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PRECISION DOSING: NAVIGATING ADHERENCE
IN DRUG DEVELOPMENT AND CLINICAL PRACTICE



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28TH ESPACOMP **2024 ANNUAL MEETING**

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Risk of bias tools for medication adherence research: RoBIAS and RoBOAS

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Abstract

Introduction: An important aspect of adherence research is the identification and mitigation of biases that may impact the inferences from adherence studies. Guidance to assist researchers in the understanding of bias risk when conducting or reviewing adherence research is currently not available. To address this gap, tools to identify and gauge the magnitude of important biases that may impact adherence research have been developed.

Aim: To present the finalised risk-of-bias tools for medication adherence studies.

Methods: The Items in the tools were derived from a literature review including the identification of important sources of bias from the Oxford Catalogue of Bias, the EMERGE guidelines and TEOS framework. Draft versions of the tools were evaluated using a cohort of expert adherence researchers. Feedback from reviewers were collated to inform the finalised bias tools.

Results: Two risk of bias tools were developed; the Risk of Bias tool for Interventional Adherence Studies (RoBIAS) and the Risk of Bias tool for Observational Adherence Studies (RoBOAS). The tools encompassed four Domains relating to the design, measurement and analysis of adherence research, including a Domain based ranking scale. Each Domain consisted of detailed items/statements, each mapped to specific biases relevant to adherence research and study designs.

Discussion and Conclusion: Tools tailored to identify and assess important biases in randomised and observational adherence studies were developed. The tools are intended to have utility when systematically reviewing published adherence research and to inform the design of future adherence studies.

Global attempts to improve patient initiation adherence via the New Medicines Service – Lessons learned in view of implementation and sustainability

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Abstract

Aim: In the UK, the New Medicine Service (NMS) was developed to target patient initiation adherence. Subsequent improvements in patient adherence and cost savings to the health system led to an international scale-up of the NMS in 10 other countries, however, implementation barriers were experienced, and the effect was not replicated in all settings. This study investigates potential implementation and sustainability issues that can explain the suboptimal scale-ups.

Methods: A multi-country case study was conducted between May 2023 and January 2024 (11/13 research teams) using semi-structured online interviews informed by an implementation science perspective. Interview guides were developed based on the TiDIER framework and the Basel Heptagon of Implementation Science. A deductive thematic analysis was conducted using the Consolidated Framework for Implementation Research (CFIR).

Results: Barriers to implementation and sustainability were experienced across all domains of the CFIR including project timeline pressures, inefficient healthcare technological infrastructure for data collection and interprofessional care, underdeveloped interprofessional collaboration between pharmacists and physicians, time constraints within pharmacies, insufficient patient uptake and unsustainable financial models. Only three countries were able to sustain the NMS in practice. Almost all research groups indicated that stakeholder engagement and formative needs assessments prior to implementation would have increased the likelihood of implementation success as context specific barriers were not identified nor addresses specifically with implementation strategies.

Discussion and Conclusion: The implementation and sustainability issues observed in the scale-up of the NMS points to the need of using an implementation science approach for the implementation of complex intervention in varying contexts.

Identifying longitudinal medication adherence patterns of antipsychotic treatments: A real-world cohort study in Catalonia, Spain.

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Abstract

Introduction: Suboptimal adherence to antipsychotics leads to poorer outcomes and relapse. The adherence behaviour of people over time may be influenced by several factors including the number of antipsychotics used and their formulation.

Aim: To identify longitudinal adherence patterns to oral and long-acting injectable (LAI) antipsychotics in monotherapy or polypharmacy through group-based trajectory modelling (GBTM).

Methods: A retrospective cohort study that linked prescription and dispensing data of adult patients with a new antipsychotic prescribed between 2015 and 2019 in Catalonia (Spain). GBTM was used to classify patients following a similar longitudinal pattern of adherence. The response variable was adherence, estimated through the calculation of the continuous medication availability measure (CMA), in each 30-day period during 12 months of follow-up. Identified trajectories were compared in their baseline and treatment characteristics.

Results: Among the 7,730 people included in the study, we identified seven clinically distinct trajectory groups: “non-adherent” (19%), “low adherent” (9%), “early-decline” (6%), “mid-decline” (5%), “late-decline” (5%), “high adherent” (21%), and “fully adherent” (35%). Trajectories with better adherence were more likely to receive prescriptions from a psychiatrist, receive LAI and have previous exposure to other antipsychotics. Intermittent medication use patterns and high levels of polypharmacy were characteristics of both the low and high adherent groups.

Discussion/Conclusion: The trajectories reflect three different adherence behaviours: stable over time (fully adherent or non-adherent); patients who discontinue treatment at some point and; patients with an intermittent refill pattern. Interventions should be specifically designed to target each behaviour that leads to a suboptimal adherence outcome.

A deep learning model can predict early treatment discontinuation from electronic dosing history data

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Abstract

Introduction: Participants enrolled in clinical trials for drug development are asked to take the investigational product consistently (implementation) until the end of the trial (persistence). Participants who stop taking the treatment too early decrease the power of the clinical trial, potentially leading to its failure.

Aim: The objective of this work was to develop a machine/deep learning model to predict early treatment discontinuation from electronic dosing history data.

Methods: Electronically compiled dosing history data from subjects following a once-daily regimen and enrolled in trials lasting one year were extracted from the MEMS® Adherence Knowledge Center. Several machine/deep learning models were trained on 80% of this data to predict whether a participant would discontinue taking medication before one year. Models were evaluated using the area under the receiver operating characteristic curve (AUROC). A test set containing 20% of the data was kept aside for final evaluation of the best model.

Results: Data from 3,442 participants included in one-year trials with once-daily regimens were analyzed. Early treatment discontinuation had occurred in 22%. The best-performing model was a convolutional neural network (CNN). Its AUROC on the test set was 0.70.

Discussion: A CNN works with images representing a participant's dosing history data (a.k.a. "chronology plots"). Such a model does not require extracting features from data, making it easier to use.

Conclusion: Deep learning models can predict early treatment discontinuation from electronic dosing history data, allowing to flag and intervene on participants at risk.

An R tutorial on the Waiting Time Distribution for estimating dispensation length to compute medication adherence

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Abstract

Aim: Electronic data on medication dispensations are widely used to conduct drug-utilization, effectiveness and safety studies. When only dates of dispensations are available, a necessary first step in medication adherence studies is to estimate dispensation lengths, i.e. how long an individual is considered to be in treatment after the dispensation. The parametric waiting time distribution (WTD) is a data-driven alternative to the commonly used strategy of using the Defined Daily Dose (DDD) assigned by the WHO.

Methods: The WTD is a frequency distribution of either the time to the first dispensation for each individual within a fixed time window or the time from their last dispensation within the time window to the end (reverse WTD). The duration is estimated as a pre-specified percentile of the distribution of time between subsequent dispensations, representing the time for that proportion of continuous users to get a new dispensation. This method allows to tailor the prediction of the dispensation length to important variables, such as age, gender, and comorbidities.

Results: An R package is now available, joining the existing Stata module.

Conclusion: The rWTD is a statistically robust, data-driven method for assigning duration to pharmacy dispensations. Its strength lies in the possibility of estimating tailored durations by considering relevant covariates. The present work is a tutorial on the application of the WTD, providing a step-by-step guide for implementation in R, with a detailed explanation of the function output.

New Medicines Service to support patients' transition to primary care: a living lab study assessing drug-related problems, patient satisfaction and self-efficacy at initiation of cardiovascular medication

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Abstract

Background: Patients transitioning from hospital to home while starting long-term cardiovascular medicines are likely to experience drug-related problems. The New Medicine Service may support their readmission to primary care.

Aim: To evaluate the implementation of the NMS on drug-related problems, satisfaction with information and self-efficacy in patients who start with cardiovascular medicines. Secondary objectives included identifying risk factors for DRPs and first-fill discontinuation.

Methods: A living-lab study in an outpatient pharmacy and 14 community pharmacies in Almere, the Netherlands, involved patients ≥ 18 years receiving new cardiovascular prescriptions. Two weeks after dispensing, a telephone counseling session aimed to identify and resolve DRPs. Patient satisfaction and self-efficacy were assessed during a follow-up call. First-fill discontinuation was measured using dispensing data, and logistic regression identified risk factors for DRPs.

Results: Of the 1647 eligible patients, 743 received the NMS. Pharmacist unavailability (33.3%, $n=548$) led to substantial drop-out. Of all patients, 72.5% experienced ≥ 1 DRP. NMS improved patients' satisfaction with information and self-efficacy ($p < 0.001$). Outpatient visits (adj. OR 0.64), cardiovascular medicine in use (adj. OR 0.65), and use of chronic medicines (adj. OR 1.71) influenced DRPs. First-fill discontinuation was the same post-NMS, but patients who experienced a DRP discontinued more often (14.8% vs. 8.6%, $p=0.030$).

Conclusions: Implementing the NMS in a real-world transitional care setting allowed pharmacists to identify DRPs and provide counseling tailored to patient needs. Patients reported higher satisfaction with information and increased self-efficacy. Priority should be given to at-risk patients for DRPs, and deploy other pharmacy staff to perform the NMS.

Tailoring the Consolidated Framework for Implementation Research (CFIR) to assess the implementability of medication adherence interventions

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Abstract

Background: Predicting whether an intervention can be successfully implemented a priori would be beneficial. Although several theories and frameworks exist to guide the implementation process, none are specific for medication adherence interventions.

Aim: To tailor an implementation framework for assessing the implementability of medication adherence interventions in a specific context.

Methods: In a three-round Delphi study, implementation experts rated determinants based on constructs of the Consolidated Framework for Implementation (CFIR) on their importance in assessing implementation success of medication adherence interventions. Consensus was defined as more than 70% (dis)agreement on level of importance (five-point Likert scale). In four living labs, determinants for implementing medication adherence interventions were identified using project meeting documentations and interview transcripts, analysed using the CFIR framework. Results were compared to assess agreement between Delphi results and determinants in real-world practice.

Results: Eighteen experts rated 29 of 41 determinants as important for implementation of medication adherence interventions. Seven of these determinants were observed as determinants in all four living labs (compatibility; available resources; access to knowledge & information; competence; motivation; engaging; reflecting & evaluation). Of the 12 determinants identified to be of no importance, 2 were indeed not important in any living lab (external pressure; learning-centeredness culture).

Conclusions: This study demonstrates a discrepancy between expert opinions and observed determinants important during implementation of medication adherence interventions. At a minimum, determinants identified as important by both the Delphi study and real-world practice should be considered when predicting implementation success of medication adherence interventions in specific contexts.

Stakeholder co-development of an interprofessional service targeting initiation adherence - the myCare Start - Implementation project

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Abstract

Background: Based on the UK's New Medicine Service (NMS), myCare Start is a pharmaceutical care service to improve patient initiation adherence to a newly prescribed long-term medication. To ensure the services applicability to the Swiss setting, the myCare Start - Implementation project (myCare Start-I) has developed and engaged a stakeholder group to co-develop the intervention and select contextually appropriate implementation strategies.

Methods: The stakeholder team was developed based on Barkhordarian et al.'s (2015) recommendations, comprising a systematic identification of relevant stakeholders, mapping their potential contribution, capacity and interest. Guided by contextual analysis findings, factors affecting intervention design and implementation of the myCare Start service were identified. Open-ended questionnaires were created based on these factors to gather further input from stakeholders to optimize the intervention and co-develop strategies to facilitate the delivery of myCare Start. An exploratory qualitative approach will be used, involving repeated semi-structured co-creation focus groups with stakeholders to continuously refine and enhance the intervention through iterative feedback and development cycles.

Results: The myCare Start-I Stakeholder group (n=36) is comprised of policy-level government representatives, health-insurers, representatives from pharmaceutical technology organisations, pharmacists, physicians, patients and nurses. Co-development of the myCare Start intervention and implementation strategies is ongoing, with the anticipated output being a contextually appropriate interprofessional service model to support patient initiation of new long-term medications.

Discussion and Conclusion: Stakeholder-driven co-creational implementation process will ensure the development of a revised myCare Start service tailored to the needs of the end-users.

Psoriasis and biologic drugs: estimating adherence using Tuscan administrative databases with GBTM models

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Abstract

Background: Psoriasis is an inflammatory skin disease and adherence to pharmacological therapy is a crucial aspect of the treatment. Methods currently used to estimate adherence often provide a single point estimate relative to an observation period, and they do not highlight the temporal dynamics of the phenomenon. This study aims to model the adherence to biological drugs over time and identify its predictors in individuals with psoriasis residing in Tuscany, Italy.

Methods: A retrospective cohort study was conducted, which included subjects who received their initial dispensing of a biologic drug between January 1, 2011, and December 31, 2016. Only new users with confirmed psoriasis were included and followed for 3 years from the date of their first dispensing. Group-Based Trajectory Modeling (GBTM) was employed to assess adherence, identifying distinct groups of subjects and modeling a trajectory for each group.

Results: The final cohort consisted of 1838 subjects. We identified four trajectory groups: early decline in adherence, late decline in adherence, high adherence, and moderate adherence. Additionally, we identified several covariates that enabled prediction of group membership: the specific drug used, age, use of non-biological drugs, and use of glucocorticoids.

Discussion and Conclusion: GBTM proved to be a useful tool for understanding and predicting patient behaviors over time. Limitations includes the lack of information on the reason for the reduction in adherence, affecting the interpretation of its trend.

Co-designing a medication adherence visualization user interface: A qualitative study of the perspectives of patients with cardiovascular conditions and type-2 diabetes living with polypharmacy.

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Abstract

Background: Adherence to medication is an essential behaviour for achieving intended health benefits, however, up to 50% of patients do not take their medications as prescribed. Although effective methods such as real-time digital monitoring for assessing and supporting medication use are on the rise, there is limited research on user perspectives and involvement in their development.

Aim: The aim of the study was to explore users' perspectives on medication adherence and co-design a visual adherence-support interface, STUMedView, to enhance adherence behaviour among people with cardiovascular disease and type 2 diabetes.

Methods: This qualitative study was conducted in two phases, using co-design methodology. Phase 1 explored participants' views on medication adherence and in phase 2, existing prototypes of the STUMedView interface were presented for feedback. Data were collected through focus group or telephone interviews (n=16) and analysed using thematic analysis.

Results: In phase 1, participants identified motivation, adherence support and self-management as key influencers for adherence. Lack of medication reviews was also recognised as a barrier to adherence due to challenges in communication and time constraints with healthcare-providers. Participants agreed that using visual adherence interventions could facilitate the review process. In phase 2, STUMedView prototypes were comprehensible and acceptable, although the use of simple descriptive texts and a traffic-light coding system were recommended for improvement.

Conclusion: Overall, findings indicate factors influencing medication adherence and reviews while highlighting participants' preference for developing an adherence-support interface. Involving users in adherence intervention development may be useful to ensure they address patients' needs and preferences.

Population pharmacokinetics of trametinib and impact of nonadherence on drug exposure as part of the Optimizing Oral Targeted Anticancer Therapies Study

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Abstract

Aim: Poor adherence to trametinib, an oral anticancer therapy, leads to sub-optimal drug exposure and unfavorable clinical outcomes. This study aimed to assess the impact of non-adherence on drug exposure.

Methods: Simulations based on a previously developed in-house population pharmacokinetic model, including effect of fat-free mass and age on clearance, were performed on 4000 virtual patients receiving a standard daily dose of 2 mg. The scenarios of medication implementation simulated at steady state were: missing a single dose, one or two random or consecutive doses per week, interrupting treatment for one week and then continuing treatment for two weeks. Concentration-time profiles from these scenarios were compared with an optimal adherence profile with no missed doses. The percentages of patients achieving the therapeutic target (minimum concentration ≥ 10.6 ng/mL), and the time to reach it were calculated.

Results: After a single missed dose, 31% of the 69% of patients who reached the therapeutic target needed a median of 3 days to recover, while the others remained within the target range. Frequent missed doses increase the risk of subtherapeutic exposure, e.g., only 44% of women under 65 years old remained on target after missing two random doses per week, compared to 71% with optimal adherence. For the two weeks on, one week off treatment, none of the men under 65 maintained the target concentration at the end of the week off.

Conclusion: Medication nonadherence leads to underexposure. Patient partnership and interprofessional collaboration are crucial to support trametinib adherence and improve patient outcomes.

Smart blister packaging and mobile application to monitor and support medication adherence: a two-arm randomized controlled trial and usability study

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Abstract

Introduction: Digital adherence monitoring provides an accurate method to measure and manage medication adherence in clinical trials and daily practice. A new digital pill blister, 'Cerepak[®]', paired with the MEMS[®] Mobile smartphone app, aims to enable objective adherence monitoring and management. Its usability is however unknown.

Objective: This study evaluates the usability of Cerepak[®] (with /without the app) in healthy volunteers for optimal implementation in clinical trials and practice.

Methods: Healthy volunteers were randomly allocated to two groups: Cerepak[®] with MEMS[®] Mobile App vs. Cerepak[®] alone in a randomized controlled trial. Volunteers were assigned based on age, gender, education level, and chronic medication usage experience. Participants were dispensed placebo tablets twice daily for two months, then completed a questionnaire and interview. Cerepak[®] usability was assessed using the System Usability Scale (SUS), and adherence was monitored by Cerepak[®] and manual pill counting.

Results: Of the 36 participants randomized, 35 completed the study. Mean[SD] age was 44[15] years; 66% were female, 43% were healthcare professionals, and 49% were chronic medication users. Overall SUS score indicated good usability (mean [SD] 70.9 [11.3]). The Cerepak[®] + app group had a significantly higher mean [SD] SUS score versus 'Cerepak[®] alone (76.5 [8.8] vs. 64.9 [10.7], p=0.001). Adherence data from Cerepak[®] differed from manual counts. The Cerepak[®] and app were considered easy to use, with no major patient burden foreseen for trials or practice. Concerns were noted for older individuals and patients with polypharmacy using the system.

Acknowledgements: AARDEX Group, WestRock

How do community pharmacists address medication adherence when dispensing a hospital discharge prescription?

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Abstract

Introduction: Community pharmacists (CPs) are often the first healthcare professionals encountered by the patient post-hospital discharge and play a crucial role in assessing and supporting medication adherence during this period, yet their practices and clinical reasoning remain underexplored.

Objective: Explore how CPs address medication adherence when dispensing a hospital discharge prescription.

Methods: A simulated CP-patient encounter was videotaped using a case scenario to evaluate CPs' practices, followed by an audiorecorded CP-researcher retrospective think-aloud to better understand CPs' clinical reasoning. The case scenario consisted of a discharged patient with type 2 diabetes requiring medication reconciliation, assessment of their medication knowledge and management skills to ensure medication initiation and implementation. Quantitative analysis examined the items addressed by the CPs during the simulation. Qualitative analysis of clinical reasoning used inductive and deductive methods, based on Charlin et al. clinical reasoning model and the Calgary-Cambridge medical interview model.

Results: Fourteen volunteered CPs participated in the study. While eleven offered adherence aids, only seven assessed non-adherence and five considered the patient's perspectives and resources. When analysing their clinical reasoning, some CPs assessed past adherence, medication knowledge and management, and applied shared decision-making, while others demonstrated shortcomings in their clinical reasoning by failing to consider the overall context and reaching conclusions prematurely. CPs highlighted ideas for improvement such as structuring the encounter or better involving the patient.

Conclusions: Most CPs addressed post-discharge medication adherence but partially. Practices are heterogenous and could be improved through training in assessing non-adherence and patients' needs using shared decision principles.

The SystemCHANGE intervention improves medication-taking habit in Turkish kidney transplant recipients

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Abstract

Introduction: SystemCHANGE, which harnesses patients' established, reoccurring, reliable personal systems to support medication-taking to become a dependable routine, has previously been shown to improve medication adherence in adult kidney transplant recipients.

Aim: The goal was to perform a secondary data analysis from the previous trial, the Turkish MAGIC study, investigating the effect of SystemCHANGE on medication-taking habit in adult Turkish kidney transplant recipients.

Methods: Twenty participants received the SystemCHANGE intervention and 20 others received an attention-control intervention. Their electronic medication adherence data (MEMS®) was analyzed. An objective habit index, quantifying week-by-week consistency in the pattern of medication intakes, was computed during screening, and during each month of intervention (6 months) and maintenance (6 months). Non-initiation and non-persistence were not evaluated in this research.

Results: Participants had a median age of 46 years, were mostly males (70%) and had a median time since transplantation of 7 years. The SystemCHANGE intervention positively impacted habit during intervention ($p=0.001$). This positive effect remained during the maintenance period, after the intervention had stopped ($p=0.018$). In addition, habit strength at the end of the intervention period significantly correlated with adherence 6 months later, at the end of the maintenance period ($p=0.002$).

Discussion: The SystemCHANGE intervention, focused on linking medication-taking to habits, reflects numerically in habit strength, quantified using an objective index. In addition, habit strength is shown to predict long-term medication adherence.

Conclusions: The SystemCHANGE intervention aimed at linking medication taking to existing habits has a positive effect on habit and, consequently, on medication adherence.

COMPASS model: Computational Model for Adherence and Support Solutions. Behavioral and adherence model for improving quality, health outcomes and cost-effectiveness of healthcare (BEAMER project)

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Abstract

Introduction: Understanding and addressing the diverse needs and supports of patients is crucial for improving outcomes and experiences in relation to adherence. Factors related to the socioeconomic position and the characteristics of the individuals together with the characteristics of the healthcare system, the disease and the treatment have been found to have a direct effect or association to the level of adherence during its different phases.

Aims: Within this context, the aim of the model is to enable patient-specific supports that are tailored to the patients' needs to improve adherence to treatment, covering all phases of medication.

Methods: The model is disease-agnostic and copes with the challenges related to the heterogeneity of different factors by segmenting patients into different groups based on psychological determinants of health behaviour and subjective personal related variables while providing a prediction of the patients' level of adherence. The model has been operationalised using a questionnaire with three modules (Behavioural, Health and Socio-demographics), including existing measurements related to Acceptance, Control, Necessity, Concerns and Health Consciousness. The model has been tested using data from an online survey targeting 4,000 individuals with chronic conditions in six different countries (US, Spain, Germany, France, Netherlands, Norway).

Results: The results generalize well to different contexts, diseases and adherence phases as they are capturing the psychological determinants as well as the subjective related variables.

Conclusions: The logistic regression allows the identification of different types of patients based on their needs and allows for the creation of an elicitation process of effective and targeted supports for patients.

Medication adherence during the run-in phase of clinical trials: A systematic review of methodological and reporting rigour

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Abstract

Aim: Trial run-in phases are sometimes used to select adherent patients, but the methods employed lack clear regulatory guidance and there are concerns about the transparency of reporting. This review aims to characterise the methods utilized for adherence measurement and reporting in run-in studies.

Methods: Clinicaltrials.gov was searched using the terms "run*in" OR "lead*in" OR "enrichment" OR "single-blind placebo." Studies were included if they were phase 2 or 3 interventional studies with published results, containing the protocol and statistical analysis plan. The study start date (first patient enrolled) was restricted to 01/01/2010 to 04/03/2024. The Risk of Bias tool for Observational Adherence Studies (RoBOAS) and the ESPACOMP medication adherence reporting guidelines (EMERGE) were used to assess methodological and reporting quality.

Results: 249 studies were identified, 34 were included for the analysis, of which 8 specified adherence to be the main purpose of the run-in. Run-ins were generally of poor methodological and reporting quality, with most using pill counts to measure adherence over 2 weeks, and only 23/34 having complete reporting of the adherence measurement, metric, and method of data aggregation. No studies reported the adherence phase studied.

Conclusions: Our review suggests that medication adherence is poorly reported in the run-in phase of drug trials, with the methods prone to bias. The findings support the need to develop guidelines on the reporting of medication adherence during the run-in phase, and should serve to inform future trial design, conduct and reporting, as well as have regulatory implications.

Mobile-messaging to improve medication adherence for type-2 diabetes in primary care: Economic outcomes from the SuMMiT-D trial

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Abstract

Aim: The SuMMiT-D trial aimed to compare the clinical- and cost-effectiveness of short text messages to improve medication adherence (implementation and persistence), in patients with type-2 diabetes.

Methods: 1037 participants recruited to the multicentre, primary care based, randomised, controlled, parallel-group trial, were followed-up for 12-months. Messages were grounded in behaviour change theory and tailored to participants' medications history and smoking status. Participants could stop or pause messages, change frequency, and select morning/afternoon for receiving messages. Healthcare resource use was estimated from questionnaires and electronic health records, and EQ-5D utility data were used to estimate Quality-Adjusted Life Years (QALYs). Costs and QALYs were calculated over 12-months, and incremental net-benefit (INB) calculated.

Results: Healthcare resource use was higher in the intervention group. On average, the control group had 3.19 (SD 3.34) in-person appointments at the GP surgery, versus 3.27 (SD 5.46) for the intervention group; with baseline contacts being 0.10 higher for the control group. For remote contacts, intervention group participants had 0.27 additional contacts during the trial; with the control group having more contacts at baseline (3.58 (SD 0.17) versus 3.41 (SD 0.17)). Differences were not significant. Intervention group costs were higher, with a QALY gain, however the intervention was unlikely to be cost-effective (INB<0).

Discussion: SuMMiT-D is amongst the largest, most rigorously-developed studies of mobile phone messaging for adherence in primary care, and showed that messages are unlikely to be cost-effective in patients who are generally adherent, with stable HbA1c and mean duration of diabetes of ~10 years.

Enhancing patient comprehension: evaluating the effectiveness of icons, text, and combined formats for medication instructions

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Abstract

Aim: Good information about use of medicines contributes to the level of understanding and hence improves adherence. Icons that illustrate instructions may enhance comprehension at the start of using medication and during use. The aim of this study was to investigate if patients comprehend icons for medication instructions correctly, and to study the role of health literacy.

Methods: Prior to the study, a national consortium developed icons to support 50 medication instructions. We studied nine of these: 3 simple instructions ('use in the ear') and 6 more complex instructions ('do not use grapefruit'). In 8 community pharmacies, visitors assessed the meaning of these instructions in the formats: icon, text, or combination. The researchers assessed correct interpretation and analysed the influence of health literacy (SBS-Q).

Results: In total, 93 visitors (43 with limited, 50 with adequate health literacy) participated. Less complicated instructions were interpreted correctly by 93% of the visitors, irrespective of the format and without differences between limited and adequate health literacy. More complex instructions were interpreted correctly by 74%. The text-only format was interpreted correctly most frequently (93%). Instructions combined with icons were understood less by visitors with limited compared to adequate health literacy (63% vs 92%, $p=0.000$ Chi-square).

Discussion: In general, combinations of written and verbal instructions can be beneficial. Hence the use of icons in combination with verbal instructions needs to be studied.

Conclusion: The use of icons in medicine information did not improve correct understanding of medication instructions, also not in patients with limited health literacy.

“I thought salbutamol was less damaging than steroids”: patient perspectives of asthma treatments as barriers to guideline implementation

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Abstract

Aim: For the last 40 years the first line of asthma treatment has been short acting beta2 agonists (SABA) used as symptom relief often prescribed alongside daily inhaled corticosteroids (ICS) as preventers. New guidelines recommend replacing SABA relievers with the ICS-based relievers (ICS-formoterol). This study aimed to explore patient perceptions of SABA, ICS and ICS-formoterol, with a focus on identifying barriers to adherence to new recommended treatments.

Methods: A qualitative study investigating UK asthma online community forum posts using keyword searches between July 2021 to July 2023. A sample of 184 adult patients with asthma were identified through 277 posts.

Results: Thematic analysis highlighted that many patients remained attached to their SABA and viewed it as a key element of their treatment. Patients reported being unconvinced by warnings around SABA over-use. In contrast, patients reported a range of concerns about ICS and ICS-formoterol. It was felt that combination ICS-formoterol relievers did not provide the same relief as SABA, with many who were prescribed an ICS-formoterol reliever continuing to carry their SABA as a preferred reliever. Results also highlight a perceived lack of individualised care from healthcare professionals and a scepticism around guideline or target driven care.

Conclusions: This analysis highlights a number of potential patient barriers to adherence to recommended asthma treatment, with many patients being reluctant to stop using their SABA and engage fully with an ICS-formoterol reliver. The results highlight the need to understand and consider patient perspectives of treatment.

Accessibility of healthcare services for Ukrainian war refugees: Barriers to continuity of care and medication adherence identified in the RefuHealthAccess Europe Study

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Abstract

Background: The Russian war against Ukraine, started in 2022, forced approximately six million Ukrainians to flee abroad. These refugees were granted access to local healthcare systems under the European Commission's Temporary Protection Directive. However, it remains unclear to what extent this access has met their needs. As the military conflict prolongs, a pressing question is whether they are being provided adequate management of their noncommunicable diseases (NCDs), ensuring continuity of care.

Aim: This study aimed to assess the access of Ukrainian war refugees to various types of healthcare services across Europe.

Methods: A cross-sectional anonymous online survey targeting Ukrainian war refugees was conducted across Europe from July 12, 2023, to April 16, 2024, using multi-channel invitation and snowball sampling. Descriptive statistics were employed in analysis.

Results: Responses were obtained from 594 individuals self-identifying as adult Ukrainian war refugees, of which 550 reported experience with medical care. Access to NCD management received the poorest evaluation among various health services: as many as 41.9% of those needing it for themselves or their family members reported poor access. The main reported barriers to NCD services were logistic difficulties, lack of coverage with health insurance of the host country and registration procedures, cited by 63.2%, 32.8% and 31.9% of those needing NCD care, respectively.

Conclusions: The survey highlighted several potential barriers to NCD care for Ukrainian war refugees that may significantly impact continuity of care and medication adherence. Concerted actions are needed to address these barriers and optimise healthcare outcomes for this vulnerable population.

Interim analysis of ONE TEAM randomized controlled trial: Long-term medication adherence in cancer patients with cardiovascular comorbidities

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Abstract

Introduction: With improved cancer treatment, cardiovascular comorbidity is the leading cause of mortality among cancer survivors.

Aim: Our aim was to conduct an interim analysis of the ONE TEAM Study, focusing on medication adherence (the process by which patients take their medications as prescribed) for cardiovascular comorbidities.

Methods: The ONE TEAM Study is an 18-month cluster-randomized controlled trial involving adult outpatients treated with curative intent for six cancer types, all having at least one cardiovascular comorbidity, and a primary care provider. During four visits (baseline, 6, 12, and 18 months), patients had blood pressure and laboratory values measured and completed a survey. Adherence and implementation (the extent to which patient's actual dosing corresponds to the prescribed dosing regimen) were assessed using the self-reported Voils questionnaire and pharmacy dispense data. We included patients who completed the study in the interim analysis. Herein, we present the baseline data. The study was approved by local institutional review board.

Results: The analyzed population comprised 61 patients, with a median age of 64 years, 62.3% white, 72.1% women, 59.0% diagnosed with breast cancer. Of them, 48 were diagnosed with hypertension, 37 with dyslipidemia, and 20 with diabetes mellitus. According to the Voils questionnaire responses, 80.8% of 47, 76.5% of 34, and 83.3% of 18 patients with hypertension, dyslipidemia, and diabetes, respectively, were adherent.

Conclusions: Analyses with a complete sample size will explore further statistical associations. These findings illustrate the current adherence patterns to cardiovascular treatments in oncologic survivors in North Carolina.

Machine says yes, Doctor says no: A qualitative application of the Necessity Concerns Framework on antibiotic prescribing in intensive care

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Abstract

Aim: Rapid molecular diagnostic (RMD) tests are designed to improve antibiotic stewardship (AMS) by providing swift results, enabling clinicians to: (i) avoid using a broad-spectrum antibiotic (BSAB), and (ii) stop a BSAB early, if indicated by the test result. The INHALE trial (ISRCTN16483855) examined whether RMDs improve AMS. We report on an embedded behavioural study exploring the psychology of prescribing, specifically examining clinicians' perceptions of RMD and their effects on prescribing behaviour.

Methods: Semi-structured interviews were conducted with 20 intensive care clinicians after using RMD to guide antimicrobial prescribing for patients with suspected pneumonias. Transcripts were analysed using thematic analysis, applying the Necessity Concerns Framework.

Results: Most were convinced by the necessity for AMS and valued the speed of RMD. However, the impact of RMD results on individual prescribing decisions to (i) guide the initial prescription, and (ii) to stop a BSAB early, was limited. Concerns about the potential consequences of under-treatment to the patient (e.g., mortality) and prescriber (e.g., litigation) were frequently described as more salient in the prescribing decision-making process, with an antibiotic sometimes prescribed just-in-case of infection. This resulted in the recommendation from RMD to avoid prescribing a BSAB, or to stop one early, often being overridden by clinicians' perceived necessity for a BSAB prescription as a mechanism to protect the patient, 'erring on the side of caution'.

Conclusions: Technological and guideline solutions to antimicrobial resistance alone fail to recognise the human-to-human nature of medicine. Doctors' beliefs and emotions are often key drivers of their antibiotic prescribing.

Medication underuse and food insecurity: Opportunities for health care systems to improve detection and response

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Abstract

Aim: The terms “compliance” and “adherence” can frame medication underuse as an attribute related to personal responsibility and minimize the role of structural factors. Other factors, such as food insecurity (FI), or the lack of access to nutritious food contributes to suboptimal medication adherence. The Duke University Health System (Durham, North Carolina, USA) has implemented initiatives to identify medication underuse and FI as part of routine care. We aim to describe FI contributing to medication underuse electronic health record (EHR) technologies.

Methods: This cross-sectional cohort study evaluates the correlation between medication underuse, FI, and health outcomes. We used e-prescription pharmacy network database data on medication (re)fills. We calculated a proportion of days covered (PDC) measure of adherence based on refill frequencies and defined underuse as PDC <80% over 12 months (07/10/23 – 07/10/24) during the implementation phase of adherence. FI was identified using system-wide data from screening for social needs during clinical encounters.

Results: Food insecurity and nonadherence were both associated with higher blood pressure for all patients and hemoglobin A1c levels among patients with diabetes mellitus. Patients at risk for nonadherence had a higher average body mass index (32.02 for nonadherent; 29.79 for adherent) and were almost 30% more likely to report FI.

Conclusions: These findings highlight the role of social and economic barriers to medication adherence that may contribute to underuse. Implementation of EHR-based social needs and medication underuse detection technologies are valuable for targeting efforts to support medication adherence across initiation, implementation, and discontinuation phases.

What would define the ideal smart inhaler for asthma patients and healthcare professionals? A discrete choice experiment

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Abstract

Introduction: Smart inhalers offer advanced functionalities beyond traditional inhalers (recording actuation, sending reminders, and supporting inhalation techniques), aiming to improve asthma management and therapy adherence people with asthma. However, smart inhalers may differ in function.

Aim: To determine which smart inhaler attributes are valued most by asthma patients and healthcare professionals (HCPs), their willingness to trade-off between attributes, and how these preferences vary between groups.

Methods: An international Discrete Choice Experiment (DCE) was conducted across seven countries using the PAPRIKA approach. Participants included asthma patients (≥ 18 years) using regular inhalers and HCPs involved in asthma care. Nine smart inhaler attributes were evaluated: aesthetics, device compatibility, active feedback, inhalation monitoring, data visibility/ownership, data connectivity, sustainability, technical support, and costs. Participants ranked the attributes from 1 to 9, with lower numbers indicating greater importance.

Results: Of 560 respondents, 15 were excluded due to quality check failures, leaving 545 for analysis (349 asthma patients, 192 HCPs, and four others). Asthma patients most valued costs (mean $3.21 \pm \text{SD } 2.39$) and visibility and ownership of data (3.74 ± 2.09). They preferred not to pay for the inhaler and wanted both patients and HCPs to have access to the data. HCPs prioritised the ability to monitor actuation, inhalation, and technique (3.61 ± 2.18) and the provision of active feedback on inhalation (3.88 ± 2.25).

Conclusions: Further analysis will explore detailed subgroup preferences. The findings will have important implications for future design and implementation of smart inhalers.

Medication adherence interventions in Italy through a benchmarking survey: The ElderCare Project

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Abstract

Introduction: Medication adherence (MA) in older adults with polypharmacy is a complex phenomenon influenced by various factors. Study aim is to investigate on strategies already implemented for improving MA in different healthcare settings in Italy and analyse them. This research is embedded within an EU-funded Project (NextGenerationEU).

Methods: A cross-sectional survey was conducted from May to July 2024 among healthcare professionals in Italy. Survey included questions regarding professional and demographic information, factors related to MA and type and description of known MA interventions. Participants were recruited via email and professional networks. Data were quantitatively and qualitatively analysed to identify variations and common trends in adherence practices.

Results: A total of 342 responders were reached, with a 55.8% response rate. Most participants were from Northern Italy (Emilia Romagna 30.5%, Lombardy 14.0%). The majority were affiliated with professional orders, including nurses (39.8%), surgeons (15.7%), and pharmacists (10.5%). Overall, 64% of respondents declared to routinely monitor MA and the most effective tools identified were direct patient communication (60.2%) and prescription/drug delivery data monitoring (24.6%). Furthermore, health entity recommendations and disease-specific guidelines from scientific societies were recognised as known interventions locally implemented for MA improvement. Finally, main MA barriers identified were the complexity of treatment regimens, lack of patient education, and limited access to medications.

Conclusions: The survey highlights substantial disparities in MA among different Italian health settings. Addressing these disparities requires shared and approved best practice to carry out targeted interventions to improve MA in each setting.

Medication adherence to Anti-VEGF therapies in maculopathy: Impact of the treat and extend regimen personalization.

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Abstract

Aim: Patients with maculopathy often require personalized treatments, such as intravitreal injections (IVT) of anti-VEGF. Treat and Extend (T&E) regimen, tailored to each patient, reduces monitoring between anti-VEGF injections, enhancing adherence and preventing disease reactivation, yet complicates comprehensive initial adherence assessment. Study aims to identify MA levels to maculopathy IVT considering the T&E regimen.

Methods: A retrospective observational study was carried out using electronic health records from Campania region (Italy) public healthcare system (yy2017 to 2023). Maculopathy diagnoses were identified using specific ICD-9-CM codes. Adherence was evaluated according to EMERGE guidelines evaluating persistence phase with three sensibility analyses (Sensitivity1: 10-day gap for Treat phase and 30-day gap for Extend phase; Sensitivity2: 20-day gap for Treat and 60-day gap for Extend; Sensitivity3: 30-day gap for Treat and 90 days for Extend). Therapy switch was defined when a patient initially treated with one anti-VEGF drug received another within the same year. 18-months follow-up was set.

Results: Overall, 6,244 incident subjects treated with anti-VEGF were identified. At 18 months from the start of anti-VEGF treatment, adherence rates varied by sensitivity analysis and drug type. Overall, adherence ranged from 3.6% (sensitivity1) to 4.1% (sensitivity3). For Ranibizumab, adherence was 3.6% to 4.1%. Aflibercept adherence was lower, between 2.4% and 2.9%. Brolucizumab had adherence rates from 8.4% to 8.8%. Bevacizumab showed the highest adherence, consistently at 88.9%.

Conclusions: Adherence rates varied significantly among anti-VEGF therapies, with Bevacizumab showing the highest adherence at 88.9%. The Treat and Extend regimen's complexity impacts overall adherence assessment.

Medication adherence in the curricula of future European physicians, pharmacists and nurses - a cross-sectional survey

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Abstract

Aim: There is limited knowledge on how medication adherence (MA) is taught to pre-graduate students. This study explored to what extent medicine, pharmacy and nursing students receive education about MA.

Methods: A cross-sectional study was conducted with an online survey and text analysis of submitted curricula. The survey inquired about definitions of adherence and related terms (ABC taxonomy); methods to identify, monitor and support non-adherence; consequences and outcomes of non-adherence, and other course characteristics. It was distributed between February and June 2024 to 731 persons teaching relevant courses across 142 European universities. The curricula inventory and free-text answers were analyzed using word frequency and thematic analysis, respectively.

Results: In total, 212 persons from 114 universities in 34 countries completed the survey. The ABC taxonomy was extensively taught in pharmacy (73%), followed by nursing (60%) and medical education (52%). Respondents agreed to similar level on the need to emphasize MA, with 72% agreement in pharmacy, 71% medical, and 59% nursing education. The clinical impact of non-adherence was the most commonly taught topic, according to 89% respondents in pharmacy, 84% medical, and 76% in nursing education. The curricula inventory showed considerable heterogeneity in how MA content was described, and identified keywords such as: rational drug use, compliance and drug regimen.

Conclusions: Our findings indicate a lack of consistent MA education, highlighting the need to develop a unified curriculum for the subject considering the ABC taxonomy, and to facilitate a more patient-centered approach to improve MA.