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LETTERS TO EDITOR

Letters to Editor

Pharmacist interventions focus in high impact journals

Dear Editor:

A significant professional development of pharmacy practice has taken place over recent years. Pharmacists have taken on a challenging new role in patient health care, and accordingly, have assumed the responsibility to ensure the possible best patient outcomes with drug therapy.

Several major trends have converged with the shared objective of raising pharmacist's level of responsibility. The role of the clinical pharmacy[1], which is defined as "the area of pharmacy concerned with the science and practice of rational medication for the purpose of ensuring optimal patient outcomes", was the foundation for the development of the actual philosophy of practice, which consists in adopting a patient-centred pharmaceutical care. The role of pharmaceutical care, defined by Hepler and Strand[2] as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient's quality of life" has been rapidly extended. In this context pharmaceutical care could be considered as similar to pharmacotherapy follow-up[3]. However, other approaches have been made, such as medicines management, medication review, or more general like cognitive pharmacy services, which are not dissimilar concepts but introduce notable discrepancies in the terminology.

Therefore, although there is not a uniform definition of pharmaceutical care, it is clear that the process of ensuring the safe and effective drug therapy of the individual patient requires that the pharmacists accept their professional responsibility for patient outcomes. Furthermore, to attain the mentioned therapeutic goals, pharmacist intervention should be carried out on the basis of monitoring both effectiveness and safety parameters of ongoing drug therapy, followed by a subsequent assessment of the outcomes achieved.

Recent publications in high-impact medical journals examine the implementation of pharmacist-led interventions. This fact confirms the growing interest of the scientific community in the development of pharmaceutical care and pharmacy practice.

Moreover, the different studies carried out have shown contradictory results (Table I); a number of randomised clinical trials[4-6] demonstrated beneficial outcomes, and whereas others concluded that pharmacists-led intervention did not significantly improve patients' outcomes. Specifically, several articles published in three major medical American journals have reported positive effects on admissions, mortality, quality of life, and length of hospitalisation.

The FAME study[4] obtained a marked improvement in both patient adherence and health outcomes. Intervention in this study was clearly defined, consisting of the provision of individual patient education, customized medication provision, as well as appropriate outcomes measurements. As in the SCRIP study[5], which showed that a pharmacy community-based intervention enhances cholesterol management in high-risk patients, interventions were characterized by a regular follow-up of patients, which allowed pharmacists to outline modifications when the outcome was not being achieved. Lastly, in Pharmacist intervention to improve medication adherence in heart failure study[6], patients in the intervention group had greater medication adherence and fewer exacerbations resulting in emergency department visits or hospitalisations than patients in the usual care group. Intervention involved a pharmacist providing verbal and written education, icon-based labelling of medicine containers, and therapeutic monitoring during 9 months.

On the contrary, several other articles published by two British journals with high impact factor maintain that pharmacist intervention has little to no impact in patient outcomes, since they did not find significant changes either in hospital readmissions or in mortality over the study period. For these studies, namely the Homer[7], the Medman[8], and the Heartmed[9] trials, intervention design consisted of isolated interventions by community pharmacists aimed at patients discharge from the hospital.

As a consequence, there is currently some controversy among health professionals about the effect of the pharmacist intervention in patient health care. A variety of arguments have in fact been put forward by means of letters, concerning issues such as sample size, inadequate main outcome measures, health professionals who carry out the interventions, and design of the intervention. Based on this, there is a perceived need to seek out answers that support the different views provided[10].

When analysing the possible reasons for these unexpected results it makes sense to take into account the foundations of pharmaceutical care practice. In that respect, we believe that the lack of beneficial effects is due less to flaws in the study's design than to the following factors: a) The interventions approach (since they focus exclusively on the process but not on the outcomes); and b) The lack of monitoring of medication outcomes within the framework of well-defined parameters[10].

To begin with an intervention dealing with patient's results is a key element of success, of any program intended to improve outcomes for patients with chronic illness. As it can be seen in the table below, *the contradictory results across studies are seemingly connected with substantial differences in the intervention approaches; "process" vs. "results and process together"*. Those approaches centred on the process entail measurement of patient adherence and detection of errors such us taking the wrong medications, expired medications or therapeutic duplications. This kind of results can be used to support the importance of developing and using quality indicators and parameters in order to achieve the outcomes of pharmacotherapy, regarding the effectiveness, safe, and appropriate of medication.

To sum up, the implementation of effective tailored pharmacist-led interventions should be characterized by a series of key elements, which involve that the pharmacist set patient out-

Table I. Summary of study characteristics with contradictory results

Characteristics	*FAME trial*[4]	*SCRIP trial*[5]	*Pharmacist intervention to improve medication adherence trial*[6]	*HOMER trial*[7]	*MEDMAN trial*[8]	*HeartMed trial*[9]
Participants (patients)	Aged 65 years or older with coronary risk factors and taking 4 or more drugs	With cardiovascular disease or diabetes	Fifty years of age or older with heart failure	Aged over 80 recruited during an emergency admission	Aged over 17 years, and with coronary hearth disease	Aged over 18 years with hearth failure
Sample size						
Intervention	83	344	122	429	980	149
Control	76	331	192	426	513	144
Age, mean (SD)						
Intervention	77 (10.5)	64.2 (12.2)	61.4 (7.7)	85.4 (4)	68.7 (9.2)	77.6 (9)
Control	78 (6.2)	64.6 (11.3)	62.6 (8.8)	85.5 (4)	68.8 (9.1)	76.4 (9.5)
Sex male %						
Intervention	74.7	59	32	38.9	67.4	63.8
Control	73.7	62.5	33.9	36.2	70.6	63.2
Period of study	14 months	4 months	12 months	6 months	12 months	6 months
Type of intervention Intervention focused on process (P) Intervention focused on results (R)	*Regular follow up,* consisting of: Interview by the pharmacist (P) Measurement of adherence (P), BP (R) and LDL-C (R) Individualized patient education (P) Medication dispensed using adherence aid *Regular follow up* with clinical pharmacist every 2 months (R)	*Regular follow up* (2, 4, 8 and 16 weeks), consisting of: Interview by the pharmacist (P) Point of care cholesterol measurement (R) Patient education (P) Referral to the doctor according to cholesterol values (R)	*A pharmacist provided a 9-month of regular follow up and multilevel intervention:* Verbal and written education (P) Icon-based labelling of medication containers (P) Effectiveness and safety monitoring (R) Pharmacist should call physician to describe the the problem and determine alternative treatment (P)	*Two home visits* consisting of: Patient education (P) Remove out of date drugs (P) Inform GP of drug reactions or interactions (P) Inform local pharmacist if a compliance aid is needed (P)	*One or more consultations* (according to pharmacist determined patient need) consisting of: Assessments of therapy, medication compliance, lifestyle (P) Fed-Back recommendations to the GP (P)	*Two home visits* consisting of: Patient education (P) Encourage completion of sign and symptom, monitoring diary card (P) Remove discontinued drugs (P) Fed-Back recommendations to the GP and local pharmacist (P)
Outcome Primary (1) Secondary (2)	Medication adherence and medication persistence (1) Changes in BP and LDL-C (2)	Composite of performance of a fasting cholesterol panel by the physician or addition or increase in dose of cholesterol-lowering medication (1)	Adherence and exacerbations requiring emergency department care or hospital admission (1) Health-related quality of life, patient satisfaction with pharmacy services, and total direct costs (2)	Total readmissions (1) Mortality and quality of life (2)	Appropriate treatment; Health status, economic evaluation (1) Patient risk of cardiovascular death; satisfaction (2)	Total readmissions (1) Mortality and quality of life (2)
Results (conclusions)	A pharmacy care program leads to: Increase in medication adherence, persistence and reduction in blood pressure Discontinuation of the program decrease medication adherence and persistence	Community pharmacist intervention improved cholesterol management for patients at high risk for cardiovascular disease	Patients in the intervention group had greater medication adherence and fewer emergency department visits or hospitalisations than patients in the usual care group Pharmacist intervention for outpatients with heart failure can improve adherence to cardiovascular medications and decrease health care use and costs, but the benefit probably requires constant intervention	Significantly higher rate of hospital admissions Not significantly improve quality of life or reduce deaths	No statistically significant differences in lifestyle factors nor in the global score for appropriateness of of treatment Few differences in quality of life The total National Health Service cost increased Significant improvements in satisfaction score No differences in self reported compliance	Community pharmacist intervention did not lead to reductions in hospital admissions nor in mortality No statistically significant difference in quality of life

BP: blood pressure; LDL-c: low density lipoprotein cholesterol; GP: general practitioner.

come goals with the patient's involvement agreement, in collaboration with physicians and other health care professionals, drawing up a plan of action to achieve them, which include monitoring parameters and indicators for patient specific therapeutic goals, and regular follow up and intervention[3-6].

Since pharmacist role in patient care is being the centre of attention and controversy lately, this is in fact a key moment in the development of the pharmacy practice. Thus pharmacists must direct their efforts towards improving the implementation of and research on pharmaceutical care. There is a great need

that pharmacists as a profession, and the corresponding associations or working groups, ensure that future research projects focus mainly on the results, but not only on the process of patient care.

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References

1. American College of Clinical Pharmacy. ACCP defines clinical pharmacy. ACCP Report 2005; 24 (8): 1-2.
2. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm 1990; 47: 533-43.
3. Martín-Calero MJ, Machuca M, Murillo MD, Cansino J, Gastelurrutia MA, Faus MJ. Structural process and implementation programs of pharmaceutical care in different countries. Curr Pharm Des 2004; 10: 3969-85.
4. Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: A randomized controlled trial. JAMA 2006; 296: 2563-71.
5. Tsuyuki RT, Johnson JA, Teo KK, Simpson SH, Ackman ML, Biggs RS, et al. A randomized trial of the effect of community pharmacist intervention on cholesterol risk management: The Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP). Arch Intern Med 2002; 162: 1149-55.
6. Murray MD, Young J, Hoke S, Tu W, Weiner M, Morrow D, et al. Pharmacist intervention to improve medication adherence in heart failure. Ann Intern Med 2007; 146: 714-25.
7. Holland R, Lenaghan E, Harvey I, Smith R, Shepstone L, Lipp A, et al. Does home based medication review keep older people out of hospital? The HOMER randomised controlled trial. BMJ 2005; 330: 293.
8. The Community Pharmacy Medicines Management Project Evaluation Team. The MEDMAN study: A randomized controlled trial of community pharmacy-led medicines management for patients with coronary heart disease. Fam Pract 2007; 24: 189-200.
9. Holland R, Brooksby I, Lenaghan E, Ashton K, Hay L, Smith R, et al. Effectiveness of visits from community pharmacists for patients with heart failure: HeartMed randomised controlled trial. BMJ 2007; 334: 1098.
10. Amariles P, Saez-Benito L, Faus MJ. Contradictory results in randomised clinical trials concerning to pharmacists-led intervention: Looking for one possible explanation. Available at: http://www.bmj.com/cgi/eletters/334/7603/1098 (Last access june 13, 2007).