

"baseline" year served as control data. **RESULTS:** There were 1500 intervention and 286 control participants with mean age (sd) 72.75 (7.82) and 73.39 years (7.31), and past year fall rates of 22.8% and 21.8%, respectively. Males comprised 23.1% of the intervention group and 24.8% of the control group. Majority were of Chinese ethnicity (86.7% of intervention and 81.1% of controls). Improvements from baseline to 52 weeks were significantly better ($p < 0.05$) for intervention participants than controls for the Six Minute Walk Test, Step Test, Falls Efficacy Score and Life Space Assessment; Safer Score was significantly better on follow-up for the intervention group. There was no significant difference in the Berg Balance, Timed-Up-And-Go, Chair Rise and EQ-5d. Intervention participants had significantly fewer falls in the third quarter of follow-up (95%CI of the difference=0.00,0.10). Multivariate results revealed that the intervention group had significantly fewer falls for the entire follow-up year (Odds Ratio = 0.75, 95%CI = 0.58,0.97). **CONCLUSIONS:** Results suggest that the program improves physical performance and reduces the incidence of falls in the elderly. Residents may be empowered to take responsibility for preventing falls in their own community.

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SYSTEMATIC REVIEW OF FDA BREAKTHROUGH THERAPY DESIGNATED PRODUCTS

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OBJECTIVES: In 2012, the United States Food and Drug Administration (FDA) created a new expedited pathway of "Breakthrough Therapy Designation" (BTD) to enable an early approval of therapies which have shown substantial activity in early trials. The objective of this study was to assess the comparative effectiveness and pricing of drugs with BTD. **METHODS:** The data for the number of granted BTDs was obtained from FDA.gov. The data for publically disclosed BTDs was obtained from sponsor's press releases. For all products, the information for their mechanism of action, type of molecule, trial design, clinical efficacy and safety, and pricing and time to approval (for approved products) were obtained from peer-reviewed publications, conference abstracts, FDA and sponsor websites. **RESULTS:** Since the establishment of the BTD pathway, 55 products have been granted breakthrough therapy designations (2012-2015), of which, 42 have been publically disclosed by the manufacturers and 6 have been approved by the FDA. In terms of indications, 43% are for cancer, 18% are for genetic diseases and 14% are for Hepatitis C Genotype 1. The median time to approval for these three drug was ~5 years, significantly shorter than the 2012 median time to approval for priority review applications (6 years). The price premium was 30-50%, compared to other drugs in the same category. The six approved BTDs show 20-30% higher response rates than other products in the same category. The other products in the pipeline with established comparators show 36%-136% improvement in efficacy (based on active controls or previous trials). For approximately half of the products, comparative efficacy cannot be determined because of no previous evidence for a product with efficacy in the targeted indications. **CONCLUSIONS:** BTD is a promising pathway to shorten development time and provides early access, however, the high price could pose challenges for payers and patients.

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THE USE COMPARATIVE EFFECTIVENESS RESEARCH AND EVIDENCE BASED MEDICINE IN US PAYOR DECISION MAKING

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OBJECTIVES: To understand how comparative effectiveness research (CER) is being used by US managed care plans and pharmaceutical benefit managers (PBMs) to control the growth of healthcare costs and ensure appropriate utilization of products by pharmacy and therapeutics (P&T) committees. **METHODS:** Managed care (MC) medical and pharmacy directors (MDs+PDs) completed an online interactive survey. Topics included: advisor and plan information and current/future coverage of CER. The use of CER and evidence-based medicine (EBM) was evaluated using a 5-point likert scale (5=completely agreeing,1=completely disagreeing). **RESULTS:** Fifty-four percent of respondents were MDs, the remainder mostly pharmacists. Most worked for a health plan (83.6%) and 39.6% of the plans were local; 35.4% national; and 25.0% regional. Public (Medicare and Medicaid) and private (Commercial) plans were represented. When asked to select the area emerging CER is expected to affect: value of care (29.8%), optimization/improvement of clinical guidelines (27.7%), appropriateness of care (14.9%), pharmaceutical research and development (6.4%), medical and pharmacy benefit management (17.0%), and 4.3% uncertain. When asked about their agreement in "progress in obtaining usable information on CER of therapies" the results were slightly negative with 42.5% disagreeing (34%=somewhat,8.5%=completely), 38.3% agreeing (4.3%=completely,34%=somewhat), and 19.1% neutral. When asked if they expect their plan to use CER regularly in formulary decision making by 2015, more than half (53.2%,14.9%=completely,38.3%=somewhat) agreed, 27.7% disagreed (23.4%=somewhat,4.3%=completely), and 19.1% were neutral. When asked to assess how "MC commonly using EBM today in coverage decision making" the results were more favorable with 79.2% agreeing (27.1%=completely,52.1%=somewhat); 14.6% neutral and 6.3% disagreeing (6.3%=somewhat,0%=completely). The most desired change to their plan's/PBM's P&T process was for increased use of CER; and a move toward contractual risk-sharing. **CONCLUSIONS:** Formulary decision making in P&T committees is making progress in the use of comparative effectiveness research. Results suggest that the acceptance of evidence-based medicine is valuable even if not comparative.

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IMPACT OF CLERKSHIP ATTACHMENTS ON STUDENTS' ATTITUDE TOWARDS PHARMACEUTICAL CARE IN ETHIOPIA

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OBJECTIVES: The present study aimed at investigating the impact of mandatory clinical clerkship courses on fifth year pharmacy students' attitudes and perceived barriers toward providing pharmaceutical care (PC). **METHODS:** A cross-sectional survey was conducted among 5th year pharmacy students undertaking mandatory clinical clerkship in the University of Gondar, Ethiopia. A pharmaceutical care attitudes survey (PCAS) questionnaire was used to assess the attitude (14 items), commonly identified drug-related problem/s (1 item) during clerkships, and perceived barriers (12 items) toward the provision of PC. Statistical analysis was conducted on the retrieved data. **RESULTS:** Among the total of 69 clerkship students, 65 participated and completed the survey (94.2% response rate). Overall, 74.45% of participants had positive attitude toward PC provision. Almost all respondents agreed that the primary responsibility of pharmacists in the healthcare setting was to prevent and solve medication-related problems (98.5%), practice of PC was valuable (89.3%), and the PC movement will improve patient health (95.4%), respectively. Unnecessary drug therapy (43%), drug-drug interactions (33%), and non-adherence to medications (33%) were the most common drug-related problems identified in wards. Highly perceived barriers for PC provision included lack of a workplace for counseling in the pharmacy (75.4%), a poor image of pharmacist's role in wards (67.7%), and inadequate technology in the pharmacy (64.6%). Lack of access to a patient's medical record in the pharmacy had significant association ($P < 0.05$) with PC practice, performance of PC during clerkship and provision of PC as clinical pharmacists. **CONCLUSIONS:** Students attending the new clinical pharmacy program in Ethiopia have a good attitude toward pharmaceutical care. However, the barriers to pharmaceutical care need to be addressed by integrating PC provision with pharmacy practice.

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RELATIONSHIP BETWEEN COMMUNITY PHARMACY ATTRIBUTION AND PATIENT'S OUTCOMES IN HEALTHCARE SERVICE OF HOME-VISITING

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OBJECTIVES: Aim of this research was to investigate ideal attribution with revealing the relevance between pharmacy attribution and patients' outcomes. **METHODS:** A self-completion questionnaire from composed of two forms of "Pharmacy attribute" and "Patients attribute" was delivered to 3321 pharmacies across Japan which agreed to join in January 2013. Pharmacy attribute: a number of pharmacist, prescription/day, home-visiting patients/ month, cooperated medical facilities. Patients attribute: adverse drug event, change in prescription, change in adherence, finding of unused drugs, and change in the amount of unused drugs. We grouped by 2 indexes (a number of prescription/day/pharmacist as 'work load' and cooperated medical facilities as 'positivity to cooperate') to 4 groups. (Used SPSS ver.21) **RESULTS:** Among 1,890 community pharmacies data (collecting rate: 56.9%), we extracted answers to all the question items about community pharmacy attribute necessary for grouping. The 1,327 community pharmacies data was collected as the target (the number of patient data: for 4,947) for the analysis. The data of 1327 pharmacies showed the middle of attribution showed 20 prescriptions filled /day/pharmacist (work load) and 1 medical facility cooperated. The group of 'Prescriptions \leq 20 and Cooperated facility>1' and the groups of 'Prescriptions>20 and Cooperated facility>1' changed in prescription($p < 0.003$), changed in adherence($p < 0.001$), find of unused drugs($p < 0.001$), and decreased the amount of unused drugs ($p < 0.001$) more than others. There is no significant differences in adverse drug event. **CONCLUSIONS:** It was suggested that there was relationship between pharmacy attribution (work load/ positivity to cooperate) and patient's outcomes on healthcare service of home-visiting.

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A STUDY OF KNOWLEDGE, ATTITUDE AND PRACTICE OF COMMUNITY PHARMACISTS TOWARDS ADVERSE DRUG REACTION REPORTING & MONITORING

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OBJECTIVES: This study was conducted to assess the knowledge, attitude and practice of community pharmacists (CPs) towards ADR reporting and monitoring. **METHODS:** A prospective cross sectional study was conducted at selected community pharmacies. Pharmacists at selected pharmacies were administered a questionnaire by research pharmacist and two weeks' time was given to each pharmacist to complete the survey. Questionnaire was designed with various elements which can evaluate knowledge, attitude and practice of pharmacists towards ADR reporting. **RESULTS:** A total of 256 community pharmacists were approached at selected community pharmacies per study criteria and were administered a questionnaire. Of 256, only 56 CPs (21.8%) responded to the survey. Of 56 respondents, 37.5% were able to define ADR correctly, whereas 35.7% of pharmacists believed ADRs solely as allergic response. Only 46% of pharmacists could correctly identify potential risk factors responsible to cause ADRs and 57% of pharmacists were aware of the consequences of ADRs. Almost 93% of respondents admit that safety reporting is an important responsibility of pharmacist however, surprisingly almost 73.2% pharmacists were not aware of existing pharmacovigilance program in the country. As per 78.5% respondents ADR reporting in the community pharmacies lead to additional workload. Looking at willingness to report, almost 50% of pharmacists expect incentives to get involve in the safety reporting and other 50% feels it as professional responsibilities which do not require incentives. Among respondents only 20% of them had ever reported ADR to nearer national safety reporting centres. However, majority of CPs are interested to contribute for ADR reporting if appropriate training is provided. **CONCLUSIONS:** Majority community pharmacists do not possess required knowledge on ADR reporting, its importance and national safety reporting program. There is a strong need to implement educational and regulatory interventions periodically to improve the understanding of safety reporting among CPs.