

ARIZONA CLINICAL RESEARCH WORKFORCE SURVEY

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Abstract

Objective: We characterize the current clinical research workforce in Arizona with the goal of identifying possible educational training gaps for the future workforce. **Background:** The science community, government entities, educational institutions, and community programs continue to advocate for additional funding and resources to educate the bioscience workforce, of which clinical research is a part. However, there is little evidence that additional training and/or education is needed within the clinical research profession. **Method:** We utilized an electronic survey tool that was designed to solicit workforce data from clinical research professionals actively working or seeking employment in the field of clinical research within the state of Arizona. Distributed by email, the survey was sent to professional research organizations and associations, employment agencies, academic institutions, LinkedIn groups, and through a distribution list held by the Arizona Department of Health. Results were analyzed using a mixed method of descriptive statistics and qualitative analysis. **Results:** The majority of respondents to the survey were female and were between the ages of 41 and 60. When asked whether respondents thought that clinical research professionals should undergo formalized training through a college or university program that culminates in professional licensure, more than one-third indicated “no,” while the rest of the respondents indicated “yes” (29.8%) or “no opinion” (33.8%). Respondents who answered “no,” had concerns related to scope of practice, status quo, diversity of practice, and cost. Respondents who answered “yes,” indicated that professional licensure would raise levels of quality and levels of understanding. More than half of respondents indicated that they were required to obtain continuing education and that training in “good clinical practice” and “regulatory requirements” was of most interest. **Conclusion:** The survey focused on the current educational and training needs of the clinical research workforce, yet provided limited general education and training needs for the future of the profession. In order to determine educational gaps within the profession, distinctions in job titles and responsibilities are required to control for the diversity within the profession. Additional research is needed to identify the expectations of employers, professional organizations, and government agencies so that higher education can prepare the future clinical research workforce with resource allocations. **Application:** This survey offers a foundation for future research to investigate resource allocation within the clinical research area of bioscience education.

Arizona Clinical Research Workforce Survey

Introduction

Research involving humans as subjects has been in existence since the beginnings of medicine itself. Yet, rules and regulations relating to the conduct of “human subject” or “clinical research” are relatively recent, tracing their implementation to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and *The National Research Act* in 1979. Since that time, the U. S. Department of Health and Human Services, the U. S. Food and Drug Administration, and the International Conference on Harmonisation have issued an abundance of rules, regulations, and guidance documents directed toward human subject research, specifically to investigators, sponsors, institutional review boards, contract research organizations, and regulators (auditors). However, other than reference to physician qualifications for investigators, none of the rules or regulations specify minimum licensure or educational qualifications for the clinical research workforce as a whole. As such the clinical research profession is diverse, stratified, and fragmented, which has led to struggles with career validation, employment pathways, educational direction, and certification/licensure within the profession.

The lack of a requirement for clinical research certification/licensure, duplication of professional organizations that offer certifications in clinical research, and lack of standardized levels of post-secondary education and/or specific accredited training courses have made it almost impossible to determine or characterize the clinical research workforce. In fact, when the National Research Council of the National Academies (NRC) attempted to characterize the clinical research workforce (specifically investigators), the researchers noted that the “clinical research workforce is as varied as the definition of the field” (2011, p. 69). Additionally, the NRC researchers noted that “it has proved difficult to analyze the specific number of individuals in the clinical research workforce because current workforce databases focus on their current research areas [disciplines]” (NRC, 2011, p. 70). In 2011, the National Institutes of Health formed a Biomedical Research Workforce Working Group to develop a model for a sustainable and diverse U. S. biomedical research workforce “to inform decisions about training the optimal number of people for the appropriate types of positions that will advance science and promote health” (National Institutes of Health [NIH], 2012, p. 6). The group noted that it was difficult to determine if “we” are preparing a sufficient number of clinicians (investigators) for the biomedical workforce of the future, but recommended that the number of clinicians could be increased by making careers more attractive and attainable (NIH, 2012, pp. 153-154). Without specific evidence, there is a call for funding and support to increase the clinical research workforce at many levels.

Since 2002, Arizona has pursued the recruitment and training of researchers throughout the state. According to the Flinn Foundation’s 2011 Bioscience Roadmap, one of the priorities ahead is preparing the workforce of the future, which “depends on the quality in its investments in K-12, community-college, and university STEM education, including medical education” (Flinn Foundation, 2011, p. 2). Additionally, the Roadmap calls for “doctors and engineers, nurses and technicians, statisticians and laboratory scientists” to pave the bioscience road ahead

(Flinn Foundation, p. 2). The Flinn Foundation, (2011, p. 2) noted in their first decade of calling for bioscience collaborative and coordinated research that

. . . Arizona's bioscience industry jobs grew by 45%, compared to 12% for the nation as a whole. Excluding hospitals, the industry grew by 58%, compared to 5% for the nation. Bio firms in Arizona increased 31% during the same period, compared to 23% for the nation.

Then, too, the higher education community has continued to strive to address market needs with new industry-education partnership campuses across the state in 2012. The educational and economic impacts were highlighted as universities' research and development budgets reached record highs, including monies for 67 bioscience startups which generated close to \$19 million in license income for Arizona (p. 2, 2012). The pressure to train today's and tomorrow's workforce continues as higher education increased the number of programs related directly to STEM disciplines. The call to develop qualified workers in the biosciences remains an objective of industry and education alike.

Clearly, there are goals in place to prepare and educate the future bioscience workforce, of which clinical research is integral. Yet, there is no evidence that there is an actual need for additional resources to train the current or future clinical research workforce. Various organizations and government institutions continue to advocate bioscience education when it is unknown as what skills and levels of education are currently valued/needed to drive the future profession's members. Why should resources be prioritized toward clinical research education, if there is no need? This survey endeavors to answer this question by characterizing the current clinical research workforce in Arizona with the goal of identifying possible educational and training gaps for the future workforce. Specifically, the survey focuses on the educational background, roles, career disciplines, professional affiliations, employment, and perceived needs of the current Arizona clinical research workforce.

Survey Methodology

The Arizona Clinical Research Workforce survey was designed and conducted by the authors, who used a process of literature and peer review, consultation with clinical research professionals, and pilot testing to validate the survey. The survey was conducted online using an electronic survey instrument. The information gathered in the survey was aggregated such that individual information could not be identified directly or through identifiers linked to the subjects. Additionally, to ensure further privacy, the email/IP address trackers of the survey software were disabled during the survey setup, prior to survey distribution (study recruitment) such that individual responses could not be tracked.

The survey was designed for those individuals actively working or seeking employment in the field of clinical research within the state of Arizona. The survey was sent directly to 1,168 clinical research professionals using database distribution lists held by the Arizona Department of Health, Arizona Biomedical Research Commission, and the U. S. government database for Institutional Review Boards. Because the clinical research professional population is not easily identified, and in order to reach a broader audience, the survey was distributed to professional

research organizations, professional research associations, employment agencies, academic institutions, and through LinkedIn groups where it was forwarded to others within the clinical research community. During the time that the survey was open from November 14, 2012 through January 11, 2013, 238 individuals accessed the survey and 202 individuals completed it, an 85% completion rate. Seventy-five percent of the individuals who did not complete the survey were exited from the survey after responding that they were not currently employed in the clinical research field and/or were not currently working in Arizona.

Results

The majority of survey respondents were female (83.2%) and were between the ages of 41 and 60 (59.3%). Additionally, more than 90% were employed in hospitals, academic institutions, or research site settings. Most (80%) had been affiliated with the clinical research industry for five years or more.

Respondent job titles were highly disparate resulting in 22.5% of respondents providing additional job titles beyond what was provided in the survey list of options, reflecting diversity beyond semantics in the research industry's integration with many areas of health care. As examples, titles such as accountant, hospice liaison, and pharmacokinetic technician are not common clinical research titles, but reflect areas of health care where research is being conducted. For the more common clinical research job titles, most respondents identified themselves as either clinical research coordinators (17%) or directors/managers/supervisors of research (17.5%). (See Figure 1.)

Figure 1. Respondent Job Titles within the Arizona Clinical Research Workforce

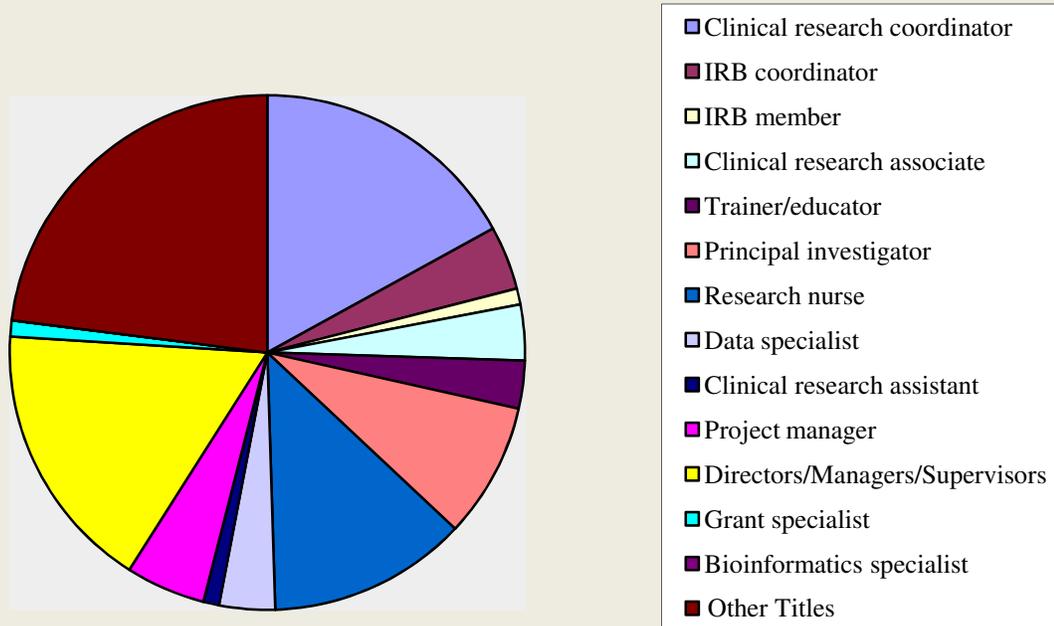


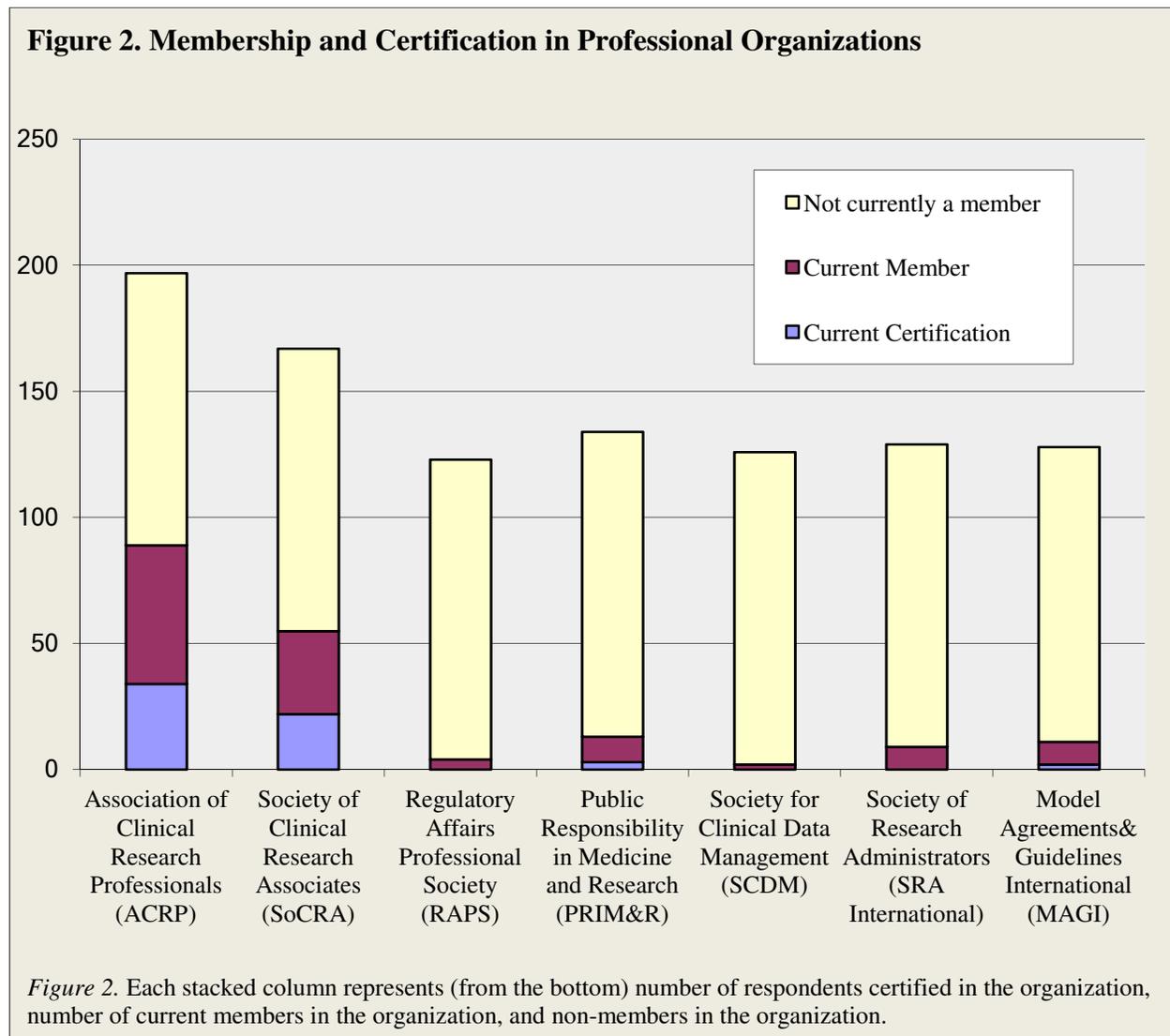
Figure 1. Pie chart illustrates the proportion and variety of respondent job titles or roles within the clinical research workforce.

The survey included representation from several professions that typically are compensated at a higher rate than other research careers. These included principal investigators, senior management, and physicians; therefore it is not surprising that many of the respondents (24.7%) reported an annual salary of greater than \$100,000. Other respondents (13.4%) reported a salary of \$50,001 – \$60,000, which is consistent with other clinical research salary surveys. As one example, *Applied Clinical Trials* reported a median annual salary for clinical research coordinators of \$51,750 (Henderson, 2012, table 2).

Training, Education, and Professional Affiliation

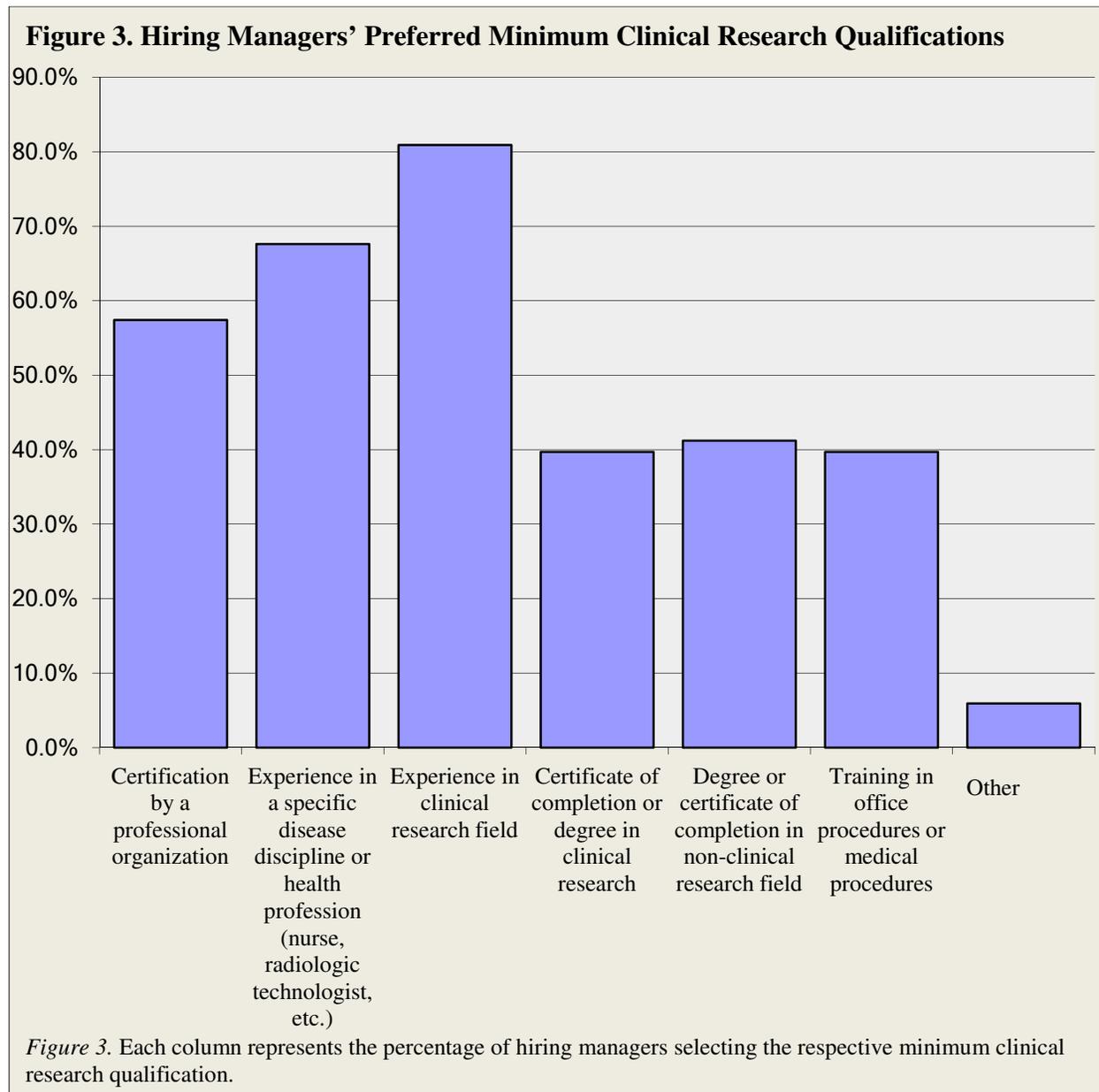
When asked for the highest degree or level of school achieved, most respondents had a bachelor’s degree or higher (78.4%) (including professional degrees) and many had a master’s degree or higher (43.2%). Thirty-two percent (32%) of respondents were registered nurses licensed in Arizona, while other respondents were licensed or certified in other professions including pharmacy (9.6%), radiography (1.8%), and other biomedical, compliance, and healthcare fields. Approximately one-third of respondents indicated that they received the majority of their clinical research training on the job and through classes that they attended on their own. Twenty-two percent (22.6%) of respondents indicated that they had completed a clinical research educational program in which they earned a Certificate of Completion or a degree in clinical research.

Professional organizations provide their members with opportunities to stay current within their profession, to determine best practices, and to gain certification. Seven clinical research professional organizations currently dominate the national and international research profession: Association of Clinical Research Professionals (ACRP); Society of Clinical Research Associates (SoCRA); Regulatory Affairs Professional Society (RAPS); Public Responsibility in Medicine and Research (PRIM&R); Society for Clinical Data Management (SCDM); Society of Research Administrators (SRA); and Model Agreements & Guidelines International (MAGI). Thirty-four percent (33.7%) of survey respondents indicated that they were current members of ACRP, and 22.4% indicated that they were current members of SoCRA. Approximately seven percent of respondents indicated that they were a member of either PRIM&R (7.6%), SRA (7%), or MAGI (7.1%). Three percent (3.3%) were a member of RAPS and 1.6% were a member of SCDM. None of the survey respondents indicated that they were certified by RAPS, SCDM, or SRA. However, respondents reported certification by ACRP (20.9%), SoCRA (15%), PRIM&R (2.3%), and MAGI (1.6%). (See Figure 2.)



Hiring Qualifications

Approximately one-third of the survey respondents indicated that they were responsible for the hiring of clinical research personnel. These respondents indicated that minimal preferred hiring qualifications for personnel included: experience in clinical research field (80.9%), experience in a specific disease discipline or health profession (67.6%), certification by a professional organization (57.4%), degree or certificate in a non-clinical research field (41.2%), training in office/medical procedures (39.7%) certificate or degree in clinical research (39.7%), or other (18.8%). Most hiring managers (41.8%) indicated that two years of clinical research experience was the most desirable attribute for potential employees. (Figure 3.)

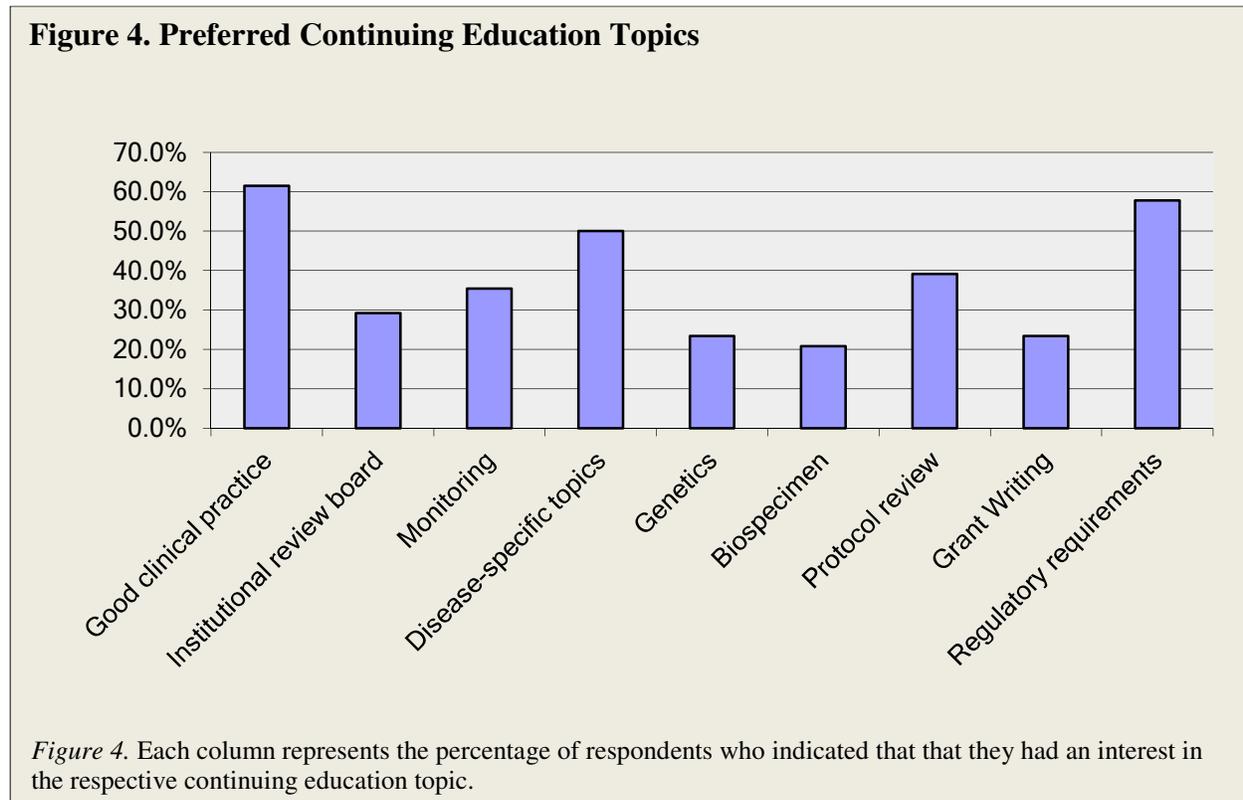


Desired Training and Education

Fifty-one percent (51%) of respondents noted that they had considered enrolling or were currently enrolled at a college or university to earn a degree to support their goals in the clinical research profession. Twenty-five percent (25%) of respondents were in the process of completing or had completed a college or university clinical research education program in which they would earn or had earned a Certificate of Completion or a degree..

The majority (57.5%) of respondents indicated that they were required to obtain continuing education to maintain their certification/licensure, or as an employment requirement. For those seeking continuing education or training not required by their employer, most (61.5%) respondents indicated that training in “good clinical practice” (GCP) was of interest. GCP is a clinical research standard of practice “for designing, conducting, recording and reporting trials that involve the participation of human subjects” and is essential knowledge to the clinical research professional (International Conference on Harmonisation [ICH], 1996, p. 2).

Other areas of training interest integral to the practice of clinical research are given in Figure 4:



Certification/Licensure

Health care careers generally begin with formal education, an internship, certification/licensure, and finally, a job. However, clinical research careers typically arise from within another healthcare profession and personnel are trained on the job. Certification is available after job experience rather than before (as in other healthcare professions such as nursing, radiologic technology, and respiratory care). Also, certification is not mandatory for practicing professionals, although many employers consider it a pre-employment qualification. Most research organizations that certify research professionals require the applicant to have one year or more of on-the-job experience prior to taking the certification examination, as seen in Table 1.

Table 1

Required Work Experience for Clinical Research Professional Certification

Organization	Certification Exam	Required Work Experience
Association of Clinical Research Professionals	Yes	At least 1500 hours of essential duties (work experience) as described in the ACRP Certification Handbook (Association of Clinical Research Professionals [ACRP], 2013, pp. 9-10)
Society of Clinical Research Associates	Yes	At least one year of full-time experience or 1750 hours of part-time work experience. (Society of Clinical Research Associates [SoCRA], 2013)
Regulatory Affairs Professionals Society	Yes	Baccalaureate degree (or equivalent) or at least 3 years of regulatory experience (Regulatory Affairs Professionals Society [RAPS], 2013, p. 5)
Public Responsibility in Medicine and Research	Yes	At least 2 years of “relevant” human research protections experience (Public Responsibility in Medicine and Research [PRIM&R], 2013, p. 3)
Society for Clinical Data Management	Yes	At least 2 years of full-time clinical data management experience (Society for Clinical Data Management [SCDM], 2013)
Society of Research Administrators	No	N/A
Model Agreements and Guidelines	Yes	None required, 2 years suggested (Model Agreements and Guidelines International)

When survey respondents were asked if they thought that clinical research professionals should undergo formalized training through a college or university program that culminated in professional licensure similar to other healthcare professions, 36.4% answered “no,” 29.8% answered “yes,” and 33.8% had “no opinion.”

Comments from the respondents were analyzed for thematic categories using a key-words-in-context analysis. Once key words were identified, the responses were systematically searched to find all instances of the word. The words and their context were sorted into categories of similar meaning. Themes from the survey responses included: scope of practice, status quo, diversity of practice, cost, quality, and level of understanding.

Respondents who answered “no” provided comments that fell within the following four categories:

- *Licensure would deter personnel from entering the field limiting nursing research and other types of research.* (scope of practice)
- *Current certification and on-the-job training are adequate for ensuring quality standards.* (status quo)
- *One college or university degree is not broad enough for the diversity of jobs and personnel in the clinical research industry.* (diversity of practice)
- *Cost of training and licensure is prohibitive.* (cost)

Comments from the respondents who answered “yes” focused on the following two categories:

- *It would raise levels of quality throughout the profession.* (quality)
- *As studies become more difficult and complicated, the level of understanding, training, and education also need to be raised.* (level of understanding)

Discussion

The purpose of this survey was to characterize the Arizona clinical research workforce and to identify possible educational gaps/needs within it. The typical survey respondent was female between the ages of 41 and 60 and employed in a hospital, academic institution, or a research site setting. More than 75% of the respondents held at least a Bachelor degree and/or had been affiliated with the clinical research industry for five years or more.

More than half of the respondents indicated that they had considered enrolling or were currently enrolled at a college or university to earn a degree to support their goals in the clinical research profession. Approximately one quarter of the respondents had completed or were in the process of completing a certificate or degree in clinical research. From the hiring perspective, it was interesting to note that hiring managers ranked experience and certification higher than a college or university degree/certificate in clinical research for both minimum and desired qualifications. This is most likely not unique to clinical research. However, most health science

professions require certification prior to practice compared to clinical research where certification is only possible after experience.

More than half of the respondents indicated that they were required to obtain continuing education through employer or professional certification requirements. The most popular continuing education topics were (in order of high to low) good clinical practice, regulatory requirements, disease-specific topics, protocol review, monitoring, institutional review board, grant writing and genetics (tied), and biospecimen collection. The two most popular topics were centered around the core of the clinical research profession that focuses on ethics, safety, and regulations within the profession.

When asked whether clinical research professionals should undergo formalized education and licensure similar to other health professions, more than one third of the respondents answered “no.” Their reasoning revolved around cost, scope of practice, protection of the status quo, and diversity of practice. Those responding “yes” indicated that formalized training would raise quality and the level of understanding for practitioners. Other than the “cost” response, both the negative and positive responses paralleled this paper’s introductory paragraphs. There appears to be a need for clinical research education to raise quality and understanding within the profession, but the diversity of the clinical research profession within other (licensed) healthcare professions challenges the scope of practice across professions. In other words, clinical research is integrated within professions such that it is very difficult to define its scope (and educational needs) without consideration of other defined professions.

Responses from the survey indicated that on the whole, both hiring managers and non-hiring respondents valued education, as evidenced by their formal education and their desires for continuing education. A formal degree in clinical research followed by licensure was not appealing to many for the reasons indicated previously. However, respondents did value the continuing support of ethical, safety, and regulatory education.

Conclusion

The survey focused on the current status of the Arizona workforce, yet provided general educational and training needs of the future clinical research profession. In order to determine specific educational gaps among clinical research personnel, distinctions in job titles and job responsibilities will be required. Although diversity is evident in bioscience positions, clearer, working definitions in a future survey would help differentiate any issues semantically in the survey results reported here. Standardization of job titles, compensation and identification in the field is one worthy goal.

Additional research is needed to identify the expectations of employers, professional organizations, and government agencies so that higher education can prepare the future clinical research workforce with resource allocations. Other issues to address in further research are the following:

(1) Are the expectations that employers will continue to cross-train workers from other professions, or will professional organizations step into the role?

(2) What is the underlying rationale for the types of education or training required by employers (i.e., ethically and safely design, conduct, record, and report trials that involve the participation of human subjects)?

(3) Is the assumption that a major educational need in the Arizona clinical research workforce is continuing education (since the survey was directed toward a working population and that the majority of responses were from a mature (aged 41-60) age group) indeed true?

(4) Do management or principal investigators have different educational needs because of their education and perspectives in finance or medicine?

Finally, because there are no comprehensive distribution lists of clinical research professionals in Arizona the survey was distributed through many sources and it is probable that many research sites and sponsors did not receive the survey. Thus the survey was not completely representative of the current Arizona workforce.

With more robust data, any specific educational gaps can be identified, and the higher education community can then ascertain their role in education and training for high-demand occupations in clinical research. The hope is that the profession will no longer be fragmented and Arizona and other states can meet their market needs.

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