermore in many cases events due to the condition treated are reported as SUSAR (e.g. bone pain in trials in patients with multiple myeloma, DVT in patients in trials of factor Xa inhibitors, infection in trials in patients with leukemia).

DSUR reports are only supplied for some part of the running clinical trials and are of very different quality from poor [line listing of previously sent SUSAR's without any useful comment] to excellent (statistical evaluation of decoded treatment groups with a profound evaluation and discussion of preclinical and previous clinical data to identify or annihilate potential safety concerns).

Conclusions: As reported previously for a limited sample (Trillenberg et al., 10. VKliPha, 85% of SUSAR reports are not according to reporting requirements) the quality and adherence to the relevant guidelines is inadequate in the vast majority of SUSAR reports sent to ethics committees. A similar situation applies to DSUR reporting.

Great efforts are necessary to streamline the reporting of safety information in clinical trials and to optimize the perceptibility of safety risks during clinical development. The actual way to spread all information – relevant or not; verifiable or rumor – to everyone involved is neither adequate to attract attention to risks nor cost effective for the pharmaceutical industry.

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15

Preventability of adverse drug reactions leading to hospital admission – assessment of inter-rater variability within the Network of Regional Pharmacovigilance Centers

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Background and aim: Preventability of adverse drug reactions (ADRs) is a matter of public concern and usually evaluated using pre-defined questions and algorithms. Assessment of preventability of ADRs is characterised by a significant inter-rater variability (IRV). Within the German Network of Regional Pharmacovigilance Centers (NRPC), ADRs leading to hospitalisation are collected in 4 hospitals (i.e. regional centers [RC]) and quality assurance (QA) is performed independently [Schneeweiss et al., 2002]. Preventability of ADRs is assessed by RC and QA using a questionnaire containing 8 items. In this pilot study we aimed to quantify IRV between RC's and QA's preventability assessments.

Material and method: Out of all cases documented in 2008 and 2009, 100 ADRs were randomly chosen. Concordance and IRV were analysed for ADRs assessed as 'probable' or 'definite' by the QA. Since there are 3 potential answers ('yes', 'no', 'not known') for each statement, a 3x3 table was used for evaluating IRV. The degree of agreement was analysed using the chance-corrected index delta taking into account the unbalance of the two marginal totals [Martin Andres et al., 2005].

Results: Out of 100 ADRs, 80 cases were assessed as at least 'probable' ADRs and included in the final analysis. Best agreement (95.0%, delta=0.86) was observed for the item „contraindications, warnings and precautions considered concerning over the counter drugs". Lowest agreements were found for „consideration of required dose

adjustments“ (68.8%, delta=0.49) and „prevention strategies“ (71.3%, delta=0.03). In 36 cases (45%), all items were assessed in complete concordance by either RC and QA.

Conclusions: In a sample of ADRs leading to hospitalisation, we observed good consensus in assessing preventability by the NRPC. Based on further analyses, we will develop an algorithm for assessing the overall preventability taking into account the complex benefit-risk-ratio of pharmacotherapy particularly in multimorbid elderly patients with increased ADR risk.

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16

Development and application of an electronic tool for the collection of medication data in pharmacoepidemiological studies

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Background and aim: The assessment of drug exposure requires detailed information on specific drug characteristics and dosage regimen. We developed a tool for electronic collection of medication data in pharmacoepidemiological studies e.g. suitable for use at home visits when drug packages are available.

Material and method: We developed the concept for a user-friendly data capture tool that allows electronic collection of detailed medication data and is equipped with an easy update and backup system to prevent data loss. The system was tested in home assessments of a large cohort of elderly patients.

Results: For a user-friendly collection of medication data drugs can be entered via a barcode reader, whenever the drug package is available. Otherwise, brand names can be searched and chosen within an actual collection of marketed drugs. In both cases a unique product identifier is entered in the database, allowing linkage to databases with detailed drug information. Therefore, a medication database containing all marketed drugs is included in the system and updated regularly. Default dosage regimen is the ‘four-times-daily-scheme’ but any dosage regimen can be entered in a structured and analyzable form. In addition, detailed information e.g. on drug handling is collected for each product. After each interview a copy of the database is stored on a medium and a unique identifier for each user, patient, and drug allows uniting databases when the tool is concurrently used at different locations.

The tool is applied in a large cohort study. Until now, medication data of 511 patients have been collected (2,569 drugs). Of all drugs 70.6% were assessed with a barcode reader. The ‘four-times-daily’ dosage regimen was chosen most frequently (83.2%).

Conclusions: This tool allows electronic assessment of detailed drug information in pharmacoepidemiological studies. Its practicability has been demonstrated in a large prospective cohort study.

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Medication review of patients community-dwelling seniors using high-level homecare service

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Background and aim: Investigations on polypharmacy and problems arising from polypharmacy (e.g. medication burden, falling, and inappropriate dosing in renal impairment) in functionally impaired or disabled patients have been obtained in patients living in residential care homes and nursing homes. Data from home-dwelling patients in high-level ambulatory care (one or more daily visits by a care-giver) a scant. Usually, the medication of these patients is prescribed by general practitioner, but administered and supervised by the care-giving nurse, and the patient is seen by the GP less frequently than a mobile patient.

Material and method: In an observational study (March 2008–March 2009), we evaluated the medication in a cohort of patients who were daily visited by an ambulatory care giver (site: Wiesbaden). The cohort consisted of 102 patients (72 w; 30 m; age 80 y (median, range 52–93y), most frequent diagnoses: hypertension [N=63], coronary artery disease [N=57], hyperlipidemia [N=37], diabetes mellitus [N=25], chronic heart failure [N=23]). We documented data on diagnoses, occurrence of falls, laboratory values obtained by the general practitioner, chronic medication and medication used at demand at

altogether 3 visits (V1, V2, V3) at intervals of 4 months, data were taken from the GP records (laboratory) or the medical records available to the care-giving nurse.

Results: The medication burden increased slightly within one year, at V1 patients had 5 chronic prescriptions (median, range 3– 15), at V3 6 (3–17) medications were prescribed. A total of 8 daily doses (median, range 3–21) were given at V1 and increased to 8.5 (4–25) at V3. Within one year, 2 (median, range 0-21) changes in the medication (discontinuation, newly added medications) have occurred; 15% of all prescriptions at V1 have been discontinued and most replaced by a new medication. At V2, 41/102 patients had their serum creatinine measured within the last year, 21 of these 41 patients had a GFR <50 ml/min (calculated according Cockroft & Gault formula), these 21 patients had 52 medications which need adjustment in renal impairment, from these 52 medications 18 were not appropriately adjusted. At V3, in 13 of 33 patients with a GFR <50 ml/min altogether 6 of 31 medications which need adjustment were not adjusted. Within one year, 29 of 102 patients had at least one falling event (total 38 falls), 20 patients had been either admitted to the hospital or visited by an emergency doctor. 18 of these 29 patients had a benzodiazepine prescribed regularly, whereas in 46 patients which were not immobilized and did not fall have, a benzodiazepine was prescribed in 6 cases (x2-test p = 0.004).

Conclusions: This survey in home dwelling patients requiring high-level care proves a high medication burden, reflecting the morbidity spectrum of these patients. Deficits have been detected in the surveillance of the medication (infrequent and scant control of creatinine), and an association between benzodiazepine prescriptions and falls can be demonstrated.

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How are asthma types coded in the out-patient sector? Analysis of claims data from 2004–2007

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Background and aim: Aim of the study is to assess physicians coding of Asthma in the out-patient sector using health insurance claims data. We conducted the study with focus on the four-character ICD10 code to find out how often different asthma types were diagnosed.

Material and method: Out-patient claims data of the Gmünder ErsatzKasse (GEK) between 2004 and 2007 were used. Persons classified as having asthma were included (at least 3 quarters per year with ambulatory documentations of asthma diagnosis). During physician-related assessment one diagnosis coding was counted once per patient and quarter.

Results: The most frequently coded asthma type in 2007 was "asthma, unspecified" (ICD10:J45.9; 1.28% of all insured persons). Allergic asthma (ICD10:J45.0; 0.62%) was the second most frequent type. The diagnoses nonallergic asthma (ICD10:J45.1; 0.12%) and mixed asthma (ICD10:J45.8; 0.10%) are coded to a much lesser extent. In young persons the proportion of persons with allergic asthma is higher, whereas the nonallergic type is slightly more frequent in the elderly. No noticeable change over time was observed when comparing results from year 2007 with those of 2004–2006.

In 64.4% (2007) of the cases physicians coded asthma unspecifically (J45.9), with paediatricians (68.9%) and GPs (69.6%) above average. Physicians specialized in dermatology/allergology (J45.9: 45.6%) and internal medicine/pneumology (J45.9: 50.1%) differentiated types most frequently.

Conclusions: The predominantly ICD10-coded asthma type in all age groups is "Asthma, unspecified". Due to this result, it is not possible to assess the frequencies of different asthma types more comprehensively. Claims data are collected for administrative rather than for research purposes. Though asthma is in the disease pool of "Morbi-RSA", no change is expected, because a more precise asthma categorization is not relevant for administrative purposes. We identified noticeable differences in coding behaviour of various specialist groups, with a stronger subcategory differentiation on the part of allergologists and internists/pneumologists, respectively.

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Is there a correlation between hormone therapy and the prescription of antidepressants?

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Background and aim: Since the results of the Women Health Initiative (WHI) and the Million Women Study (MWS) had been published in 2002/2003 the prescription of Hormone medicals registered for peri- and postmenopausal therapy decreased in Germany. Nearly at the same time the prescription of Antidepressants has increased. The aim of this study is to clarify if there is a

correlation and/or is there a difference between women with Hormone Therapy (HT) and those without HT.

Material and method: For the following analysis secondary data of the Gmünder ErsatzKasse (GEK) was used. This data was related to individuals but non-identifying. The choice of the medicals that were taken into consideration were in accordance with the ATC-Code (ATC = Anatomical Therapeutic Chemical Code). Outpatient data was used to identify patients with depression and/or psychotherapy. Only data of women who were insured the whole time in 2007 and were aged between 40 and below 100 were taken into account. The analysis was done by using SAS Statistic program.

Results: 338.055 women were permanently insured in 2007 and between 40 and <100 years of age. Of those 43.401 got a prescription of HT. Women taking HT had more diagnoses of depression and a higher prescription prevalence of antidepressants. And these women got also more psychotherapy than women not taking HT.

It is demonstrated that the prevalence of depression plus a prescription of antidepressants increased by age for women without HT. Women taking HT showed a stagnation of this prevalence during the climacteric period.

Regarding the subgroups of antidepressants we found out that Selective Serotonin Reuptake Inhibitors (SSRI) were less prescribed than Tricyclic Antidepressants (TCA) for women taking HT. Higher SSRI prescription rates can be stated for women not taking HT and who were older (70+).

Conclusions: Women taking HT got more prescriptions of antidepressants and more psychotherapy but had also more diagnoses of depression. It is shown that the prevalence of depression plus a prescription of antidepressants increased with age in women not taking HT. Women taking HT had an increased rate until the age of 55 than it stagnated up to 70 years of age and after this it increased again. Contrary to German recommendation Psychotherapy is only marginal prescribed and particularly for older women.

With regard to the subgroups of antidepressants it can be stated that women taking HT had less prescriptions of SSRI's and therefore more of TCA which are discussed to have more side-effects especially on older women. SSRI's show a higher prescription prevalence for women taking not HT and were older (70+). This was not expected because for SSRI's it is described in the literature that high estriol levels are necessary for the effectiveness of SSRI's.

Women with depression should get more psychotherapy and for the prescription of antidepressants hormone levels and also hormone medication should be taken into account.

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Prescription patterns of drugs inhibiting the renin-angiotensin-aldosterone-system (RAAS) in the Federal State of Saxony – an analysis of the AOK health insurance service database in the years 2003 and 2004

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Background and aim: RAAS-blockade plays a pivotal role not only in the management of arterial hypertension but also in congestive heart failure, post myocardial infarction and nephropathy with albuminuria, especially in diabetic patients. However, so far little is known about the physicians' prescription preferences of ACE-inhibitors (ACE-Is) and angiotensin-receptor-blockers (ARBs) in Germany on a regional level.

Material and method: We systematically analyzed the prescription patterns of ACE-inhibitors (ACE-Is) and Angiotensin receptor blockers (ARBs) in the federal state of Saxony, Germany, using the database of the largest health insurance service (AOK Krankenkasse) in Saxony for the years 2003 and 2004. Prescriptions for all insured individuals who received either an ACE-I or an ARB were analyzed. Data were evaluated quarterly and an average was calculated for each calendar year.

Results: A total of 301.510 patients were treated with a RAAS blocking agent (either ACE-I or ARB) in 2003 and 304.272 patients in 2004. In 2003, 74.6% of these patients were treated with an ACE-I, 23.1% with an ARB and 2.3% received double RAAS-blockade with an ACE-I and an ARB. In 2004, 72.6% of patients received an ACE-I, 25.1% an ARB and 2.3% of patients were on ACE-I-ARB-combination treatment. Of all ACE-I prescriptions, captopril (23.1%), enalapril (21.9%) and lisinopril (19.7%) were the most frequently prescribed drugs in 2003. Valsartan (27.3%), candesartan (24.2%) and losartan (18.5%) were the most frequently administered ARBs in 2003. In 2004, ramipril (24.3%), enalapril (21.5%) and captopril (19.9%) were the most commonly used ACE-Is. The pattern of ARB prescriptions in 2004 was similar to the previous year: valsartan (27.0%), candesartan (24.1%) and losartan (15.3%). Much less RAAS blocking agents were prescribed in the first quarter of each year compared to the fourth quarter, an observation which might be linked to economic reasons.

Conclusions: The number of prescriptions for ACE-Is was three times higher compared to ARBs. Dual RAAS-blockade with ACE-I – ARB combination treatment was uncommonly prescribed which is in line with limited evidence of benefit from double RAAS inhibition.

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Prescription of antidepressants and comorbidity of depression

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Background and aim: In the last years prescriptions of antidepressants increased substantially. Their efficiency was discussed and also analysed in numerous publications with regard to evidence and effectiveness. Guidelines recommend the prescription of psychotherapy.

The aim of the study was to present the prescription prevalence for people aged 18 years and older according to age, sex, different drugs types and sufficient drug treatment. In addition, we analysed the outpatient care data in regard to psychotherapy and comorbidity.

Material and method: Statutory health insurance data (Gmuender ErsatzKasse (GEK)) from 2000, 2003, and 2005 to 2008 were analysed for the prescription of antidepressants. Prevalence, prescribed packages and DDDs were calculated. Outpatient data of the prescription of psychotherapy and secondary disorders from 2005–2007 was linked with the prescriptions of drugs in 2005–2007 additionally.

Results: The chance for a depression diagnosis is more than twice as high for females than for males, especially in older persons. Likewise, the prescription of antidepressants is higher. The number of prescribed psychotherapy is very low in both sexes. Regarding comorbidities, we found musculoskeletal disorders at the top, followed by mental and behavioural disorders, excluding depression.

Conclusions: People with a depression should be early diagnosed and adequately treated; this especially applies to older patients. A systemic analysis on psychosomatic comorbidity should become important for future research.

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Private prescriptions of zolpidem and zopiclone: What medication claims data won't tell us

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Background and aim: Medication claims data of several statutory health insurances (SHIs) have been increasingly used for research purposes over the last years. However, these data might have several limitations, e.g. private prescriptons (Privatverordnungen) are undocumented because these information are not recorded in insurance claims data. Any doctor can provide private prescriptions for prescription drugs. They are fully funded by the patient. This may be a reason why physicians prescribe drugs that are associated with abuse and dependence more frequently on private prescriptions. The aim of this study was to analyse the amount of private prescriptons of zolpidem and zopiclone (Z-drugs) over a period of 15 years in Germany.

Material and method: We compared utilization data from statutory health insurance claims with wholesale sales data from community pharmacies for the years 1993–2007. The differences between both databases were assumed to be private prescriptions [1].

Results: Throughout 1993 and 2007, purchased packages of zolpidem (1.4 million to 3.7 million) and zopiclone increased (0.8 million to 3.9 million). A rising proportion of additional private prescriptions for zolpidem resp. zopiclone has been written between 1993 (+6 resp. +6%), 1999 (+43% resp. +34%) and 2007 (122% resp. 72%).

Conclusions: Z-drugs, and especially zolpidem, are increasingly dispensed on private prescriptions over the last years. However, transactional data captured at the point as drugs move from wholesalers to pharmacies are only a proxy of use. Private prescriptions are not recorded in SHI claims data. This should be considered when analysing drugs that might have an abuse and dependence potential.

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Insulin glargin stellt eine kostengünstige Alternative im Vergleich zu NPH-Insulin bei der Behandlung insulinpflichtiger Diabetiker dar: Ergebnisse einer Verordnungsdatenanalyse

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Hintergrund und Ziel: In mehreren pharmakoökonomischen Analysen wurden Insulin glargin (Lantus®) und NPH-Insulin hinsichtlich ihrer Behandlungskosten bei insulinpflichtigen Patienten mit Diabetes Typ 2 miteinander verglichen. Dabei konnte gezeigt werden, dass aus Sicht der gesetzlichen Kranken-versicherung (GKV) eine Therapie mit Insulin glargin gegenüber einer Behandlung mit NPH-Insulin kostenneutral oder sogar kostensparend ist [1], [2], [3]. Ziel der vorliegenden Analyse ist es, die bereits vorhandenen Ergebnisse anhand einer größeren und repräsentativen Stichprobe von Krankenkassendaten (Patienten-Tracking National, INSIGHT Health) zu verifizieren.

Material und Methoden: In der Datenbasis werden monatlich mittels anonymisierten Patienten-IDs rund zehn Prozent des deutschen GKV-Marktes (70,2 Mio. Patienten) über alle Bundesländer repräsentativ abgebildet. In der vorliegenden Studie wurden über drei Kalenderjahre (2006–2008) diejenigen Patienten ermittelt, die in zwei aufeinander folgenden Quartalen mindestens eine Insulin glargin-Verordnung bzw. eine NPH-Insulin-Verordnung erhielten. Auf Basis dieser Patientenselektion wurde für insgesamt sechs Kostenträger(gruppen) die zeitgleiche Co-Medikation in den Indikationsgruppen Bolusinsuline, orale Antidiabetika, Teststreifen sowie Lanzetten/Nadeln ermittelt. Die mengenbezogenen Verordnungsinformationen wurden mit den jeweiligen Apothekenverkaufspreisen multipliziert. Das Ergebnis stellt die durchschnittlichen jährlichen Behandlungskosten pro Diabetespatient dar.

Ergebnisse: Die aggregierten absoluten jährlichen Gesamtkosten pro Diabetespatient betragen in der vorliegenden Analyse für Insulin glargin-basierte Behandlungsregime 1262 € (2006), 1295 € (2007) bzw. 1338 € (2008) über alle Kostenträger. Die korrespondierenden jährlichen Gesamtkosten pro Diabetespatient für NPH-Insulin-basierte Therapieregime betragen 1283 € (2006), 1330 € (2007) bzw. 1379 € (2008). Für die drei betrachteten Kalenderjahre (2006–2008) liegen die Behandlungskosten für Insulin glargin-basierte Therapien tendenziell leicht unter den Kosten der jeweiligen NPH-Vergleichsgruppen. Die Analyse der Einzelkosten zeigt, dass die höheren Beschaffungskosten für das Basalinsulinanalogon (Insulin glargin) durch Einsparungen beim Bolusinsulin- sowie beim Teststreifenverbrauch überkompensiert werden. Dieser Behandlungskostenvorteil zugunsten der Insulin glargin-basierten Behandlungsregime findet sich durchgängig über alle drei Jahre für die Diabetespatienten der Allgemeinen Ortskrankenkassen (AOK), der Betriebskrankenkassen (BKK), der Innungskrankenkassen (IKK), der Barmer Ersatzkasse (BEK) sowie der Deutschen Angestellten Krankenkasse (DAK) . Die Differenzen der durchschnittlichen jährlichen Gesamtkosten über alle Kostenträger zeigen über die Analysedauer von drei Jahren eine leichte, aber kontinuierliche Zunahme des Einspareffekts zugunsten der Insulin glargin basierten Behandlungsregime.

Schlussfolgerungen: Unter realen Versorgungsbedingungen zeigt sich aus Sicht der gesetzlichen Krankenversicherung (GKV) eine Kostenneutralität zwischen Insulin glargin- und NPH-Insulin-basierten Behandlungsregimen. Die vorliegende Datenbankanalyse bestätigt die Ergebnisse aus bereits vorhandenen Versorgungsforschungsstudien. Sekundärdatenanalysen liefern trotz methodischer Einschränkungen (mangelnde Strukturgleichheit) wichtige Erkenntnisse zum Verständnis des realen Versorgungsgeschehens und stellen für Entscheidungsträger deshalb eine wertvolle Ergänzung zu randomisierten kontrollierten Studien (RCTs) dar.

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Resource utilization and treatment costs in type 2 diabetes on intensified insulin therapy with insulin glargine compared to insulin detemir under real world conditions in Germany

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Background and aim: To compare resource utilization and costs of type 2 diabetic (T2D) patients either treated with insulin glargine (GLA) or insulin detemir (DET) in a basal-bolus regimen.

Material and method: LIVE-COM* was a non interventional, cross sectional, retrospective study in 138 primary care centers in Germany (representative sample) performed from April–Sep 2008. 1731 T2D patients with statutory health insurance (SHI) status were enrolled when either treated with GLA (n=1150) or DET (n=581) in a basal-bolus therapy for at least 6 months prior to documentation. Total

direct diabetes treatment costs (DTC) derived from antidiabetic medications (insulins, oral drugs), blood glucose self-monitoring (test strips, lancets), needles and hypokit use for severe hypoglycaemia were assessed retrospectively over 6 months.

Results: Patient characteristics for GLA (53% male) and DET (49% male) were (mean) age: 66/65 years, BMI: 31.3/32.7 kg/m², HbA1c: 7.50/7.69%, fasting blood glucose: 140/148 mg/dl, onset of diabetes (>10 yrs: 60/59%), start of insulin therapy (>5 yrs: 62/64%), number of diabetic complications and risk factors (3.0/2.9). Resource use: GLA patients had on average fewer basal insulin injections per day (1.1 vs. 1.3) and required significantly less test strips for blood glucose self-measurements (3.2 vs. 3.6). Mean daily total insulin dose (basal/bolus) was significantly lower in GLA (27.7/40.3 U) compared to DET (32.1/47.1 U). Reported hypoglycemic events, hospitalization rates and frequency of physician contacts did not differ between groups. Adjusted mean DTC per patient and 6 months were 932 € (GLA) vs. 1061 € (DET); p<0.001. Adjusted mean single costs (GLA vs. DET): basal insulin 223 vs. 246 € (p<0.001), bolus insulin 241 vs. 289 € (p<0.001), oral drugs 37 vs. 36 € (ns), test strips 347 vs. 393 € (p<0.001), needles 68 vs. 80 € (p<0.001), lancets 14 vs. 16 € (ns).

Conclusions: Insulin glargine based basal-bolus regimens resulted in annual cost savings of 256 € per patient compared to DET from the SHI perspective in Germany. Under routine care conditions GLA patients showed better glycemic control.

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Consumption of intranasal corticosteroid-containing sprays (INS) for the treatment of allergic rhinitis – a comparison of "real life" prescription data of treatment with budesonide and mometasone in Germany

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Background and aim: Intranasal corticosteroids (INS) are approved for the treatment of seasonal allergic and persistent rhinitis. Comparison of INS treatment cost often based on the assumption of one single defined daily dose for all different corticosteroids. The aim of the analysis was to quantify and compare INS doses consumed in real-life treatment.

Material and method: The German IMS Disease Analyzer database was analyzed which contains representative data on prescriptions and diagnoses of more than 11 mil patients (pts) reported from office-based physicians. Pts with allergic rhinitis were initially prescribed for budesonide- (BUD) or mometasone- (MOM) containing INS between Oct 2004 and Sep 2006. Follow-up period was 2 years and pts had to have at least one additional INS prescription in the second year. Descriptive analysis and multiple linear regression modelling was performed for comparing the INS consumption of pts treated by general practitioners (GP) and ear-nose-throat specialists (ENT).

Results: 2350 (BUD)/14.554 (MOM) pts from GP and 660/8516 pts from the ENT were analyzed. The portion of pts with persistent allergic rhinitis was 13.1% (BUD) vs 7.6% (MOM) in the GP and 7.4% vs 7.0% in the ENT cohort. The average number of puffs prescribed per patient was BUD/MOM: 183.0/77.0CHECK (at index day), 198.6/ 83.2 (after 45 days), 215.0/ 91.0 (after 90 days) and 318.2/129.7 (after 365 days) in the GP cohort and 190.7/97.9, 218.1/113.3, 255.2/127.9 and 468.4/195.5 in the ENT cohort. Regression analysis showed significant factors of –105.4 to –186.6 in the GP cohort (ENT: –90,9 and –260,2) for the influence of the INS type on the consumption over time.

Conclusions: The mean consumption of MOM in INS treatment of allergic rhinitis was much lower compared to BUD. This finding is against the common practice in Germany to assume an identical defined daily dose of the two different INS substances for comparison of treatment costs.

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ATC-based determination of the specialization of Statutory Health Insurance Accredited Physicians

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Background and aim: There are yearly "goal agreements" on regional levels between Statutory Health Insurances and the National Association of Statutory Health Insurance Accredited Physicians orientated on principals given by national law. Additionally or sometimes excluded are checking's on total budget level (so called "Richtgrößenprüfungen") dependent on the specialization of the physicians.

Material and method: We use cluster methods with Mathematica 6.0 to determine specializations on the basis

of ATC codes on different levels using prescription data of one year. The results are compared with historically determined groups of specialization. If given groups (in some context) are fixed, one has to determine the individual position of physicians. So one can transfer a grouping with special properties to other regions. We propose a new maximum method for he mentioned decision process. It shell not depend on the scale of a special group. It is based on the amount of an ATC fraction measured by costs or by daily drug doses for he considered specialization in comparison with others.

Results: Cluster methods offer the possibility of further differentiation without the danger of getting to small groups. Further on they show similarities of groups, as Urologists and Gynecologists. There are difficulties to separate Surgeons from a lot of other groups on this level. The determination of Neurological, Oncologists, Gastroenterologists, Rheumatics and Nephrologists can be well done; separation of Cardiologists from General Practitioners is more difficult by the used procedure. One can imagine, that Ophthalmologists with an ATC code S01 (ophthalmologic) with prescription fraction value of 96% can easily determined (but mention, that this is the value of the group, the individual values of the physicians may differ much so it is not clear at all if the positions are not such extremely). The top position G03 (sex hormones and modulators of the genital system) of Gynecologists is 38% in comparison with 24% of Urologists, their top position is L02 (endocrine therapy) with 49%. The top position of Neurological is R03 (pneumologicals) with 74% of costs. Cardiologists have a top position of only 18% in costs: B01 (antitrombotic agents). The Oncologists have a top position of 44% drugs without ATC code (special preparations). General Practitioners have top positions of 10% for both A10 (drugs used in diabetics) and C09 (agents acting on the renin-angiotensin system). The level of consideration the ATC code is important for the classification of groups of physicians (in the examples we used the ATC 3 level). For some groups there are separation problems on a global level. Then one can use hierarchical or local methods that shall mean that one has to separate only subgroups of physicians and ATC codes. The determination of subgroups shall be done by algorithms based on ATC-information and not by individual decisions using additional and personal determined information.

Conclusions: It is possible to group the Physicians using ATC codes for the prescriptions. As a first step one can use global procedures. For some details one has to use local procedures and the ATC code in deeper positions. The ATC code in comparison with the prescription behavior of physicians and groups of physicians lead to useful benchmark results. In order to ensure therapeutically and pharmacologically high quality of prescriptions while providing patients with drugs under budget conditions one has to use classifications as a result of a combination of pharmacological data bank information, market information and actual therapeutic and pharmacological standards.

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Patient information needs identified by a drug information service

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Background and aim: The Institute of Clinical Pharmacology at the TU Dresden offers a drug information service for patients, which seeks to provide independent and evidence-based information on all drug-related questions. The presented study analyzes whether increased information needs can be detected for specific drug groups or patient subgroups.

Material and method: Patients who contacted the service were interviewed concerning their socio-demographic characteristics, reason for request, number and kind of drugs taken and present diseases. All requests were documented by means of a questionnaire. The data were recorded in a relational database. In the present evaluation all requests from January to December 2008 were analyzed descriptively with a main focus on information needs by the patients.

Results: In the evaluated period, 1457 requests were registered in total. Women used the service more frequently (63.3%) than men. The largest percentage of requests originated from the age group 61 to 80 years (40.5%). The drugs that were most commonly the reason for a request were drugs for the cardiovascular system (26.8%) and drugs for the nervous system (21.2%). Although only 2% of all drugs taken were systemic antiinfectives or antineoplastic/immunomodulating agents respectively, these drugs were relatively often the reason for a request. 55% of all patients taking a systemic antiinfective also named this drug as reason for the request, 40% had a question about their antineoplastic/immunomodulation agent.

Conclusions: We identified an increased information need in elderly patients. Commonly prescribed drugs present one of the main reasons for a request, showing that there is a general information need. The high number of requests about systemic antiinfectives and antineoplastic/immunomodulating agents may be due to the fact that these are prescribed for severe diseases and can show severe side effects. Thus, a specific information need can be assumed for this drug group.

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Kurzportrait der Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie (GAA) e.V.

Die GAA ist eine Fachgesellschaft für Ärzte, Apotheker, Sozialwissenschaftler, Epidemiologen und Gesundheitswissenschaftlern, die sich mit Fragen der Arzneimittelanwendungsforschung und der Arzneimittelepidemiologie beschäftigen.

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