

The key role of public health in renovating Italian biomedical doctoral programs

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Abstract

Background. A key renovation of doctoral programs is currently ongoing in Italy. Public health and its competencies may play a pivotal role in high-level training to scientific research, including interdisciplinary and methodological abilities.

Methods. As a case study, we used the ongoing renovation of the Clinical and Experimental Medicine doctoral program at the University of Modena and Reggio Emilia. We focused on how the program is designed to meet national requirements as well as students' needs, thus improving educational standards for scientific research in the biomedical field, and on the specific contribution of public health and epidemiology in such an effort.

Results. The renovation process of doctoral programs in Italy, with specific reference to the biomedical field, focuses on epidemiologic-statistical methodology, ethics, language and communication skills, and open science from an interdisciplinary and

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international perspective. In the specific context of the doctoral program assessed in the study and from a broader perspective, public health appears to play a key role, taking advantage of most recent methodological advancements, and contributing to the renovation of the learning process and its systematic quality monitoring.

Conclusions. *From a comparative assessment of this case study and Italian legislation, the key role of public health has emerged in the renovation process of doctoral programs in the biomedical field.*

Introduction

The Doctoral Degree (PhD) is generally the highest academic achievement. Its purpose is to equip individuals with advanced research skills applicable to institutions across the public and private sectors (1), within any professional field including biomedicine. This is intended to facilitate entry and progression into professional careers and foster innovation. The objectives of doctoral training include the following: developing and adapting research programs, critically analyzing complex ideas, contributing to some of the United Nations' Sustainable Development Goals, advocating for action plans of the European Research Area, acquiring interdisciplinary and digital skills, enhancing communication, networking and quality of the research environment (2, 3). Educational programs are considered critical public health interventions for the improvement of such aspects (4-7). Therefore, improving postgraduate specialists' skills is necessary to gain appropriate expertise and information relevant to their respective fields. From this perspective, incorporating state-of-the-art scientific and innovative approaches is essential to enhancing individual skills and abilities, particularly in an educational environment such as doctoral schools, as widely recognized (8-17).

At the end of 2021, key regulations for all doctoral programs were introduced by the Italian Ministry of University and Research (MUR). Such rules aimed to achieve an enhanced level of adaptability, allowing for diverse post-doctoral career paths while properly implementing stringent criteria of scientific and organizational excellence. Oversight and monitoring of research doctorates will be undertaken by the Italian National Agency for the Evaluation of Universities and Research Institutes (ANVUR) (18).

Educational activities performed in doctoral programs must be explicitly outlined within the overall doctoral plan, focusing on advanced research endeavors and high-level training within an interdisciplinary, multidisciplinary and transdisciplinary perspective

(19). While these terms are often used interchangeably, they have distinct characteristics: key differences lie in the level of integration and collaboration among different disciplines, within a broader research area such as the biomedical one. Interdisciplinary work involves collaboration while maintaining disciplinary boundaries, multidisciplinary work involves parallel contributions without deep integration, and transdisciplinary work aims to create a unified framework transcending disciplinary barriers. Such training involves language and computer proficiency refinement, interactive teaching, engaging education, research methodology and management, and knowledge of the European and international research systems. Taken together, these result in the implementation, promotion and dissemination of scientific research, intellectual property, open access to research data and products, fundamental ethical principles, gender equality and integrity (19-21). These guidelines, drawn from the MUR in March 2022, highlight prerequisites for doctoral programs, including those in the biomedical field. Within this area in particular, many of these principles are part of the traditional core curriculum of public health, such as the relevance of methodology in study design and data analysis, educational programs, health policies and health promotion in primary care settings (22, 23). Furthermore, the ongoing reform of doctoral programs stresses the importance of their quality monitoring and improvement: in particular, it is emphasized that universities must implement a quality assurance system for the design and management of doctoral education in accordance with Standards for Quality Assurance in the European Higher Education Area (EHEA) (24).

Based on such recommendations from the national authority, the Clinical and Experimental Medicine (CEM) Doctoral Program of the University of Modena and Reggio Emilia (UNIMORE) started a major iterative restructuring, in order to meet ministerial criteria and enhance quality of education for its doctoral students, within a collaborative effort by

the faculty and the doctoral students and in line with recent methodological indications (9, 16, 25). Here we describe how public health-related competencies may play a major role in such an effort to renovate a doctoral course.

Methods

Case-study description

CEM is a three-year doctoral program and features three main curricula: “Translational Medicine”, “Public Health” and “Nanomedicine, Medicinal and Pharmaceutical Sciences”. It currently includes nearly 100 doctoral students and 48 faculty members, along with foreign faculty members who are widely renowned researchers in the biomedical fields. The program, affiliated with UNIMORE’s Department of Biomedical, Metabolic and Neural Sciences, requires that an original research project be proposed and managed by a doctoral student under the control of one faculty member (“supervisor”). Training generally necessitates daily in-person participation and is not available through remote or distance learning methods. No formal quality assurance system was explicitly required for doctoral schools so far in Italy, but it was first implemented in 2023.

For this case study, we put in place a two-pronged intervention during 2023. First of all, the educational program was restructured according to the new proposed guidelines. Secondly, we created a quality assurance system for the doctoral course.

Educational program

The revised framework of the educational program lays strong emphasis on ethical research practices and integrity. Candidates are therefore guided in conducting research that upholds the highest ethical and methodological standards. Sharing scientific knowledge clearly and effectively is another critical aspect of disseminating progress across the various fields of the doctoral program. This is actively promoted with a view to successfully presenting research findings in diverse settings (e.g., conferences and seminars). Training also addresses student needs in epidemiology and statistics, research methodology and data analysis software, in order to provide the necessary tools to independently perform data management and analysis in an effective and reproducible manner. Great attention is paid to overcoming old and mistaken concepts, such as statistical significance/null hypothesis testing,

in keeping with the most recent methodological perspectives, as illustrated in more detail later on. The program also focuses on artificial intelligence and its application to the biomedical research field, by highlighting its powerful strengths as well as relevant potential limitations.

The renovation of the doctoral program is being implemented by a task force. This is composed of an interdisciplinary team including the PhD coordinator and deputy coordinators, and a few doctoral students. Since the beginning of this process, students’ opinions have played a major role in providing feedback on educational needs and in essentially leading the renovation process itself through periodical online and physical meetings.

Results

The PhD Quality Assurance System

The PhD Quality Assurance System (QAS) is embedded in the renovation process being implemented by an interdisciplinary team. Two official bodies have been established for the doctoral assurance process. The first one is the *Review Group*, composed of the coordinator and deputy coordinators, and PhD students in representation of the three cycles, in line with most recent methodological indications (16). It is entrusted with the task of supporting the PhD coordinator in implementing and analyzing the quality of the doctoral program. The second board is an *Advisory Committee* composed of international scientists from widely renowned international institutions in the US (Boston University, Harvard University, Stanford University, University of California Los Angeles, and the University of Maryland), the UK (University of Liverpool), Belgium and Germany (Ghent University and University of Hamburg), and Italy (National Institute of Health and the High Health Council). The Advisory Committee is in charge to provide advice, feedback and recommendations about the proposed educational and research program, and its appropriateness in training researchers able to fit the expectations of the public and private sector in the biomedical field.

The Review Group provisionally implemented CEM’s planning and management during 2023, in accordance with the guidelines from UNIMORE’s Quality Office and the MUR-ANVUR guidelines. For instance, feedback on ongoing courses, including a newly established residential “Spring School” offered in early 2023 to all CEM doctoral students and

devoted to advanced topics of research methodology, has been collected at its end via anonymous online questionnaires, and discussed during subsequent meetings between the coordinator and the PhD student representatives (18). Data collected through the surveys have been processed, aggregated and then sent to the CEM Faculty Council, the Department of Biomedical, Metabolic and Neural Sciences, the Advisory Committee and the Independent Evaluation Unit. For the purpose of QAS, the indicators proposed by the MUR were used, while a specific time-point assessment was set to check iterative changes to the planned intervention. For instance, feedback from participants in the Spring School included appreciation of course organization, lecturers' clarity and usefulness of course contents. Participants also provided suggestions in relation to extending the duration of some courses (e.g., on epidemiologic and statistical methodologies as well as scientific dissemination), and incorporating practical examples from diverse biomedical research fields. Specifically, the Spring School was praised for fostering networking and interdisciplinary interactions, along with the residential setting, the possibility of fruitful exchange of ideas and the suitability of the location. At the same time, suggestions were made for improvements: a sharper focus on methodological aspects for basic sciences, comprehensive English program delivery, workshops for practical applications, and a refinement of study design lectures. An appetite emerged for a more comprehensive coverage of lessons beyond clinical aspects, along with increased accessibility for diverse knowledge levels. Such suggestions also encompassed more personalized lessons, the discussion of practical examples and the availability of more time for discussion. Some advocated subdividing participants into smaller groups based on fields of interest. Besides the overall positive feedback, a stronger diversification of the courses and more inclusivity have been recommended for a more valuable experience.

Additionally, it is well known that international collaborations in terms of both doctoral student training abroad and implementation of collaborative research projects (26) play a pivotal role in the improvement of doctoral programs. Such growing internationalization is currently highly valued by the local and national authorities assessing the quality of doctoral schools in Italy. This is especially the case with periods spent abroad by doctoral students, and the inclusion of highly-qualified foreign researchers in educational activities. With reference to the case

study under investigation here, CEM has recently included in its statutory bodies a number of widely renowned foreign scientists from the fields of public health, epidemiology, biostatistics and scientific methodology, more generally. These researchers are affiliated with prestigious international public health institutions which we have already mentioned in the "Results" section. In addition, a CEM faculty member in charge of internationalization has been identified to foster such international collaborations. Moreover, the faculty are currently considering to provide additional financial support for students who aim to spend a period abroad (3 or more months) at highly qualified scientific institutions (27). An effort has been eventually made to enhance English skills through an advanced Technical-English course. This is devoted to the use of language in scientific research and communication, and also includes teaching units on how to write a grant and a scientific paper (28, 29).

The role of public health

A key role of biomedical education is to provide adequate training to plan, design, implement and interpret biomedical studies, independently of design and topic. Generally speaking, studies in humans are classified into experimental and non-experimental (epidemiologic) studies, the first ones including mainly randomized and non-randomized trials, the second type including ecologic, cross-sectional, case-control and cohort studies (30). Epidemiology and public health may help doctoral students, and more generally researchers, to design and carry out such studies, not least by taking account of risks of bias and ethical issues, as well as summarize findings and assess the reliability of causal relations, based on the Bradford-Hill criteria (31). In this regard, the recent trend in dismissing traditional P-value cutpoints and null hypothesis/statistical significance testing is crucial to data analysis and result interpretation. This is in line with the most recent methodological trends in scientific research, where focus is on risk and effect estimates, their statistical stability, interactions and subgroups analyses, and eventually the potential for bias of studies and related estimates (30, 32-37). Such knowledge must be refined by all students entering a doctoral school in the biomedical field, by providing cutting-edge education and by sharing the most recent relevant methodological literature. When designing a study on precision of the expected estimates (and no longer on power, a concept embedded in statistical significance testing (38, 39)), students should also shift

their focus to consistency of human and laboratory findings by mixing evidence from epidemiologic studies with biological plausibility from laboratory investigations.

Another key contribution of public health to the renovation and advancement of doctoral education in the biomedical field concerns the design and implementation of systematic reviews and meta-analyses, preferably in the form of dose-response meta-analyses (40). Although this methodology is not exclusively related to public health and epidemiology, its systematic use is now part of assessing the certainty of evidence (41-44). Training is therefore required in the following areas: systematic data search of the main online literature databases, including methods for citation chasing, the handling of gray literature, software for reference handling such as Rayyan (45) and RevMan (46), tools for the risk-of-bias analysis such as ROBINS-I (47), ROBINS-E (48, 49), RoB 2.0 (50), OHAT (51) and DistillerSR (52), quality controls and checklists for systematic reviews such as PRISMA (53), appropriate extraction tables to abstract, store and process results from the single eligible studies and, finally, preliminary registration of reviews into databases like PROSPERO (54). In particular, efforts should be devoted to training doctoral students in understanding if and how study biases may affect the entire review and meta-analysis, along with the potential for *ex-post* correction of such bias. Moreover, doctoral candidates should gain familiarity with the most recent tools for rating evidence from biomedical findings, e.g. the well-known GRADE system or the OHAT tool (51, 55, 56). In addition, students should be trained to avoid traditional but erroneous approaches in systematic reviews and meta-analyses. These include the following; counting the number of studies supporting or not supporting a specific overall finding, rather than measuring study quality and certainty of evidence; the presence of statistical significance in pooled estimates; evidence deriving from forest plots, favoring instead implementation of non-linear dose-response meta-analyses based on spline modeling (40, 57-59). All doctoral students in the biomedical field should therefore become well accustomed to systematically reviewing and meta-analyzing results from studies carried out on the same topic, along with the interpretation of such pooled analysis. CEM is currently ensuring that doctoral candidates are trained to independently implement systematic (and narrative) reviews and meta-analyses as some already did with recently published papers in the field of adverse health effects of artificial light (60-62), acrylamide intake

(63, 64), fluoride exposure (65-68), neonatal disease (69, 70) and cardiovascular disease (71, 72).

Ethics

The implementation and submission of protocols to ethics committees are relevant activities on the working agenda of biomedical researchers, especially for those studying human subjects in clinical, epidemiologic and toxicological settings (73). For this reason, the doctoral program includes a course on ethics that covers the European and Italian regulatory frameworks related to the submission of various types of studies, including the implications of European Regulation 536/2014 (74, 75). For this reason, ethics training has been introduced in several graduate and postgraduate programs in order to raise full awareness of ethical aspects (76, 77). Training sessions focus on the reorganization of ethics committees nationwide, detailing the role of technical-scientific secretariats with practical examples of research protocol submissions (78). Beyond biomedical research, the course underscores the importance of reaffirming ethical principles governing the protection of individuals and their personal data (76). Research activities may face ethical and legal uncertainties, necessitating analysis and resolution for the achievement of research goals. Emphasizing the application of ethical principles, privacy by design and privacy by default throughout research projects is crucial to adequately safeguarding the rights of those involved (77). Issues related to data protection regulations are therefore fully addressed alongside treatments in retrospective and prospective studies as well as procedures for formulating and submitting biomedical study requests to ethics committees (79) in light of the latest regulations and local/national organizational structures (80). The course eventually delves into the regulatory framework for various study types, highlighting the functions of research offices in health companies and the technical-scientific secretariat of the ethics committee, offering practical examples of common challenges posed by the process of research protocol completion and submission (81, 82).

Open science

The doctoral program includes a course designed to explore the principles of open science, including open access publication. The availability of "open data", i.e., data that can be freely used, modified and shared by anyone for any purpose (83), has become a key aspect in scientific research, clearly including the biomedical

field (83). In particular, its use has widely enhanced especially in the most recent years, with a sharp increase during the COVID-19 pandemic (84). Open access implies greater availability of research results, allowing anyone to access and reuse them with very few (if any) restrictions (85). The course organized by the CEM doctoral program in collaboration with the UNIMORE library (86) aims at reinforcing the notion that research data, results and publications should be available as freely as possible for discussion, further analysis and dissemination. By recognizing the importance of making research data and results universally accessible, the course emphasizes their contribution to more effective science and innovation in both the public and the private sectors. Finally, the course specifically addresses open access policy and opportunities for publications and research data management, offering guidance and tools to promote open science practice and ensure compliance with research funders' mandates.

Conclusions

The pivotal contribution of public health to a number of key aspects of doctoral student education is a key element to foster and strengthen the quality of doctoral programs in the biomedical field. The training framework outlined in this study is an example of the ongoing Italian effort to improve the quality of biomedical doctoral programs across the country, and of the substantial contribution to this process by public health, particularly (but not only) in the field of research methodology. This is fundamental to shape the educational and research background of young researchers, and to allow them to gain more extensive expertise in designing, performing and finalizing scientific projects, data analysis, result interpretation and dissemination. Public health may also help in keeping the right balance between specialized research-focused topics and interdisciplinary and international expertise, given the essence of public health practices in advocating for comprehensive approaches. Emphasis on specialized and cross-disciplinary competencies from public health may indeed provide doctoral students with advanced research skills. Epidemiology and statistics in particular may play a crucial role in data analysis and in identifying causal relations within studies carried out in laboratory settings and about patients, single individuals and communities. Such studies may also include health-event monitoring, assessments of public health interventions and

policies, and healthcare quality and safety (87). This comprehensive approach embodies public health principles and lays the foundations for the training of future researchers capable of responding to global health challenges. Under this perspective, also ethical considerations are a core element of biomedical doctoral courses, ensuring integrity in research conduct. Finally, quality assurance appears to be a core public health principle, since it aims to ensure accountability of higher education institutions while improving the quality of higher education (88), and also for the case study here presented both internal and external quality assurance appear to rely on public health. The aim of quality assurance in a biomedical doctoral program appears to be the development of a culture of quality, so that all individuals involved, i.e., doctoral candidates, faculty and study participants, can constructively engage and enhance methodological quality and ethics of biomedical research, and effectively foster the dissemination of its results.

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Riassunto

Il ruolo fondamentale della sanità pubblica nella riqualificazione dei corsi di dottorato di ricerca di area biomedica in Italia

Introduzione. In Italia è attualmente in corso un rilevante sforzo di qualificazione e rinnovamento dei corsi di dottorato. Tra gli elementi fondanti di tale riqualificazione formativa sono di particolare rilievo quelli interdisciplinari e metodologici, per i quali la sanità pubblica appare in grado di offrire competenze innovative e peculiari.

Disegno dello studio e Metodi. Prendendo spunto da un caso-studio specifico, il Corso di Dottorato in Medicina Clinica e Sperimentale presso l'Università di Modena e Reggio Emilia, ci siamo proposti di individuare gli aspetti qualificanti di tale contributo offerto, tra le diverse discipline, dalla sanità pubblica e dall'epidemiologia, in linea con le indicazioni ministeriali ed al fine di pervenire ad una più efficace formazione allo svolgimento di attività di ricerca scientifica.

Risultati. Il processo in corso di rinnovamento dei corsi di dottorato in Italia, con specifico riferimento all'ambito biomedico, conferisce particolare rilievo al ruolo della metodologia epidemiologico-statistica, dell'etica, delle competenze linguistiche e comunicative, dell'*open science* e di una forte prospettiva interdisciplinare e di internazionalizzazione dell'attività di ricerca. Nel contesto specifico del corso di dottorato preso in esame ed in una prospettiva più generale, la sanità pubblica appare in grado di apportare un contributo particolarmente significativo, traendo beneficio dalle innovazioni metodologiche più recenti e contribuendo all'individuazione di nuove modalità didattiche e alla verifica sistematica della qualità del processo formativo.

Conclusioni. Da una valutazione comparativa di questo caso-studio e della legislazione italiana, è emerso il contributo particolarmente rilevante della sanità pubblica al rinnovamento dei corsi di dottorato in area biomedica.

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