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Development of the distance education course Principles and Practice of Clinical Research: 9 years of experience in the Dominican Republic

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Abstract:

Introduction: Critical thinking is an ideal tool for evaluating information as a guiding action. With the conjunct use of the internet and applied pedagogy, PPCR looks to develop its alumni's superior cognitive skills. We aim to characterize alumni and their experiences in the Dominican Republic for over nine years.

Method: This descriptive, cross-sectional study used a survey instrument formatted with closed and semi-closed questions, which was sent to each participant's email. The survey had two segments, the first with twelve questions related to the participant's personal information and characteristics related to their background education and profession. The second section evaluated satisfaction during their participation in the PPCR course.

Results: Out of a total of 62 graduates from 2012 to 2019, data was collected from 52 participants, of which 92% are medical doctors. The mean age was 36 years, with a predominance of the female gender (56%). The vast majority of participants are Dominican (90%), with a postgraduate program (61.2%). More than half carry out university teaching activities (54%), and a part of them continued to be affiliated in the program as Teaching Assistants, performing pedagogical assistance tasks (38%). The global satisfaction rate was high (92%), with a low dropout rate (2%).

Conclusions: Based on our study's characteristics, this course is estimated to be a novel element capable of promoting scientific production and promoting clinical research activities in developing countries. It creates connections and exploits virtuality to improve knowledge through the critical analysis of information. This experience plays a prominent role in the enrichment of many teachers by providing them with methodological tools, developing the excellent training of educators.

Keywords: Critical thinking, online learning, student-centered learning, clinical research, Dominican Republic, medical education, Principles and Practice of Clinical Research.

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Abbreviations:

DR: Dominican Republic

PPCR: Principles and Practice of Clinical Research

TA: Teaching Assistant

PUCMM: Pontificia Universidad Católica Madre y Maestra

INTRODUCTION

Evidence-based medicine uses results from clinical research, consciously, taking the use of the clinician's critical judgment as an essential component of this process to make the best decision towards how to manage patients and their diseases (Lozano et al, 2004). The vital role that the development of clinical research plays in the effectiveness of evidence-based

medicine has been shown by many authors (Lu & Li, 2013).

Critical thinking is a process that involves conceptualizing, applying, and evaluating information gathered from observing, reasoning, experiencing, or communicating; it is more than a mode of thinking (Wang & Zheng, 2016).

Nowadays, we count on an extraordinary tool, the Internet, which could play a positive and a negative role in education. The impact of using online resources on teaching and learning is certainly evident (Fregni & Sanchez, 2020); however, to keep up with this rapid development of using technology in the educational process, providers (teachers) need to continually find new approaches to teaching online in order to innovate the programs to follow the market's demands (Christensen et al., 2011). As a result, the motivation for enrollment in online programs and positive results in the learning process are shown after engaging in this schooling modality. It has been found that the use of online resources to learn stimulates critical thinking to a great extent (Gernsbacher, 2015).

For these reasons, we decided to discuss a program that follows the online learning experience to evaluate the satisfaction and compliance of clinical investigation in the Dominican Republic (DR). The program Principles and Practice of Clinical Research (PPCR) began in the year 2008, as an idea by Prof. Felipe Fregni, a professor at Harvard Medical School and Harvard T.H Chan School of Public Health. PPCR offers an accessible clinical research course based on collaborative learning among individuals from different backgrounds who share a common goal of optimizing their clinical research skills and knowledge.

The effectiveness of online education, compared to offline methods, has already been evaluated. A meta-analysis compared the differences in the pre- and post-assessment (referring to the course) scores of undergraduate students over 17 years, yielding results in favor of online learning, with significant improvements in 56% of the sample (Pei & Wu, 2019). However, they also highlight that these results depend on the level of education and the student's abilities. Therefore, they suggest taking into account other characteristics to affirm these considerations such as learning style, gender, level of commitment, satisfaction, and attitude (Pei & Wu, 2019; Robinson & Hullinger, 2008; Terrell & Dringus, 2000; Johnson et al., 2000; Dahalan et al., 2012).

The basic design of PPCR is a student-centered course that consists of training the participants on the

most up to date information on the basics and advanced techniques in clinical trials. The program encourages students to properly analyze and discuss articles, along with creating a community of their peers and emphasizing communication as the vital component of this learning environment. One of the most amazing resources this program has to offer to each student is the feeling of personalized guidance; this is promoted by assigning a small group of participants to a teaching assistant (TA), that would be in charge of offering guidance and support by following the student's activities and program performance closely, allowing for a one-on-one interaction when needed.

Over the past 12 years, the PPCR program has shown significant advancements regarding their teaching modalities along with an expansion in the number of countries, reaching up to more than 90 different countries, and 49 site centers from all around the world. The course is available for the public to join. To date, more than 3,000 professionals from different areas have been trained in clinical research thanks to this program. The growth of the innovative-networked remote learning technique has been broadly accepted by the community that lacks the time or the opportunity to attend a live lecture in Boston (Bonilla-Velez et al., 2015; Narita & Ueda, 2020).

In the specific case of PPCR in the DR, in 2014, at the Pontificia Universidad Católica Madre y Maestra (PUCMM) located in Santiago, nine medical doctors were interested in enhancing their critical thinking by learning clinical research, supported by Annette Sengers, Ph.D. of the Academy of International Sciences who facilitated the enrollment of all students; therefore, the first site center was opened. Later in 2019, the second PPCR site opened in the city of Santo Domingo. The enthusiasm generated has a significant impact on the recommendation of PPCR graduates which motivates the perseverance of the program up to this year, with more than 63 alumni seeking to improve their critical thinking and acquire new knowledge from this program.

However, research is limited. To the best of our knowledge, there is no study in the DR that has shown the characteristics of students' that engage in online distance learning or its influence on their academic production, thus making it essential to further investigate this learning system. To address this knowledge gap, we developed and surveyed the participants that enrolled in the online course Principles and Practice of Clinical Research in the DR from the year 2012 to 2019 to learn and describe the socio-

demographic characteristics and their level of satisfaction. With this study, we will have the necessary information to support these types of programs in order to expand the opportunity to have more quality clinical researchers in the Dominican Republic.

METHODS

This descriptive cross-sectional study used an online survey instrument formatted with closed and semi-closed questions, which was sent to the email of each PPCR participant after consenting to participate.

Survey Design

The survey was divided into two main sections; the first one includes twelve questions related to the participants' personal information and characteristics related to their education and profession. The second section evaluates satisfaction during their participation in the PPCR course. It was required that all questions were answered.

Recruitment

Eligible participants included all PPCR alumni from Dominican Republic sites, who graduated from 2014 to 2019. The survey was distributed from July 11th to July 12th, 2020.

First, the study instrument was sent via email to the 62 alumni of the PPCR course from the last nine years through a link to a Google form (<https://docs.google.com/forms/d/e/>); this included the survey explanation and informed consent to be signed. Up to 2 reminder emails were sent if they did not respond. We also promoted the survey by social media in the PPCR alumni groups of DR.

Statistical Analysis

Data was analyzed in a dynamic table in Excel 2020 and SPSS 26 software based on descriptive statistics using mean, median, and range for continuous variables, and the frequency for categorical variables.

RESULTS

Out of the 62 contacted alumni, 53 (85.48%) responded to the survey, resulting in a significant response rate. The reason for declining was a change in contact information. From the original participants list of those who completed the survey, one participant was excluded for not having completed the entire PPCR course. Only the data from the remaining 52 participants were included in the analysis.

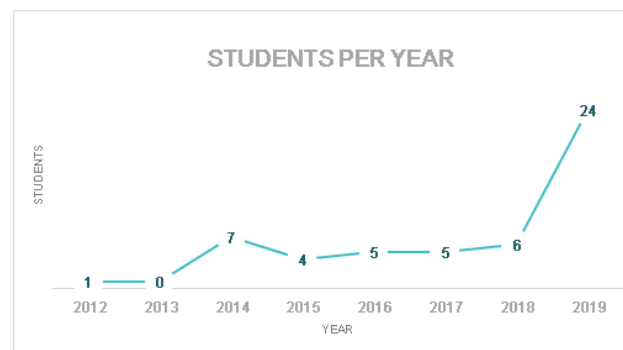


Figure 1. This linear graph shows the number of students who have taken PPCR in the Dominican Republic per year, throughout the period between 2012-2019; the variables involved are years, and the number of students who participated in the program. We must consider that during 2012, there was only one student who took the course in Boston.

Looking into the behavior of students' enrollment in the PPCR program throughout the years in the DR, we have identified an increase in the number of students since 2014, which was the opening year of the site with seven students. The following years, 2015 (n=4), 2016 (n=5), 2017 (n=5) and 2018 (n=6) showed a steady trend of interest in enrollment, with an uprise in 2019 (n=24).

VARIABLES	n	PERCENTAGE (%)
Gender		
Male	23	44%
Female	29	56%
Age (years)		
Mean	36	-
Range	23-64	-
Nationality		
Dominican	47	90%
Other	5	10%
Occupation		
Medical doctor	48	92%
Other	4	8%
Medical specialty		
Yes	25	48%
No	27	52%
Performs as teaching faculty		
Yes	28	54%
No	24	46%
Received grants for research papers		
Yes	15	28%
No	37	72%
Range	1-8	-
Number of published research papers		
Mean	3.7	-
Range	0-30	-
Teaching assistant in PPCR		
Yes	20	38%
No	32	72%

Table 1. Sociodemographic characteristics of PPCR participants in the DR sites.

SATISFACTION	MEAN	RANGE	PERCENTAGE (%)
Student Satisfaction Level *	4.66	3-5	-
Interaction Satisfaction *	4.44	3-5	-
Learning based on critical thinking satisfaction *	4.65	3-5	-
Collaborative Learning Satisfaction *	4.50	3-5	-
Course Content Satisfaction *	4.72	3-5	-
Global rate of Satisfaction	-	3-5	92%
Drop-out rate	1	3-5	2%

* : Based on a likert like scale from 1 to 5, being 5 the maximum value.

Table 2. Level of satisfaction of students and Drop-out rate from PPCR course in the DR sites.

Table 1 summarizes the socio-demographic characteristics of the participants; from the entire population that took part in the study, we observe a mean age of 36 years (range: 23-64 years). Regarding gender, 56% (n=29) are females and 44% (n=23) are males. In regard to the nationalities of the students, the majority are Dominican (n=47, 90%) while the rest are distributed among the USA, Mexico, Peru, Haiti, and Iran (n=5; 10%).

A total of 92% (n= 48) are medical doctors; 2% Psychologist, and 6% are undergraduate medical school students (n=3). Considering the physicians alone, 61.5% (n=32) have completed postgraduate programs, with the most common being: Internal Medicine (n=3; 6%), Cardiology (n=3; 6%), Epidemiology (n=3; 6%), and General surgery (n=2; 4%). The remaining 23% of the specialties include Surgical Pathology, Imaging, Radiation Oncology, Public Health, Obstetrics and Gynecology, Rheumatology, Family Medicine, Public Health, and Forensic Medicine.

More than half of the graduates (n=28; 54%) have a faculty position at universities; 15 of these professionals have earned funds to conduct research studies (range: 1-8 funds).

Concerning the PPCR alumni, 38% (n=20) decided to continue their participation in the program and help new students in their learning experience. These students served as teaching assistants (TA I, TA II, and STA), due to their satisfactory performance in the course.

The graduates from this remote Program evaluated their satisfaction level in five categories, which were assessed based on a Likert-like scale grading from 1 to 5, with 1 being the minimum and 5 the maximum value (**Table 2**). The categories were divided into the following:

- Student's satisfaction regarding the online modality of the lectures (mean: 4.66).
- Learning based on critical thinking (mean: 4.65).
- Satisfaction regarding students' interaction with the teaching faculty from PPCR and their on-site center directors in the Dominican Republic (mean: 4.44).
- Learning based on collaboration with international colleagues (mean: 4.50).
- Satisfaction regarding the course content, teaching strategies used by the faculty, and course methodology (4.72).

The global student satisfaction rate was high (92%) with a low dropout rate (2%).

In the last section of the questionnaire given to the participants, they were asked to state the reasons that motivated them to join PPCR, as shown in **Table 3**. The main reasons mentioned, in order of frequency, are as follows: increase their clinical research knowledge (47), improve their statistics comprehension (28), as coadjutant in their USMLE process (13), as a way to make their Curriculum Vitae more appealing for job searching (13), by colleagues' recommendations (7) and lastly, for the curiosity of incurring in the clinical research field and learning about the topic (4).

MOTIVATIONS	FREQUENCY* (%)	
	YES	NO
Increase their clinical research knowledge	47 (90%)	5 (10%)
Improve their statistics comprehension	28 (53%)	24 (47%)
Coadjutant in their USMLE process	13 (25%)	39 (75%)
Improving their Curriculum Vitae	13 (25%)	39 (75%)
Colleagues recommendations	7 (13%)	45 (87%)
Curiosity of the topic	4 (7%)	48 (93%)

*: The frequency was counted from 52 students.

Table 3. Main motivations for joining the PPCR course

DISCUSSION

Education focusing in methodology is a tool of globalization, which promises a problem-solving alternative by focusing on evidence based solutions. Developing these education programs on a virtual modality allows international cooperation, motivating students to interact with peers. This can be seen in the tendency in the number of participants', as seen in **Figure 1**. There is a latent need to migrate the analog research platforms to virtual means, permitting more significant interaction with open, accessible, and reusable resources (Baker et al., 2019). As for the possible reasons for this surge in participants, we hypothesize that the main drives include increased government support on the economic sphere and the incorporation of a new site center in the country's most important urban center.

Our described sample contains a significant number of young participants (less than 40 years old) (69%), as a confirmation of the course geared towards an early introduction into the academic career. These participants are a new generation of enthusiasts with the preparation and potential to generate more evidence over an extended time-lapse, increasing the mean active years of the country's scientists. The program's efficacy, based on the described human experience, is partially proven by the auto-evaluation, which resulted in a global satisfaction of 92%. We recommend future evaluations of this efficacy by the impact of these researchers on their disciplinary community and how their project formulation changed after completing the course.

Most of our participants were Dominicans, posing an opportunity for the country as a developing one. This last characteristic represents a challenge in clinical research, as evidenced by anecdotal reports such as scarce and unprepared human resources, lack of infrastructure, and insufficient practical experience (de Baessa, 2008). This virtual environment eases some regional deficiencies by giving access to varied methodological experiences from many teaching assistants and peers. This promotes a professional connection to a global plethora of human resources for support.

PPCR participant characteristics were first analyzed in 2015 by its staff (Suemoto et al., 2015). The results suggested points for its improvement to be explored subsequently. The findings included a dropout rate of (30%) which was striking; there was a higher tendency of dropout occurring at the beginning of the course and in the statistics modules. The dropout rate

has decreased to 12% in subsequent years. In contrast, our study shows a dropout rate in the DR sites of 2% and a 100% passing rate defined by grades, indicating a high level of engagement from the participants. This could be explained by an increased engagement and intrinsic motivation towards the process from these students, a key skill needed for success in the labor market.

The factors that contribute to the compliance of students at a PPCR site in Japan from 2013-2016 were explored and described with an observation of their impact on subsequent decisions (Narita & Ueda, 2020). Unlike in the DR, the majority of the population in Japan were male (62.5%). A total of 2% of students dropped out for personal reasons which prohibited them from continuing in the course; 83.3% were medical doctors, similar to our reports of 92.3% with the same degree. Additionally, there were no academic failures in either study as measured by the PPCR program staff. Moreover, there was a striking participation of students who would have reached an undergraduate degree as their highest academic level (32.7%).

As for our study's strong points, it aims to create evidence on a poorly described methodology in the literature. The participants' strong connection after the course conclusion helped develop an effective network to gather this information. For the limitations, we recognize a possible response bias as the collection was based on direct contact, therefore involving the gathering of identifiable information. Our quantitative approach limits our capability to generate reasons for most of the phenomena exposed, for which we recommend future studies with a qualitative approach. Finally, due to our population being mostly Dominicans, our conclusions are limited to this experience and may be comparable to countries with a similar socio-economic context.

CONCLUSION

This study was the first to characterize alumni from the Dominican Republic Sites in the history of PPCR. The program has had an essential impact on the participants' professional careers, demonstrating that online distance programs can be effective, when appropriately designed.

Funding

The research team received no economic retribution for the development of this academic work.

Ethical considerations

The data obtained from the questionnaire were used exclusively and confidentially by the team of researchers for this study without releasing any personal information from the participants that might compromise their identities. In the event that the data is needed for a different study, each participant will be contacted to obtain a new authorization using another informed consent form.

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Conflict of interest

VN, EP, MM, AS, and MN are staff members of the PPCR program. The authors declare no other conflict of interest at the time of submission.

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