

# An educational process to transfer research into the pharmacist's daily practice: An observational study in community pharmacies

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## Abstract

### Background

Pharmacists, as primary health care professionals, are being assigned in following drug therapy. This increased responsibility requires pharmacists a more patient-centred role.

### Aims

The aim is to assess the learning method promoting knowledge and awareness of community pharmacists regarding the occurrence of stressful life events in women who use anxiolytic and antidepressant medicines.

### Method

The educational activities were carried out during 2008 in three phases: pharmacist training, epidemiological observational study and reflection.

### Results

The high participation rate (88%) and the large number of women were recruited ( $n = 11357$ ) during the observational study, indicates that the community pharmacists were motivated and interested in this project both for its epidemiological and learning aspects.

Pharmacists during this experience were not only involved in dispensing advice on medication purposes and side effects, but they also showed interest in listening to women's expressed needs.

### Conclusion

It is important to develop strategies that improve understanding of modern communication models among community pharmacists.

**Keywords:** *Counselling, learning, mental health, research, pharmacist, women*

## Introduction

For decades, community pharmacists have performed an invaluable service for patients and their communities centred on provision of medication (including advice) (Cerulli 2002). This traditional core role has moved into one that adopts a patient/client centred care model which requires them to work in concert with patients and other health care providers (Bell 2005, Rodis 2008).

Pharmacists provide information about pharmacotherapy and monitor patients regarding medication adherence. They also point out the presence of side effects and communicate with general practitioners (Bell 2005, Bell 2006, Scheerder 2008). International literature highlights how community pharmacists, as primary health care professionals, are in a

good position to contribute to the management of mental illnesses (Bell 2005).

In light of the current awareness, the common mental health disorders of depression, anxiety and somatic complaints, in which women predominate, affect approximately 1 in 3 people in the community and constitute a serious public health problem (Duetz 2003, Hatch 2007, WHO 2011). In Italy, these emotional disorders, are increasing and spreading, involved more frequently women than men and occur to a greater extent with the increase of age (Eurispes 2010). In addition, central nervous system (CNS) drugs are in the third position for both expenditure (AIFA 2008) and consumption of which the selective serotonin reuptake inhibitors (SSRIs) are at the top. The prevalence of use of CNS drugs is different between men and women, 27% and 36% respectively. (AIFA

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2008).

Given the extent of mental illness in the community setting and the rapid increase in prescribing psychotropic medications, services directed toward optimising the use of medications for mental illness fulfil an important public health need (Bell 2005, Bell 2007). Considering the community pharmacists professional role change, few well-documented and properly evaluated programs of research and few training projects on mental health involving pharmacists directly have been developed (Ludwig Boltzmann-Institut for Sociology of Health and Medicine, 2001).

The "Lifestyles: state of psycho-physical health of women" project, an Italian epidemiological study conducted by Veneto Region community pharmacists, was promoted to investigate women's issues that may be related to the use of anxiolytic and antidepressant medicines.

This research was developed within a continuing pharmacist education program (CPE) focused on psycho-physical health of women (D'Incau 2009) following a request of the Equal Opportunities Commission of Veneto.

The project was conceived from two perspectives: an observational study conducted on women (having epidemiological value) and continuing pharmacist education (CPE) activity in the "field training" (learning value) (Spencer & Jordan, 1999). As consequence, the objectives were two-fold:

- i) epidemiological: describing the occurrence of stressful life events in the women's use of anxiolytics and antidepressants in a community pharmacy setting;
- ii) learning: promoting knowledge and awareness of community pharmacists regarding the association between the use of anxiolytics and/or antidepressants and potential factors, including stressful life events, social-demographics and health factors, so as to provide a better service and to respond to patients' needs (Rouse, 2004).

One of the key issues of "Lifestyles" was the so-called "field training", which gave importance to scientific and research activities in terms of education and professional development.

This paper is focused on the learning features of "Lifestyles" study, reflecting upon the learning method, adopted to translate the epidemiological research in a continuing medical education activity (Guilbert, 1987), and the learning results obtained through the "field-training".

All the epidemiological data achieved from the observational study conducted on women were extensively described in a specific article (D'Incau 2011)

## Methods

### Design of field-training

"Lifestyles" was carried out during 2008 in three phases. The choice to promote an epidemiological study (phase 2) in a training program (phase 1 and 3) was based on the andragogical assumptions of the adult learner (Kaufman 2003): specifically adults are more self-directed, have a need for direct application to their work, and are able to contribute more to collaborative learning through their experience.

### Phase 1: pharmacist training (April 2008)

One thousand eight hundred and seventy-six community pharmacists were contacted by email given by Professional Associations and Association of Owners of Italian Pharmacies (Federfarma) of Veneto. 283 pharmacists agreed to take part voluntarily to the first meeting (1 day seminar) which was organised to give the required information to carry out the entire study. The attention was focused on the role of the community pharmacist in ensuring appropriate treatment of depression and anxiety disorders, considering psycho-social issues connected to women's issues. The seminar was conducted by the research staff of the Clinical Pharmacology Unit of the University of Verona (Italy). During the first part of the day three lectures were organised to discuss the fundamental information related to the epidemiology of psychotropic drugs in Italy and specifically in the Veneto region (I lesson). The second lesson highlighted the differences between appropriate and inappropriate use of antidepressants and anxiolytics (following the guideline NICE 2004) (II lesson). A focus analysis was dedicated to "gender" (referring to a set of economic, social, political and cultural attributes and opportunities) and "sex" (referring to a set of physical aspects) differences between men and women on the occurrence of depressive and anxiety disorders (Verdonk 2009). How women express a physical and emotional need and how health care providers (i.e. pharmacists) interpret this need was also analysed (Hohmann 1989) (III lesson).

During the second part of the seminar two active learning sessions (lecture followed by class discussion) was organised: interpersonal communication skills (McDonough 2006) necessary to conduct the "Lifestyles" study and how to perform all the steps of the study. Two sessions of discussion were organised. The first was on how to "open" and "close" the interviews, the second on how to manage some serious problems that could occur during the study (e.g. women referring sexual violence, alcohol problems, crying, distress, etc.).

### Phase 2: pharmacist epidemiological study (May and October 2008)

Following the investigator's guide each community pharmacist selected 24 women: 8 women were taking medicines for depression and anxiety disorders (defined as user) and the remaining 16 were not treated with these medicines (defined as non-user). Specifically, pharmacists recruited one user and two non-users per day, including as user the third woman who attended the pharmacy during each working day per week. Both users and nonusers were excluded from the study if they were younger than 18 years and if they did not sign the informed consent. Each user was matched by age ( $\pm 5$  years) with two non-users.

The selection took place twice, first in May and then in October, as mental disorders symptoms usually start in October/November, remit in February/March and exacerbate in spring (Howland, 2009).

### Study design

At the time of interview, pharmacists informed the selected women about the project and requested them to give informed consent. After that, women who accepted to be involved in

the project completed a personal survey. This consisted in a series of questions concerning demographic and social aspects (family, employment, hormonal state, self-sufficiency, psychological-psychiatric and social state) and a set of items about life events elicited from the Interview for Recent Life Events (IRLE) (Brugha & Cragg, 1990) and from the List of Threatening Experiences (LTE) (Paykel, 1997). The attention was directed to housing problems, proximal relationship problems, illnesses, negative experiences, such as physical and sexual abuse, poverty and gender discrimination, which can significantly influence future episodes of depression (Gwendolyn, 2007).

### **Phase 3: pharmacist reflection (From May to November 2008)**

This phase was developed as a complex process of thinking about and interpreting an experience in order to learn from it (Rouse, 2004). Reflection was performed in two ways: (1) "reflection in practice", during the observational study (from May to October); (2) "reflection on practice", after the observational study (during the final meeting).

In detail, the first consisting of a self-assessment questionnaire called "Pharmacists' questionnaire" which was filled out by each community pharmacist involved in the project. It gathered information about community pharmacists' attitude to support women who show psychological distress as anxiety and depressive disorders. The second included a "Satisfaction questionnaire" about the continuing pharmacist education (CPE) activity and a "Final questionnaire" regarding pharmacists' awareness about counselling, filled out during the final meeting organized in November, after the epidemiological study.

Learning outcome measures:

Two primary outcomes were defined:

1. pharmacists' knowledge and awareness of women psychological distress: women's signs/symptoms and life events related to the area of feelings and emotions; advice about antidepressant and anxiolytic therapy; communication between general practitioner (GP) or other medical and allied health practitioners about women's emotional condition or antidepressant and anxiolytic medication;

effectiveness of the field training program (including all the phases: 1, 2 and 3): pharmacists' assessment of the continuing medical education program.

These outcomes were gathered from the overall analysis of data obtained from the three types of questionnaires developed for the reflective phase (phase 3), described in the pharmacist' questionnaires paragraph.

From the analysis of these two outcomes the potentiality of the approach to integrate the epidemiological research with the CPE was pointed out.

### **Instruments**

**"Pharmacists' questionnaire"** (Crockett et al, 2007)

This is a semi-structured questionnaire with closed (yes / no) and open questions regarding the following aspects:

1. pharmacists' characteristics,
  2. pharmacists perception of signs/symptoms and life events related to the area of feelings and emotions related,
  3. advice given on antidepressant and anxiolytic therapy,
  4. communication between pharmacist and general practitioner (GP) or other health operators,
- women's adherence to antidepressant and anxiolytic therapy.

At the end of the questionnaire a space was dedicated to additional comments..

### **"Final questionnaire"**

The questionnaire consisted of four questions about pharmacists' opinion and practice of counselling in their professional daily practice.

### **"Satisfaction questionnaire"**

In this questionnaire pharmacists assessed the project in terms of their knowledge, skills (i.e. verbal communication skills, ability to perform an epidemiological study, problem solving and decision making skills required when pharmacists have to manage women who reported problems related to depression and anxiety disorders), competence and professional practice growth. A quantitative [ranging from 1 (the lowest level) to 7 (the highest level)] and a qualitative scale (useful, useful but can be improved, not useful) were used.

### **Data analysis**

Descriptive statistics were calculated for all the variables. The open questions were analysed using Atlas.ti 5.5 software, a program based on sociological methodology (Grounded Theory Methodology) which emphasizes generation of theory from data in the process of conducting research (Chiarolanza & De Gregorio, 2007). Atlas.ti enables the researcher to extract words, paragraphs or sentences from imported documents which can be related to a conceptual category.

To estimate the association and the differences, in terms of life events, between users (women treated with anxiolytics and/or antidepressants) and non-users women, the odds ratio (OR) and 95% confidence intervals (95% CI) were used.

### **Results**

The project was certified by Veneto's System of Continuing Medical Education. After the training phase (phase 1), 249 community pharmacists participated in each phase of the project, representing a 88% response rate. These participants recruited 11357 women for the study during the two months of investigation (phase 2) with an average of 48 women selected both in May and in October.

Of the 249 participating pharmacists 237 completed the "Pharmacists' questionnaire", 239 the "Final questionnaire" and 234 the "Satisfaction questionnaire", with an average of 95% response rate.

Women sample characteristics

On average, women (users and non-users) were 52 years old

(range: 18-97 years); married, housewives and/or employed, not pregnant, and able to perform normal daily activities. These women were not followed by a psychologist/psychiatrist or by a social worker but were known in person to the pharmacists.

The medicines most frequently taken were in line with Italian drug usage during 2008 (AIFA 2008). In fact, cardiovascular, alimentary tract and metabolism and musculo-skeletal drugs were the most frequently used classes. In users women, anxiolytics were the most frequently purchased psychotropic drugs, in particular 48% ( $n = 1839$ ) of women were treated with anxiolytics, 33% ( $n = 1277$ ) with anxiolytics and antidepressants and 19% ( $n = 732$ ) with antidepressants alone. Benzodiazepines (94%) and SSRIs (57%) were the most frequently prescribed molecules. Both antidepressants and anxiolytics were mostly taken for over six months.

One or more stressful life events occurred in 90% of the women treated with anxiolytics and/or antidepressants (users) and in 74% of the women not treated with these drugs (nonusers) (OR = 3.19; 95% CI = 2.83-3.60). Of the six categories of life events reported in Table I the most frequent were death and problems with the family and close friends. All the odds ratio numbers reported in this table show a significant association between the six categories of life events and psychotropic drug use.

On average, the life events occurred or began during the 6 months preceding the interview and women considered their influence on their well-being as severe.

### Questionnaire results (phase 3)

#### Results from "Pharmacists' questionnaire"

The participating pharmacists came from all the seven Provinces of Veneto. They were mostly female (82%), working in urban pharmacies (public or private) (67%), full-time workers (84%), with an average of 67% of customers that they consider to be regulars. The pharmacists' professional experience ranged from less than 5 years to more than 30. The highest percentage (26%) was registered in the younger professional age group (0-5 years).

Few possessed a postgraduate qualification (15%) and only 18% had attended continuing education on mental health.

As demonstrated in Table II, participants identified 527 signs/symptoms related to the area of feelings and emotions of which 81% were mental and 16% physical. The most common signs were restlessness/ irritability (42%) and sleep disorders (28%). One hundred and thirty-six (57%) pharmacists identified 201 life events "conflicts with spouse

or partner about parenting" (36%), "conflicts with child's grandparents (or other important person) about parenting relational problems" (21%) and "death of family member or close friend" (14%) were the most prevailing.

Concerning the advice about antidepressant and anxiolytic therapy, one hundred and fifty-three (65%) of pharmacists answered women's questions about psychotropic medication, gave verbal information and talked to women about their condition. Women took counsel mainly on adverse reactions (31%), while pharmacists advice on "how the medicine works in the body, how it is absorbed and eliminated, and its effects" (29%) (Table III).

Almost all pharmacists did not contact GP or other medical and allied health practitioners to discuss the women's condition (81%) and/or medication (66%) (Table IV). The two main reasons for no discussion were difficulties in communication and lack of time (the women were in a hurry).

Regarding pharmacists' perception of women's adherence to antidepressant and anxiolytic therapy, for 70% of participants women chose not to take these treatments and for 71% of them women chose not to keep on taking them. While for 65% of pharmacists, women discussed with them about the potential side effects of antidepressant and anxiolytic therapy.

#### Results from "Final questionnaire"

Of the participating pharmacists who completed this questionnaire, 28% ( $n = 67$ ) assessed counselling efficacy for "All the time" and 23% ( $n = 56$ ) for "Most of the time" to support women with mood disorders during the drug treatment. Participants considered counselling effective in their professional daily practice ( $n = 221$ , 92%) (Rantucci, 2006) (Table V).

#### Results from "Satisfaction questionnaire"

The assessment of the continuing medical education (CME) program activity was mainly positive. Respondents gave a high evaluation in terms of knowledge (81%  $\geq$  5<sup>th</sup> level), skills (86%  $\geq$  5<sup>th</sup> level) and competence (84%  $\geq$  5<sup>th</sup> level) growth (Table VI). Taking into consideration the professional daily practice, 76% of respondents evaluated the project "useful can be improved", 18% useful and 6% not useful.

### Discussion

To our knowledge, this is one of the first studies of

**Table I** Correlation of stressful life events categories between all users and nonusers ( $N = 11357$ )\*

Category of stressful life events	Users (3848)		Nonusers (7509)		OR (95% CI)
	n	%	n	%	
Violence	303	8	348	5	1.76 (1.50-2.07)
Death	1814	47	3167	42	1.22 (1.13-1.32)
Health	919	24	1102	15	1.82 (1.65-2.01)
Family and close friends	1922	50	3008	40	1.49 (1.38-1.62)
Financial	1186	31	1905	25	1.31 (1.20-1.43)
Other	408	11	421	6	2.00 (1.73-2.31)

\*\* Total category events greater than the total number of cases and controls as multiple responses permitted

**Table II** Signs/symptoms and life events\* of depression and anxiety disorders identified by pharmacists ( $N = 237$ ) \*\*

	<i>n</i>	%
Mental symptoms ( $N = 439$ )		
Restlessness, irritability	186	42
Loss of interest or pleasure in hobbies and activities that were once enjoyed	83	19
Persistent sad, anxious, or "empty" mood	82	19
Personality disorders	48	11
Difficulty concentrating, remembering, or making decisions	26	6
Feelings of guilt, worthlessness, helplessness	14	3
Physical symptoms ( $N = 88$ )		
Sleep disorders	25	28
Decreased energy, fatigue, being "slowed down"	23	26
Trembling or shaking	22	25
Sweating	5	6
Shortness of breath	5	6
Gastrointestinal disorders	4	5
Dermatologic disorders	2	2
Tachycardia	2	2
Life events ( $N = 201$ )		
Conflicts with spouse or partner about parenting	72	36
Conflicts with child's grandparents (or other important person) about parenting	43	21
Death of family member or close friend	14	7
Inability to perform normal daily activities	14	7
Troubles at work	13	6
Major personal illness or injury	13	6
Major change in finances (increased or decreased income)	11	5
Loneliness	9	4
Fear of the future	7	3
Major change in the health or behavior of a family member or close friend (illness, accidents, drug or disciplinary problems, etc.)	5	2

\* Life events were identified by 136 (57%) pharmacists.

\*\* Variables reported were extracted from sentences given by pharmacists in the open questions. Each of them were categorized according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) and Life Events Questionnaire (LEQ) (Sarason et al, 1978). Analysis performed by using

pharmaceutical public education and field training for community pharmacists in Italy which tried to translate the epidemiological model into a continuing education activity. "Lifestyles", although limited to a geographical area (i.e. Veneto), provided some interesting insights into pharmacist's attitude in following women with mood disorders.

The high participation rate indicates that community pharmacists were motivated and interested in this "field training" project for its epidemiological and learning aspects. This was confirmed by the positive assessment of the CPE and by the large number of women recruited during the observational study.

Pharmacists were able to perceive signs/symptoms and life events related to depression and anxiety disorders of women. In fact, the main types of stressful events reported by both women (Table I) and pharmacists (Table II) concerned family and health problems, death and economic difficulties.

They were not only involved in "dispensing" advice on medication purposes and side effects, as claimed (Badger et al, 2002), but they also showed interest in listening to women's expressed needs.

As is demonstrated in Table III there is a discrepancy between types of advice asked by women (concentrated on therapeutic effects) and types of advice given by pharmacists (focused on

possible adverse reactions). Problems related to the area of feelings and emotions seem to be perceived differently by professionals (technical-scientific) and women (subjective-emotional).

Despite pharmacists consider counselling effectiveness in professional daily practice, most women chose not to take the medications prescribed and chose to abandon the treatment. It is well-known that psychotropic drugs are often used inappropriately (Mort & Aparasu 2002). More than 50 percent of patients treated with antidepressants stop taking them before the end of the therapy.

As one can clearly deduce it is relevant to improve pharmacist's ability to dialogue with patients, to create an interpersonal relationship in the course of time and, at the same time, promote patients' awareness of their disease and therapy.

Rantucci in 2006 "Pharmacists Talking with Patients: A Guide to Patient Counselling" highlighted that "patients find communication, interpersonal sensitivity, and partnership with their health care providers to improve satisfaction; they are consequently more likely to adhere to medical advice and to recall medical information provided" (Rantucci, 2006). It has been proved that coaching patients on psychological symptoms by community pharmacists resulted in less

depressed and less anxious patients compared to those without any additional coaching (Brook et al, 2003).

This concern is in agreement with our results from which emerges that community pharmacists are frequently consulted for medication advice by women. In fact, of the whole population that may be involved in mood disorders, women are twice more affected than men (Ziebland & McPherson 2006).

As was pointed out from the additional comments reported in the “Pharmacist’s questionnaire”, pharmacists often reported two types of barriers to interact with patients: lack of privacy in the pharmacy to discuss a patient's medications and lack of relaxing atmosphere that encourages patients to ask advice about their medications (Pendergast et al, 1995).

Other barriers were deduced from pharmacists’ responses: lack of undergraduate training in mental health, lack of awareness of the meaning of a counselling process, lack of communication between pharmacist and general practitioner (GP) or other health operators. The information obtained from these analyses leads us to state that: pharmacists are aware of women psychological "malaise", they potentially add value to

patient care improvement of clinical outcomes and enhancement of patient compliance (Scheerder et al, 2008); they have a potential role in depression care, considering the ample opportunity to contact patients with mental disorders.

**Limitations**

This study does promote the pharmacists’ knowledge, skills and competence regarding women’s distress and the use of anxiolytics and antidepressants, despite its limitations. A limit of the learning method adopted in this study could be the lack of a pre-post test design and the lack of a non-intervention comparison group.

A further limitation could be the use of Atlas.ti 5.5 software, although innovative in epidemiology, it was created for the analysis of interviews or of documents much more extensive compared to the unstructured questionnaires used in this study (Sleath 2003) .

**Table III** Advises about antidepressant and anxiolytic therapy (N = 153) \*

Type of advice asked by women (N = 268)**	n	%
Adverse reactions	83	31
Description mode of administration	69	26
Drug abuse and dependence	50	19
How the medicine works in the body (effects, absorption, elimination)	40	15
Indications	11	4
Contraindications	9	3
Use of complementary and alternative therapies	6	2
Type of advice given by pharmacists (N = 158)**	n	%
How the medicine works in the body (effects, absorption, elimination)	46	29
Indications	43	27
Contact general practitioner (GP)	31	20
Description mode of administration	28	18
Suggest complementary and alternative therapies	6	4
Contact mental health professional practitioner	3	2
Adopt healthy lifestyles	1	1

\* Variables reported were extracted from sentences given by pharmacists in the open questions. Each of them were categorized according to the European patient information leaflet for human medicines regulated by European Medicines Agency (EMA). Analysis performed by using Atlas.ti 5.5 software.

\*\* Responses total 268 and 158 because multiple responses permitted.

**Table IV** Communication between pharmacist and general practitioner (GP) or other medical and allied health practitioners (N = 237)\*

Discuss the women’s condition	n	%	Discuss the women’s medication	n	%
Yes	46	19	Yes	81	19
No	191	81	No	156	81
Reasons for no discussion of women’s condition (N = 97/191)	n	%	Reasons for no discussion of women’s medication ( N = 29/156)	n	%
Communication difficulties	39	40	Communication difficulties	45	35
Lack of time	34	35	Lack of time	42	33
There is no need for such cooperation	11	11	There is no need for such cooperation	35	27
Professional secrecy	13	13	Professional secrecy	7	5

\* Variables reported were extracted from sentences given by pharmacists in the open questions. Analysis performed by using Atlas.ti 5.5 software.

**Conclusion**

The promotion of a better understanding between pharmacists and patients may facilitate a “concordant approach” to mental health care (Bell et al, 2006). Lack of training in counselling is a barrier to service delivery, therefore it is important to transfer know-how in the daily practice of pharmacists. It is worth involving them concretely to develop this “approach of counselling” in order to improve, on one side, pharmacists’ performance, and on the other, drug adherence and patients’ satisfaction, especially in women.

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**Table V** Pharmacists’ assessments of counselling\* (N = 239)\*\*

Counselling efficacy in drug treatment of mood disorders	n	%
All of the time	67	28
Most of the time	56	23
A little of the time	55	23
Some of the time	27	11
None of the time	9	4
Null	25	10
Counselling efficacy in professional daily practice	n	%
Yes	221	92
No	18	8

\* Counselling was defined as a process that enables a professional (1) to guide, to support and to develop the potential of customers; (2) to promote their active, proactive attitudes; and (3) to stimulate their capacity of choice (Rantucci, 2006).

\*\* The assessment of pharmacists’ responses were extracted from their sentences given in the open questions. Analysis performed by using Atlas.ti 5.5 software.

**Table VI** Pharmacists’ assessments of the continuing medical education (CME) program activity (N = 234)

How do you assess the project in terms of knowledge growth?			How do you assess the project in terms of skills growth?		How do you assess the project in terms of competence growth?	
	n	%	n	%	n	%
0	0	0	0	0	0	0
1	0	0	1	0	0	0
2	3	1	4	2	5	2
3	15	6	9	4	14	6
4	27	12	18	8	19	8
5	44	19	47	20	39	17
6	80	34	97	41	95	41
7	65	28	58	25	62	26

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