

Transnational Evaluation of a New Continuing Professional Development Activity for Biomedical Scientists Based on the International Organisation for Standardisation for Medical Laboratories ISO 15189

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Abstract The European Union's Lifelong Learning Leonardo Program awarded funding of over 100,000 euros to a Leonardo Partnership project to facilitate the development of good practice in continuing professional development (CPD) for Biomedical Scientists. A series of high quality CPD activities along with an EU-toolkit are being developed by the project and will be made available to European hospital laboratories via the project website and Community of Practice. This paper reports on transnational evaluation of the second European CPD activity which is based on the International Organisation for Standardisation (ISO 15189) standard for Medical Laboratories. Biomedical Scientists from hospital laboratories in Croatia, Czech Republic, Malta and the United Kingdom took part in evaluation of the CPD activity by completion of an evaluation questionnaire and reflective learning sheet. The new CPD activity was exceptionally well received as scores of over 96% were acquired for useful and appropriateness to scope of practice, relevance to CPD, enhancement to scope of practice and enhancement to CPD. This CPD activity has successfully enhanced European Union Biomedical Scientist's CPD as over 95% of participants rated the exercise as either good or excellent.

Keywords: continuing professional development, training, medical laboratory science, biomedical scientist

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1. Introduction

This project aims to instigate a strategic European change to the way in which continuing professional development (CPD) activities are organised at a local level in EU hospital laboratories. CPD is imperative for biomedical scientists to maintain competence to practice thus supporting quality service delivery. Harmonisation of CPD within Europe is needed to underpin mobility of

biomedical scientists and to ensure excellence in provision of EU-patient laboratory test results. Presently, CPD courses delivered by recognised Vocational Education and Training providers are usually presented within a quality framework but no such formal framework exists for those CPD activities which are delivered locally by hospital laboratories. EU hospital laboratories play a key part in CPD provision for biomedical scientists and this novel project plans to begin the process of reshaping, updating and transforming their function as quality CPD providers. Initial motivation for undertaking this ground-breaking

project, which is unique in addressing the role of hospital laboratories as life-long learning education providers for biomedical scientists, was recommended as the way forward to build on a hugely successful Leonardo Mobility (UK & Malta) project where four teams of Biomedical Scientists from the UK spent time in hospital laboratories in Malta [1,2,3]. The goal of this Partnership project is therefore to share and develop good practice in continuing professional development for biomedical scientists and from this to collaboratively develop an EU-toolkit for delivery of high quality CPD activities provided by European hospital laboratories.

The current challenge within this specific Vocational Education and Training arena is that different countries throughout Europe have different requirements for Biomedical Scientist's CPD and these demonstrate considerable variation - from the UK system where there is a legal requirement for Biomedical Scientists to maintain a CPD portfolio, to other member states where CPD is highly recommended but non mandatory [4]. By carrying out CPD, Biomedical Scientists can ensure that their knowledge and expertise is relevant and up-to-date and learning undertaken as part of CPD seeks to ensure that it relates to continued competence to practice.

European Union Biomedical scientists' CPD is already undergoing reform. Previously successful European projects have sought to create European models for both paper based and electronic based [5,6] CPD portfolios for Biomedical Scientists. While a European Common Framework for CPD in the Biomedical Sciences has been developed for CPD courses, by 'LifeTrain - EMTrain' [7], it focuses on biomedical research rather than routine diagnostic biomedical science practice. While there is some knowledge overlap between the two fields of research and routine practice some of the courses within 'on-course' are appropriate as CPD activities for Biomedical Scientists. But what is missing? A significant proportion of a biomedical scientist's CPD activities, within all partner countries, are not carried out by participation in formal courses. Rather, they are delivered locally within the hospital setting. As such, EU hospital laboratories are life-long learning CPD education providers but there is currently no system in place for quality assurance of their CPD provision. The project's goal is to change this. Development of the EU-toolkit will provide pathways for managing and organising incorporation of quality standards and criteria for accreditation, evaluation and reflective practice within hospital CPD provision plus the EU hospitals CPD providers network is beginning to facilitate more intensive European co-operation by sharing of knowledge, collaboration and keeping pace with current initiatives via an EU Community of Practice network of Biomedical Scientists.

This partnership is beginning to raise EU Biomedical Scientist's CPD to the next level by targeting a previously uncharted territory of CPD provision i.e. that which is delivered locally by hospital laboratories. The first step towards this goal has been to bring together laboratory scientists from partner countries [8,9,10,11,12] to learn about the different approaches to CPD in partner organisations and countries thus facilitating participative interaction with European colleagues enabling EU sharing of ways of working [4]. The CPD providers' network will

be an on-going means for an EU-wide Community of Practice for EU-hospital laboratories.

The accomplishment of this project will dramatically change the way in which CPD is organised, managed and delivered by EU hospital laboratories. Thus competence to practice and EU-citizen patient safety, the heart of the profession is ensured.

2. Methods

The partnership for this project consists of a consortium between three Vocational Education and Training providers (Croatian Metrology Society, Croatia; Horvath and Dubecz Consulting Ltd, Hungary; University of Wolverhampton, United Kingdom) and two 'World of Work' partners (Regional Hospital T Bata Inc, Czech Republic; Mater Dei Hospital, Malta). The project has received funding of over 100,000 euros from the European Union's Lifelong Learning [13] Leonardo Partnership [14] Program and will run for two years with transnational meetings being held in each partner country [9] to facilitate development of an EU-Toolkit [15] plus novel CPD activities, both of which will be freely available for use by Biomedical Scientists on the project website.

All novel CPD activities undergo transnational evaluation prior to being made available on the hospital laboratory CPD providers Community of Practice network. The first CPD activity (provided by the UK) received exceptionally positive transnational feedback [16] and evaluation of the second CPD activity (provided by Croatia) provides the focus for this manuscript. Further CPD activities will be provided by Czech Republic and Malta.

A new CPD activity was designed to facilitate participation by Biomedical Scientists in all partner countries. The topic of the International Organisation for Standardisation for Medical Laboratories, 'ISO 15189: 2012 *Medical laboratories - Requirements for Quality and Competence*' [17] was chosen to enable maximum European participation as it is a multi-disciplinary topic of relevance to all Biomedical Scientists in all partner countries because it 'specifies requirements for quality and competence in medical laboratories'. The goals of the activity were to ensure that Biomedical Scientists became familiar with some of the clauses in ISO 15189 and to give participants the opportunity to investigate a selection of case study examples on how the standard relates to specific laboratory situations. Biomedical Scientists were provided with five case studies (Table 1) which they were required to relate to a specific clause(s) or subclause(s) of the standard and establish whether the scenario conformed to the specified requirements. If the scenario did not conform, participants were asked to list the changes that would be necessary to ensure compliance with the standard.

On completion of the exercise, Biomedical Scientists took part in a discussion group and completed a reflective learning sheet which asked them to comment on what they had done, what they had learned, how they will apply the learning in their future work and what the possibilities are for future development opportunities. Participants also filled in an evaluation questionnaire with questions (Table 2) which required an answer to be selected on a 5 point Likert scale along with an opportunity for comment.

Table 1. The Five Medical Laboratory Case Studies

<p>Scenario 1 Management Review</p> <p>The Head of Department (HD) is responsible for convening management reviews with, at a minimum, the Deputy Head, Chief Technician and Quality Manager. Management review is conducted every 12 months. HD has a right to shorten this interval if he/she assesses that it is necessary. Longer periods are not allowed. QM is responsible for collecting and reporting information from the results of evaluation of:</p> <ol style="list-style-type: none"> internal audits; risk management; use of quality indicators ; results of participation in PT/EQA programmes; monitoring and resolution of complaints; identification and control of nonconformities; results of continual improvement including current status of corrective actions and preventive actions; follow-up actions from previous management reviews; changes in the volume and scope of work, personnel, and premises that could affect the quality management system; other factors <p>Management team shall analyse the input information and assess opportunities for improvement of the quality management system and revision of quality objectives, policies and procedures.</p> <p>QM is responsible:</p> <ul style="list-style-type: none"> to record findings and actions arising from management review to report those information to laboratory staff to ensure that actions arising from management review are completed within a defined timeframe. <p>Learning Objectives</p> <p>Given a case scenario, the participant will be able to explain:</p> <ul style="list-style-type: none"> the process of management review which input information shall be reviewed what are the elements of the record of review output.
<p>Scenario 2 Calibration Non-Conformance</p> <p>A laboratory got an out-of-specification report for its weights that were sent out to an external accredited laboratory for its scheduled recalibration. In the accompanying letter the calibration laboratory described that the surface of weights were damaged (scratched) by improper handling. The weights were used for checking balances in the laboratory.</p> <p>The laboratory took the following actions.</p> <ul style="list-style-type: none"> They removed previous calibration label from the weight box They attached label “do not use” and removed weights from service. They logged the failure of the weights in their log They required purchase of the new weights They checked their balances with the other weights set. They found they were in tolerance so there was no risk to quality of the results issued. <p>Learning Objectives</p> <p>Given a case scenario, the student will be able to explain:</p> <ul style="list-style-type: none"> what should be done when equipment is found to be defective when corrective actions shall be applied what are the elements of the CA process
<p>Scenario 3 Measurement Uncertainty</p> <p>The Head of a biochemical laboratory said that they determined measurement uncertainty for each of their accredited measurement procedures. They found that the most significant contributors to measurement uncertainty of their routine measurement procedures were: imprecision and the uncertainty of calibrator-assign values. For imprecision they used estimates of the long-term within-laboratory precision for two concentration levels. Uncertainties of calibrator-assign values are estimated assuming uniform (rectangular) probability distribution.</p> <p>Control charts had been used to monitor long-term within-laboratory precision. For this purpose pooled patient samples and reference materials were used. They were not able to monitor instrument bias directly as their control material was not a trueness control material (Certified reference material or a reference material with a traceable assign value and stated uncertainty). They analysed PT/EQA results regularly and didn't find any evidence that their results were biased.</p> <p>They made their estimates of measurement uncertainty available to laboratory users through their web site. They didn't consider MU when interpreting measured quantity values as they found this as inappropriate.</p> <p>Learning Objectives</p> <p>Given a case scenario, the student will be able to explain:</p> <ul style="list-style-type: none"> what should be done regarding measurement uncertainty (what are requirements in ISO 15189) what are the typical sources of the measurement uncertainty in a routine examination method how can those sources be quantified
<p>Scenario 4 External Services and Supplies</p> <p>The laboratory maintains procedures for the purchase, storage, and evaluation of supplies, reagents, equipment and services. For purchasing responsible is the Department for procurement. They maintain the list of the suppliers of supplies and reagents used. Performance of those suppliers is monitored. Typical performance metrics are supplier's on-time delivery; percentage of claims and product returns, responsiveness and payment terms. This process doesn't include suppliers of laboratory equipment as they are purchased rarely – ones in few years. Performance of suppliers of services is also not monitored as the only services they purchase are calibration and equipment maintenance.</p> <p>Learning Objectives</p> <p>Given a case scenario, the student will be able to explain:</p> <ul style="list-style-type: none"> what should be done regarding purchasing according to the requirements of ISO 15189
<p>Scenario 5 Complaint</p> <p>The laboratory established documented procedure for the receipt, resolution, and maintenance of records of complaints and other feedback regarding laboratory activities. Complaints can result from clinicians and laboratory staff.</p> <p>Complaints may be lodged by various means in writing, electronically through e-mail, by telephone, web application, and in person. Staff who receive a complaint documents it on the Complaint Feedback form. It includes:</p> <ul style="list-style-type: none"> the name of the person and organization who lodged the complaint, the date when the complaint was received, and the nature of the complaint. <p>If the person receiving the complaint can determine the cause and the corrective action, they should take the corrective measures, complete the complaint form and forward it to the Head of the Laboratory.</p> <p>If the cause and corrective action cannot be determined by the person receiving the complaint, submission of the complaint is made directly to the Head of the Laboratory.</p> <p>When the corrective action has been completed, the complaint is closed. The Complaint Feedback form and corrective action form are submitted to the Quality manager who monitors the complaints received for trends, resolutions and corrective action.</p> <p>Learning Objectives</p> <p>Given a case scenario, the student will be able to explain:</p> <ul style="list-style-type: none"> what should be done regarding management of complaints (what are requirements in ISO 15189)

Table 2. Responses to Evaluation Questions

Question	Response	Croatia % n = 9	CZE% n = 1	Malta % n = 94	UK % n = 17
Do you feel that the exercise is useful &/or appropriate to your scope of practice?	Strongly Agree	0	100	58	18
	Agree	100	0	41	64
	Neither Agree nor Disagree	0	0	0	18
	Disagree	0	0	1	0
	Strongly Disagree	0	0	0	0
	Answer Not Given	0	0	0	0
Is the format of this exercise new to you?	Strongly Agree	0	100	24	24
	Agree	100	0	49	64
	Neither Agree nor Disagree	0	0	4	0
	Disagree	0	0	19	12
	Strongly Disagree	0	0	3	0
	Answer Not Given	0	0	1	0
How long did it take to complete this exercise?	Time Taken in minutes (mean)	79	51	287	21
Do you feel that this is relevant CPD? Please explain why/why not?	Yes	100	100	100	94
	No	0	0	0	6
Were instructions easy to follow/ understand? If not what would have helped?	Yes	100	100	86	35
	No	0	0	14	65
Was the discussion element useful to your scope of practice?	Yes	100	100	95	100
	No	0	0	5	0
Was the discussion element useful to your CPD?	Yes	100	100	100	100
	No	0	0	0	0
Was the reflection/reflective sheet useful to your CPD?	Yes	100	100	84	82
	No	0	0	7	18
	Answer Not Given	0	0	9	0
Overall how would you rate the complete CPD exercise?	Excellent/Very useful	100	0	85	70
	Good/Useful	0	100	10	24
	Poor/Not Useful	0	0	3	6
	Question Not Answered	0	0	2	0

3. Results

This paper reports on the second stage of the Leonardo Partnership Project entitled 'Enhance It' which involved transnational evaluation of a second new CPD activity by hospital laboratories in Croatia, Czech Republic, Malta and the United Kingdom.

Over one hundred Biomedical Scientists from four different European countries Croatia (n=9), Czech Republic (n= 1), Malta (n=94) and UK (n=17) took part in this new CPD activity. Several different grades of laboratory personnel evaluated the activity and indicated (Table 2) that the exercise had been useful and appropriate to their scope of practice (97.7%) and relevant for their own CPD (99.2%). For over 78% of participants, this was the first time that they had taken part in this novel format of CPD activity. Discussion with colleagues following completion of the activity provided useful enhancement to both scope of practice (96%) and CPD (100%). Subsequent completion of a reflective learning sheet was

shown to be beneficial for 85% of participants and over 95% of Biomedical Scientists rated the exercise overall as good or excellent. Responses indicated that some participants may have benefitted from an introductory presentation, prior worked example scenarios and earlier notification of specific chapters of the ISO Standards to read in advance of participation in the activity.

4. Discussion

One of the goals of this project was to introduce European Biomedical Scientists to new ways of carrying out CPD. This was successfully introduced with the first CPD Activity which was a series of images of good and bad practice relating to laboratory Health and Safety [16]. The theme of new ways of carrying out CPD was continued with this ISO15189 CPD activity and several Biomedical Scientists commented that previously CPD activities had been provided in an audio-visual format and this was therefore the first time that they had attended a CPD activity with this format. Overall, Biomedical

Scientists were extremely positive about the format of the exercise, particularly the discussion aspect of the activity and stated that previously they *'just used to listen'* whereas with this activity they had appreciated that *'interactive is better than just listening'* which contributed to the activity being *'an effective mode of learning'*. Reflective Learning Sheets gave participants the opportunity to reflect on the benefits of this type of learning within a CPD activity and one Biomedical Scientist commented that

'this method is more practical for learning and remembering what is going on, as you are participating directly, by giving your opinion, not just listening to someone talking on and on again'

The multi-disciplinary team working environment proved to be beneficial

'as groups consisted of Biomedical Scientists from different laboratories with different practices and it gave us a better understanding'.

This novel approach to learning within CPD activities provided participants with *'an open discussion as a method of learning which was greatly advantageous'* and it also *'encourages critical thinking.....we definitely learned a lot from this experience'*. Other feedback focussed on how

'such CPDs give us knowledge on how to better approach and solve specific problems regarding quality, competences and standards in management and laboratory procedures. It is a new learning method which enables us to better understand how to improve our service'.

The inclusive nature of these types of CPD activities was reinforced by several participants:

'With regard to the mode of learning I think it is really interesting and stimulating since everyone is much more involved hands on, thus helping in understanding the topic being discussedin my opinion it keeps the participants more attentive of the topics in discussion due to the fact that everyone is involved'.

'The participants in this exercise enjoyed this alternative form of CPD. Although none of the team members had ever read the ISO standards before, they were still able to understand and discuss the relevant points in this document. I believe that the fact of working in smaller groups helped some who are usually reluctant in speaking to participate and formulate their own thoughts on what was being discussed'.

As the ISO standard will be implemented soon within all European Medical Laboratories, most Biomedical Scientists had found that the scenarios were very relevant to their CPD as it had been *'lab oriented'* which had given them *'the opportunity to go through the ISO 15189 standards'* and had therefore provided *'a good insight into what ISO is all about'*. Other participants commented that the activity had been *'very informative and interesting'* and they felt that it had *'empowered & involved staff with keeping top quality and adhering to standards'*

Other important aspects were also mentioned in the participant feedback as Biomedical Scientists felt that participation in the activity had led to *'improved team building and development of new ideas'* plus provision of an opportunity for *'better communication with colleagues'* which had been good as there was usually *'not much opportunity to sit down and discuss as management'* and

'regular discussions are always helpful to improve lab best practice'.

Future development possibilities that were suggested by Biomedical Scientists included using *'scenarios that were more related to real life situations'* and possibly facilitating this through the use of *'interactive true scenarios and videos'*. Although several additional recommendations for improving the exercise were suggested including, provision of case studies prior to attendance at the CPD session, clearer instructions and a more detailed introductory briefing, the overall response to the activity was very positive with one Biomedical Scientist recommending that *'the exercise should be given to all laboratory personnel'*.

5. Conclusions

We conclude that successful evaluation of this new ISO15189 CPD activity by Biomedical Scientists in four different European countries has strengthened collaboration between their respective hospital laboratories, provided a way forward for further co-operation to develop European Biomedical Scientists CPD and enhanced future harmonisation towards a European profession.

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References

- [1] Martin JHJ (2010) Training The Trainers: A Transnational Approach *The Biomedical Scientist* 54 (8): 572.
- [2] Martin J, (2012) Developing Good Practice in Preregistration Training: a UK/ Malta Transnational project. *The Biomedical Scientist* 56 (1): 46-47.
- [3] Martin J, (2013) A Transnational Project to Develop Good Practice in Preregistration Training of Biomedical Scientists: UK and Malta. *The Biomedical Scientist* 57 (1) 42-44.
- [4] Martin J, Gasljevic V, Šálek T, et al (2015) Comparison of Approaches and Measurement of Continuing Professional Development for Specialists in Laboratory Medicine within Four European Countries. *Clinical Chemistry and Laboratory Medicine* 53(1): 35-44.
- [5] European guidelines for CPD EucoLABS 2012 http://www.biomed-austria.at/downloads/European%20guidelines%20for%20CPD_final.pdf.
- [6] Biomedical Scientists Portfolio EUCOLABS: A Road to a European credit system for Continuing Professional Development of Biomedical Laboratory Scientists in Europe. EU Project number: 2010-1-BE3-LEO04-02269-1 <https://vardforbundet.se/Documents/V%C3%A5rdfokus/CPD%20f%C3%B6r%20biomed%20an%20alytiker.pdf>.
- [7] European Common Framework for Continuing Professional Development in the Biomedical Sciences. Developed by LifeTrain. <http://www.emtrain.eu/index.php/lifetrain2>.
- [8] Martin J (2014) A European Project to Enhance Continuing Professional Development for Biomedical Scientists. *The Biomedical Scientist*, 58 (3): 155.
- [9] Martin J (2014) First Transnational Meeting of a European Project to Enhance Hospital Laboratory Standards for Biomedical Scientist's CPD by Developing a Quality Improvement Toolkit. *The Biomedical Scientist*, 58 (5).

- [10] Martin J (2014) European Project to Enhance Laboratory Standards for Biomedical Scientist CPD: Third Transnational Meeting. *The Biomedical Scientist* 58 (10) 550-551.
- [11] Martin J, Adkins A, Bennett T, Rice K and Taylor Y. (2014) European Project to Enhance Standards for Biomedical Scientist CPD: Developing a Quality Improvement Toolkit. *The Biomedical Scientist* 58 (6) 321-323.
- [12] Martin J, Adkins A, Bennett T, Rice K and Taylor Y. (2015) European Project to Enhance Laboratory Standards for Biomedical Scientist CPD: Fourth Transnational Meeting. *The Biomedical Scientist* 59 (3).
- [13] The European Union Lifelong Learning Programme <https://www.lifelonglearningprogramme.org.uk/>.
- [14] Leonardo Partnerships <http://www.leonardo.org.uk/default.asp?section=00010001§ionTitle=Home>.
- [15] Martin, J(2013) A European Project to Enhance Hospital Laboratory Standards for Biomedical Scientists Continuing Professional Development by Establishing a Quality Improvement Toolkit and an Online Community of Practice. National Association of Primary Care Review *Winter 2013/1429-30*.
- [16] Martin J, Buttigieg D, Silhvik J et al (2014) Enhance It - Enhancing Hospital Laboratory Standards for Continuing Professional Development: Transnational Evaluation of a Novel CPD Activity for Biomedical Scientists. *American Journal of Educational Research* 2 (11) 1110-1114.
- [17] ISO 15189: 2012 Medical laboratories - Requirements for Quality and Competence http://www.iso.org/iso/catalogue_detail?csnumber=56115.