QUALITY ASSURANCE PHAR-QA - ERASMUS PROJECT

I. CONTRIBUTION OF "CAROL DAVILA" UNIVERSITY OF MEDICINE AND PHARMACY BUCHAREST

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Abstract

PHAR-QA project funded by the EU ERASMUS Lifelong Learning Programme (527194-LLP-1-2012-1-BE-ERASMUS-EMCR, start date: 01/10/2012, end date: 20/09/2015) is a follow-up of PHARMINE project required for developing a regulatory framework which will produce and recognize qualified pharmacists, that are able to work efficiently on the European labor market.

In order to achieve this goal "Carol Davila" University of Medicine and Pharmacy contributes in the project as well as in PHARMINE project and in PHAR-EE proposal submitted on February 23rd 2012 (submission number 530147-TEMPUS-1-2012-1-BE-TEMPUS-JPCR) by participating at creating a common pattern of quality assurance in European medical, dentistry and pharmacy education and training (PET) and supplementary to the evaluation of the achievement of proposed objectives by partners in the project.

Rezumat

Proiectul PHAR-QA finanţat prin Programul de Educatie Continua UE ERASMUS (527194-LLP-1-2012-1-BE-ERASMUS-EMCR, data de începere: 01/10/2012, data de finalizare: 20/09/2015) este o continuare a proiectului PHARMINE, necesară în scopul dezvoltării unui cadru legislativ în care se vor forma şi vor fi recunoscuţi farmacişti calificaţi care pot lucra eficient pe piaţa europeană a muncii.

În scopul atingerii acestui obiectiv, Universitatea de Medicină şi Farmacie "Carol Davila" Bucureşti, îşi aduce contributia în acest proiect, participând la crearea unui model comun privind asigurarea calităţii în învăţământul european de medicină, medicină dentară şi farmacie, şi în plus la evaluarea calităţii realizării obiectivelor propuse de către parteneri în cadrul proiectului.

Keywords: quality assurance, pharmaceutical education and training.

Introduction

It is largely accepted that pharmacists play in this moment and will also play in future, an increasingly important role in the European health system, as community, hospital and industrial pharmacists. Their education and training, duration and course content were the subject of many European regulations [12, 13, 14].

Modernization of the Professional Qualification Directive 2005/36/EC proposed by Vergnaud report in 2012 includes some additional tools like for example introduction of the professional card [9] for facilitating the mobility of professionals around Europe but without envisaging substantial change of the existing rules.

The PHARMINE consortium, created in 2008 [15], consists of 50 universities from EU member states or other European countries that are members of the European Association of Faculties of Pharmacy (EAFP), EU partner associations representing community (PGEU), hospital (EAHP) and industrial pharmacy (EIPG), together with the European Pharmacy Students' Association (EPSA) and tries to create a network that debates on and analysis quality of education and training in pharmaceutical education

The consortium surveyed pharmacies and pharmacists in different settings: community, hospital, industry and other sectors. The consortium looked at how EU higher education institutions, courses and traineeship were organised.

Further it was built a database structured in seven chapters: Organization of the activities of pharmacists, Professional bodies; Pharmacy HEIs, students and courses; Teaching and learning methods; Subject areas; Impact of the Bologna principles and Impact of the EC directive 2005/36/EC, thought to be a tool for further projects, with larger objectives concerning pharmacy education in Europe.

A questionnaire based on the quality criteria of the International Pharmaceutical Federation and the Accreditation Council for Pharmacy Education (USA) was sent to European faculties. Replies were obtained from 28 countries. Just above half has a working QA system. QA scores were high concerning matters such as curriculum and training, students' representation and promotion of professional behaviour; etc. QA scores were low concerning matters such as evaluation of achievement of mission and goals. This suggests, that a Q.A. system based on competences is required [1, 2].

PHAR-QA project

PHAR-QA project *Quality assurance in pharmacy education and training in Europe* [6] was started as a Lifelong Learning Centralized Erasmus program, a follow up of the PHARMINE (*Pharmacy Education and Training in Europe-PET*) project.

Lifelong Learning Programs with an European QA system in Pharmacy education focus on the improving / diversifying capabilities / competences of a qualified pharmacist to work efficiently in any area of expertise.

PHAR-QA **aims** at producing a quality assurance (QA) system for EU pharmacy education and training. The project has the following six **objectives** [10]:

1. the establishment of a European network in QA for PET, that will provide a source of information on QA in any given Higher Education Institution and / or country.
2. to survey existing QA systems and to create a report.
3. to develop a model for QA for PET based on (2) and modified Delphi/TUNING interaction with partners. This will allow harmonization of the multitude of very diverse QA frameworks.
4. to test the model and readjust as required.
5. to propose a model for application of QA in Europe and elsewhere. This will provide a basic harmonized model for QA for PET in Europe.
6. to disseminate and to exploit the final model through EAFP and other channels so as to create the European QA in PET networking system and agency.

The project is run jointly by the Faculty of Pharmacy of the Vrije Universiteit Brussel (P1-Prof. Bart Rombaut) and the Pharmacolor Consultants from Nancy, France (P2-Prof. Jeffrey Atkinson). Other seven partner organizations came from Spain (P3-University of Granada, Prof. A.S.Pozo, Prof. L. Recalde), Greece (P4-National and Kapodistrian University of Athens, Prof. D.M. Rekkas), Estonia (P5-University of Tartu, Prof. D. Volmer and Prof. P. Veski), Finland (P6-University of Helsinki, Prof. J. Hirvonen), Slovenia (P7-University of Ljubljana, Prof. B. Bozic), Poland (P8-Jagiellonian University of Cracow, Prof. S. Polak and Prof. A. Skowron) and Romania (P9-University of Medicine and Pharmacy ″Carol Davila″ Bucharest, Prof. C. Mircioiu).

Among stakeholders there are the European Association of Faculties of Pharmacy (P10) and other European organizations, as well as MEDINE (Medical Education in Europe). Experts in QA in pharmacy education from

USA, UK, as well as representatives from TUNING (Prof. A. Cumming, Prof. M. Ross, Prof. P. Ryan) form the international advisory board.

PHAR-QA project includes 5 work packages (WP): WP 1 *Management*; WP 2 *Implementation*; WP 3 *Quality Assurance* (Quality Plan); WP 4 *Dissemination*; WP 5 *Exploitation of results*.

Leaders of the WP 1 *Management* were Bart Rombaut (Faculty Pharmacy of the Vrije Universiteit Brussel-VUB, deceased in January 2014) and Jeffrey Atkinson (Pharmacolor Consultants Nancy-PCN, France). Management will be run on central and regional levels. WP1 will coordinate and harmonize the activities of the rest of WPs. The group will create a methodology for the construction of PHAR-QA regional network, modified Delphi questionnaires and will coordinate the elaboration of the final report for EACEA, white papers and recommendations.

WP 2 *Implementation* will establish a PHAR-QA regional network and will operate in 4 overlapping phases: research (months 1 through 6-12, planned at the V.U.B consortium), development of an interactive website for modified Delphi analysis using TUNING methodology, production of the QA model using modified Delphi questionnaires (months 6 through 12-18), testing (months 30 through 36).

In WP 3, the Quality Plan will be coordinated by "Carol Davila" University of Medicine and Pharmacy, Bucharest. The project manager and the project team will inspect the accomplished work to ensure that it is aligned with the proposal. For this, the P9/UMFCD team will work on WP QPLN together with P2/PCN.

Regarding WP 4 *Dissemination* (lead by University of Tartu, Estonia), information on ongoing activities and the state of advancement of the PHAR-QA project will be posted on the PHAR-QA, EAFP and other websites.

For *exploitation* of results, WP 5- Jagiellonian University of Cracow, Poland will continue to cooperate with MEDINE and will propose its know-how in fields such as QA for education and training in health sciences.

Role of "Carol Davila" University of Medicine and Pharmacy in the project

Quality Plan -QPLN (Work Package 3 - coordinated by P9) concerns the assurance that the methods, practices, records, and final results are in accordance with predefined deliverable. Albeit WP QPLN will apply the grip / build / engage (GBE) model developed by A.B. Jones in Princeton [3, 4, 5], (based on documents such as those of the U.S. Department Of Health And Human Services Food And Drug Administration [11]) concerning the

assurance that the facilities, equipment, personnel, methods, practices, records, and controls are in accordance with predefined regulations.

"Grip" - establishment of foundations. Basic methodology [8] and standard operating procedures (SOPS) and rules of engagement will be discussed, edited, used and revised as required.

"Build" - training and education. The lead on WP QPLN will firstly ensure that good communication exists amongst the consortium partners and that details on QPLN are efficiently disseminated within the consortium.

"Engage" - gauging effectiveness. WP QPLN will produce audit reports evaluating: effectiveness of the work, root causes of outlier results [6], degree of risk involved high/medium/low [3].

It is to note that a better approach has to include a continuous feedback between phases.

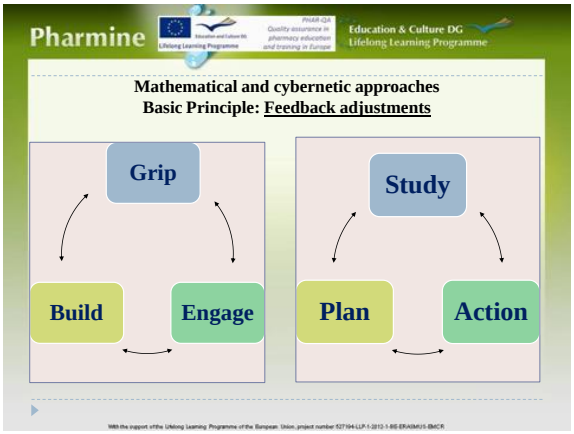

Figure 1.
GBE model/SPA model

And, beyond the new terminology, this method is not essentially different from Study - Plan - Action (SPA) partition of the activities set (Figure 1).

The „Grip" stage refers to studying previously to acting, and matches the "Study" and "Act" phases. Analyzing details, coordinating, practice/training and anticipation of possible problems are comprised in „Build"/„Plan" stage. The „Do" part refers to „engaging" (involving people, establishing tasks, facing challenges and using opportunities) in order to produce the expected results [4, 5].

The actions for the Bucharest team corresponding to the three proposed deliverables grip, build, engage are presented in Table I.

Table I
Proposed deliverables for QPLN

<table>
<tr><th>Deliverables - 3.1 Grip</th><th>Deliverables - 3.2 Build</th><th>Deliverables - 3.3 Engage</th></tr>
<tr><td>Collaboration with WP MNTG and WP IMP</td><td>Interaction with all partners ⇒ improve awareness of QPLN</td><td>Reports and feedback for action, initially by P1 and P2, then to consortium to evaluate efficiency and a basis to the establishment decision by WP MNGT.</td></tr>
<tr><td>Defining the principles for QA and monitoring</td><td>Ensure:
-existence of good communication;
- efficient dissemination</td><td>Retirement to predefined fall-back position (reserve alignment) and/or restart the actions</td></tr>
<tr><td>Discussion, editing, revision of SOP and rules of engagement</td><td>Information of consortium concerning:
-applicable rules and regulations of QPLN
-future developments</td><td rowspan="3">Elaboration of audit reports (M18, M36).</td></tr>
<tr><td rowspan="2">Report / feedback to consortium for action initially by P1 and P2, then decision by WP MNGT</td><td>Collection of data concerning QA by questionnaires. Statistical analysis and harmonization</td></tr>
<tr><td>E-mail exchanges and preparing sessions in WP MNTG meetings</td></tr>
</table>

Activities of WP QPLN will consist in **monitoring,** timely audit reporting and corrective actions and follow-up, **assurance** of effective communication between advisory board and QPLN, **checking** that compliance documentation is reviewed in timely manner, **evaluation** of the extent to which the QPLN can be applied in future developments of QA in PET in WP EXP.

The final deliverables for QPLN will be refining the previously implemented techniques and tools (PHARMINE WP6 / QPLN) by:

-increasing the number of responders; using different dissemination techniques/networks (dissemination in faculties and to professional organizations, publishing articles etc.);

-applying a mosaic of methods for analyzing and interpretation of data;

-changing the type of questions;

-surveying different target groups (like PhD students in Medicine, Dentistry, Pharmacy, Chemistry, Biochemistry).

Results and Discussion

At the kick-off meeting held in Brussels on 30th October 2012, P9 presented in a report the steps (which will become Standard Operation Procedures in the PHAR-QA project) to be followed for evaluation of quality plan in the project.

The Bucharest team will check, during these 3 years, the concordance between the tasks provided in project and the achieved ones [7], quality of achievement of tasks (using questionnaires: "Workshop Evaluation Form" and "Mx-My Activity Evaluation Form". Responses obtained in Ankara concerning M1-M8 activities, respectively M1-M13 in Brussels, in 2013 were analyzed using a mosaic of statistical methods. Results were used for validation both of activities and evaluation methodology.

Furthermore, in November 2013, the Romanian team proposed a new type of survey concerning statistical methodology running in the project phases.

Evaluations given in M13 meeting by P2 and P9 partners validated the results obtained in the first phase and consequently the project is going further in the second stage of the Delphi process within the consortium ("Delphi 2 consortium" - [IMI Delphi 2 Consortium Report November 2013]).

After accepting the use of descriptive and decisional statistical methodology, the Delphi 2 consortium questionnaire was launched on 16th September 2013. The panel was asked to rank 61 competences, divided into 36 personal competences and 25 patient care competences, as: essential (4), very important (3), quite important (2), not important (1).

In January-May period - regional directors will collect answers, responses being clustered in six categories: community pharmacists, hospital pharmacists, industry, academy, students in terminal years, others.

In a final phase, in November 2014 - data will be analyzed and the quality assurance (QA) system for EU pharmacy will be proposed to European institutions involved in education and training.

Conclusions

In both cases of pharmaceutical education and training and lifelong learning it is necessary to look for a European harmonized model.

Project PHAR-QA objectives were conceived to extend and complete the achievements of PHARMINE project beyond the description to the direct action and tuning of quality assurance systems.

The new approach is based rather on competence than harmonization of curricula.

UMF-CD is involved in the networking, models elaboration and consensus to a final general pattern for QA systems. Supplementary, the university coordinates activities concerning assurance of the quality of the management of project.

Implication of UMF-CD in the first phases of the project significantly contributed to foundation of analysis methodology and to the further evolution of the project.

Acknowledgements

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