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NRG Oncology Medical Physicists' Manpower Survey Quantifying Support Demands for Multi-Institutional Clinical Trials

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Abstract

Purpose: A survey was created by NRG to assess a medical physicists' percent Full Time Equivalent (FTE) contribution to multi-institutional clinical trials. A 2012 ASTRO report, 'Safety Is No Accident', quantified medical physics staffing contributions in FTE Factors for clinical departments. No quantification of FTE effort associated with clinical trials was included.

Methods: To address this lack of information, the NRG Medical Physics Subcommittee decided to obtain manpower data from the medical physics community to quantify the amount of time medical physicists spent supporting clinical trials. A survey, consisting of sixteen questions, was designed to obtain information regarding physicists' time spent supporting clinical trials. The survey was distributed to medical physicists at 1996 radiotherapy institutions included on the membership rosters of the five NCTN clinical trial groups.

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Conflicts of interest: Dr. Moran reports grants from Blue Cross Blue Shield of Michigan and Blue Care Network, grants from National Institute of Health, grants from Varian Medical Systems, outside the submitted work; and serves as Chair of AAPM Task Group 113: Physics Practice Standards for Clinical Trials.

Results: Of the 451 institutions who responded; fifty percent (226) of the respondents reported currently participating in radiotherapy trials. On average, the designated physicist at each institution spent 2.4 hours (SD: 5.5 hours) per week supervising or interacting with clinical trial staff. On average, 1.2 hours (SD: 3.1 hours), 1.8 hours (SD: 3.9 hours), and 0.6 hours (SD: 1.1 hours) per week were spent on trial patient simulations, treatment plan reviews, and maintaining a DICOM server, respectively. For all trial credentialing activities, physicists spent an average of 32 hours (SD: 57.2 hours) yearly. Reading protocols and supporting dosimetrists, clinicians, and therapists took an average of 2.1 hours (SD: 3.4 hours) per week. Physicists also attended clinical trial meetings, on average, 1.2 hours (SD: 1.9 hours) per month.

Conclusion: On average, physicist spent a non-trivial total of 9 hours per week (0.21 FTE) supporting an average of 10 active clinical trials. This time commitment indicates the complexity of radiotherapy clinical trials and should be taken into account when staffing radiotherapy institutions.

Introduction

Clinical FTE Current Practice

In clinics that choose to expand the standard scope of practice and participate in clinical trials (‘protocols’) the participation of a medical physicist is essential. The American Association of Physicists in Medicine (AAPM) Scope of Practice lists the several obligations a Qualified Medical Physicist (QMP).[1] However, while the scope of practice includes clinical trial support by inference, current personnel requirements for clinical support do not explicitly address the additional burden on the physicist beyond their typical clinical duties.[2–4]

In order to advance patient care, the medical science community conducts clinical trials. The Radiation Therapy Oncology Group alone has conducted over 460 protocols, with over 40 currently active within the RTOG Group.[5] For studies to be effective, the clinic must follow strict protocols for those patients’ treatments. Protocols utilizing radiation therapy by their nature must involve medical physicists. They ensure the clinic meets the physics requirements listed by the trial group conducting the study. Physical credentialing measurements and physics data submission are normally required before the study begins. During the study, physicists are frequently tasked with reviewing individual patient cases to ensure the protocol specifications are being met, and can be tasked with submitting patient data to the study group. Both tasks require personnel resources that are not normally provided in any characterization of routine clinical practices.

Clinical personnel resources are measured in Full Time Equivalent (FTE) units. One full-time employee (1.0 FTE) is defined as working 52 weeks per year, 5 days a week, 8 hours a day yielding 52×5×8=2,080 hours per year. Individual employers use variations of this simplified formula.

Abt 1995 Study and 2003, 2008 Updates

In 1995, Abt Associates measured Qualified Medical Physicists (QMP) workloads for the American College of Medical Physics (ACMP) and the American Association of Physicists

in Medicine (AAPM).[6] An update and analysis of the study was published in 2005: Analysis and Practical use: The Abt Study of Medical Physicist Work Values for Radiation Oncology Physics Services: Round II[7]. Additional data and a new report, Round III, were published in 2008.[8] While the updates added new special radiotherapy procedures not accounted for previously, no mention was made of workloads required to support clinical protocol patients.

The Abt studies developed a relative value work scale and measured the amount of QMP work required for medical physics services. Round III may have missed institutions that were heavily involved in trials. The Abt study excluded colleges and universities using the stated assumption that QMPs in these settings were “not involved in the day-to- day practice of providing radiation oncology physics services to typical patients”.[8]

ASTRO SINA Report

The ASTRO report titled “Safety is No Accident (SINA)” addresses staffing requirements for the radiation oncology team in the second chapter.[9] SINA quantified medical physics staffing contributions in FTE Factors for clinical departments. Detailed medical physicist duties in all aspects of radiation oncology were quantified, but clinical trials where not addressed.: Equipment Sources and Systems, Number of Patient Procedures, and Nonclinical Estimated Total FTE Efforts. SINA data relied on surveys by professional organizations. Additional personnel required for ‘research, education and administration’ is mentioned but without any specific details that might suggest clinical trial activity is included. Protocol participation may fall under their designation of ‘progressive’ clinics or research for which ASTRO acknowledges their recommended staffing requirements are insufficient. No quantification of FTE effort associated with clinical trials was included.

ESTRO/EFOMP Joint Task Group

In 1996, a joint task group in Europe consisting of ESTRO (European Society for Therapeutic Radiology and Oncology) and EFOMP (European Society for Therapeutic Radiology and Oncology) published a report on staffing levels for physics support to radiotherapy.[10] Clinical trials were singled out as a factor that should be considered in staffing requirements for medical physicists. However, no mention is made of the work force demands associated with these duties. In fact, the report emphasizes the staffing levels recommended only cover core services common to all clinics. Clinical trials are not listed.

Methods and Materials

Radiotherapy institutions (n=1996) listed as trial participants by the IROC Houston QA Center were invited to participate in the survey. A total of 451 institutions responded to the survey which was sent to the person listed with the IROC Houston database as the contact. The questions included in the survey are listed in Table 1 Questionnaires were distributed to all facilities without regard to institution size, radiotherapy equipment, beam type, etc. The only common feature was that all institutions were listed as members of one of the five National Clinical Trial Network groups. The origin of the clinical trial, i.e. government, pharmaceutical company or internal, was not distinguished in the survey.

Question Review

Questions 1–3 include identifying questions establishing the survey participants for each data set. Question 4 establishes the relevance of the clinic to this inquiry in terms of current trial participation. Many locations in the IROC Houston database do not enroll many patients in clinical trials and many have medical oncology trials open that may not require the services of a medical physicist. Each individual trial carries an associated workload of both qualifying for the trial and overseeing the active trial. Surveyors felt the number of different trials active in a clinic and the number of patients enrolled onto those trials would be strongly tied to the workload demand on the physicist thus making Question 5 crucial, since many clinics have dormant or low usage protocols.

Question 6 provides a means of testing the direct correlation between the numbers of patients on trial and the number of trial supporting staff including the physicist. Institutions sometimes provide additional help in clinical trial administration. This study does not address dosimetrists' time and effort. Question 7 assumes the physicist filling out the survey is the same one acting as the 'protocol physicist'.

Submitting patient data to clinical trial databases can be a time-consuming job. Physicists are frequently tasked with this since they are usually the most skilled of the clinical staff in handling electronic data transfers. Just how many protocol physicists have data submission roles should come out of question 8. Anecdotal evidence suggests this task elicits the greatest complaints, probably due to its repetitive and time-consuming nature.

Question 9 identifies the special effort required to image protocol patients prior to planning and treatment. Physicists are routinely required to participate in the patient simulations to ensure that protocol specifications are followed.

Perhaps the most time-consuming aspect of the physicists' duties involve treatment planning because of the detailed trial specifications and analyses required for some protocols. Some of the required data are not listed in standard plan reports and must be extracted by the physicist. Prime examples include the frequent rules associated with Dose-Volume Histogram (DVH) results and required structure naming. Question 10 is an attempt to quantify this task. The survey assumes the physicist understands this is extra time above and beyond normal plan review, which should be clarified for future surveys.

Frequently, physicists are tasked with uploading data to a clinical trial Group or QA Center. Digital submissions are the norm, and require a high level of technical skill to put in place, use, and maintain. This duty is not limited to DICOM servers, and may involve any of several systems used to upload and manage patient data submitted for protocols. Question 11 gives an assessment of the time required by the physicist to accomplish these tasks. It was assumed the physicist responding to this survey noted support time is that of physics, not IT personnel.

In order to participate in human subject protocols funded by the National Institute of Health (NIH), physicists are required to pass an online research-training course [11]. Physicists must

maintain eligibility through specified continuing education courses. Question 12 and 13 will assess how much time physicist take to meet these requirements.

Since most modern advanced technology protocols require some form of credentialing, the annual time required for credentialing is identified by question 14. Credentialing can be demanding on the physicists' time depending on the requirements of a specific protocol, as the entire simulation-plan-treat-analysis-reporting task becomes their responsibility.

Every active protocol requires a level of familiarity by the physicist and Question 15 tries to discover how much time is dedicated to understanding protocols by the physicist. Furthermore, dosimetry, therapy, and any other relevant clinical personnel must be trained by the physicist on what is expected of them when dealing with a protocol patient. For large institutions, this can be a challenge when personnel are not available on a consistent basis due to the rotational nature of clinical medicine.

Administrative tasks such as Cancer Committee meetings, clinical process meetings, case review, etc. are additional duties frequently added to the standard workflow of a physicist. These meetings alone can be disruptive to normal clinical duties. The last question is an attempt to quantify this effort by the protocol physicist.

Results

Q1,2,3: Institution name, RTF number, name of Physicist

Of the 1,996 actively participating clinical trial institutions sent the survey, 451 responded. The raw response data were presented in two spreadsheet formats to the surveyors. One format presented responses organized by question, and one presented data in a table format with clinics in rows and questions in columns. Data was extracted using native functions found in the spreadsheet program (Excel 365). Not every question received a response. Some responses were not included in the analysis due to clerical issues such as inappropriate dates or alphabetic entries where numerical answers were required.

Q4: How many clinical trials that include radiotherapy does your institution participate in?

When limiting the survey's responses to institutions participating in clinical trials that include radiotherapy, the number of institution responses decreased from 451 to 226. An average clinic participates in nine trials (STDP = 12) with the total number of trials summing to 1,996. Thirty-four clinics reported no active radiotherapy trials at their institution.

Q5: How many patients have been enrolled in the above trials?

On average, clinics enrolled 32 patients (STDP 76) onto their trials (7,216 total). Note the large number of 'zero' patients reported for potentially open trials at institutions. The data from Question 4 indicated that 34 institutions did not have any open radiotherapy trials, and the data from Question 5 showed 50 clinics had trials open but no patients.

Since patients in a protocol may be at any point in that protocol, it is desirable to include the total number of patients that have participated, finished or not. However, when a protocol ends how are those patients counted? The question of when to count patients becomes highly convoluted and thus only addressed in one question. Detailed studies need to be carried out by a researcher with time and resources to adequately describe the patient population status in protocol participation. This survey is bringing to light just how difficult and important this issue becomes when one starts to look closely into these questions. Hopefully, an institute will take on this challenge. However, our final figure showing an average of 9hrs/protocol/week is not dependent on this issue.

Q6: How many dedicated clinical trial staff does your department or institution have?

In retrospect, the wording of Question 6 may have been unclear regarding the definition of a 'dedicated clinical trial staff' person. As one responder noted, "Our Cancer Center has a Clinical Trials Office, and our department has no assigned clinical trials support." Indeed, one institution reported 40 personnel, implying either a huge institution or they were counting every clinical employee as a protocol worker. However, what one can derive from these results is that a majority of reporting institutions rarely have dedicated clinical trial staff (37.6%). 23.5% report having one dedicated staff member for clinical trials, 15.5% report having two staff members, and 23.5% report having more.

Q7: How many hours per week do you spend supervising or interacting with the clinical trial staff?

A total of 137 physicists reported spending at least one or less hours per week supervising or interacting with other staff involved with clinical trials (Figure 1). Three physicists claim to be employed full time (40 hours/week) in only working with clinical trial staff. Retrospectively, this question should have been phrased more clearly by asking how many hours per week are spent in clinical trial activities. Assuming the question was interpreted as intended, the average physicist spends, on average, 2.4 hours per week supervising clinical trials.

Q8: Who performs the electronic data submission for each protocol patient?

The data from Question 8 (Table 2.) indicate that a majority of the data submissions are performed by the physicist (52.6%).

Q9: On average, how many hours per week do you get involved in the simulation process for protocol patients?

The Figure 1 bottom graph shows the hours per week physicist spend involved with simulations. The vast majority (79%) of the responses to Question 9 indicated that physicists spent ≤ 1 hour per week dedicated to this effort.

Q10: On average, how many hours per week do you spend reviewing treatment plans for protocol patients?

From the responses to Question 10, physicists spend nearly two hours per week (average=1.8 hr.) reviewing charts for protocol patients (Figure 2).

Q11: On average, how many hours per week do you spend maintaining your DICOM server?

Respondents reporting time spent maintaining servers (110 total) spent just under an hour per week (average time 0.6 hours ± 1.1 hr. (std. dev)). The other half of the respondents (108 total) reported spending no time maintaining servers.

Q12: Are you credentialed in the Continuing Research Education Credit Program (CREC)?

Due to the small number of responses to this question, it was omitted from this study.

Q13: If yes, how many hours per year are required of you to become credentialed and maintain the CREC?

Due to the small number of responses to this question, it was omitted from this study.

Q14: How many hours per year do you or your physics group spend for Protocol credentialing process?

Institutions have a wide range of protocols open or in the process of opening, so the amount of time spent by physicists on credentialing varied greatly. The average respondent spends 32 hours per year maintaining their or the institution's credentials for protocols with a standard deviation of 57. The involvement and committed effort for the credentialing processes are highly dependent on which protocols were open at each institution.

Q15: On average, how many hours per week do you spend reading clinical trial protocols and supporting dosimetrists/clinicians/therapists?

The required effort to read clinical trial protocols and support dosimetrists/clinicians/therapists for each trial patient that fall on the protocol physicist are rarely addressed (see Figure 2, bottom). Physicians and administration should acknowledge accounting for these additional workloads. On average, 2.1 hours (STD=3.4 hr.) were spent reading and supporting staff.

Q16: On average, how many hours per month do you spend attending clinical research meetings in your department/institution?

Almost half of the 226 responders do not attend clinical research meetings, but on average, the remaining half of the responders spend approximately 0.3 hours each week attending these meetings (Figure 3).. It was assumed that the majority of these clinical research meetings focus on clinical trials, but the actual content of the meetings was not requested from the respondents.

Discussion

Generally, the findings from this survey should be no surprise to physicists currently tasked with providing clinical trial support. With an average of 32 patients per site and 38% of the respondents with no dedicated clinical trial support staff, the demand on physicist time can be substantial at an average of 9 hours per week for every 10 protocols supported.

We did not differentiate therapy types (photon, proton, particle, etc.) with the questionnaire. The limited number of proton and particle facilities would require further investigation in order to provide meaningful data.

When designing the survey, including all physicists vs. the contact physicist at each institution was discussed. It was decided to go with including only the contact physicist in the survey to avoid possible multiple claims for one credentialing/involvement by multiple physicists within an institution. It is possible the contact physicist included other physicists' time since the physicist knew the purpose of this survey.

While radiotherapy credentialing may require effort, it also has an important secondary benefit of providing an independent external peer review of the department. Such peer review, benefits all patients treated at the institution rather than only the protocol patients.

Conclusion

This report by the NRG Medical Physics Subcommittee quantifies an overlooked aspect of clinical operations, i.e., medical physics support for clinical trials. It is worthwhile to consider the variation of support models where some duties are shared among other staff, such as dosimetrists, and some clinics where the support work is mainly performed by physicists.

These data will be used as a baseline for comparative evaluation by YYY and XXX for clinical trial quality assurance burden as well.

Acknowledgments

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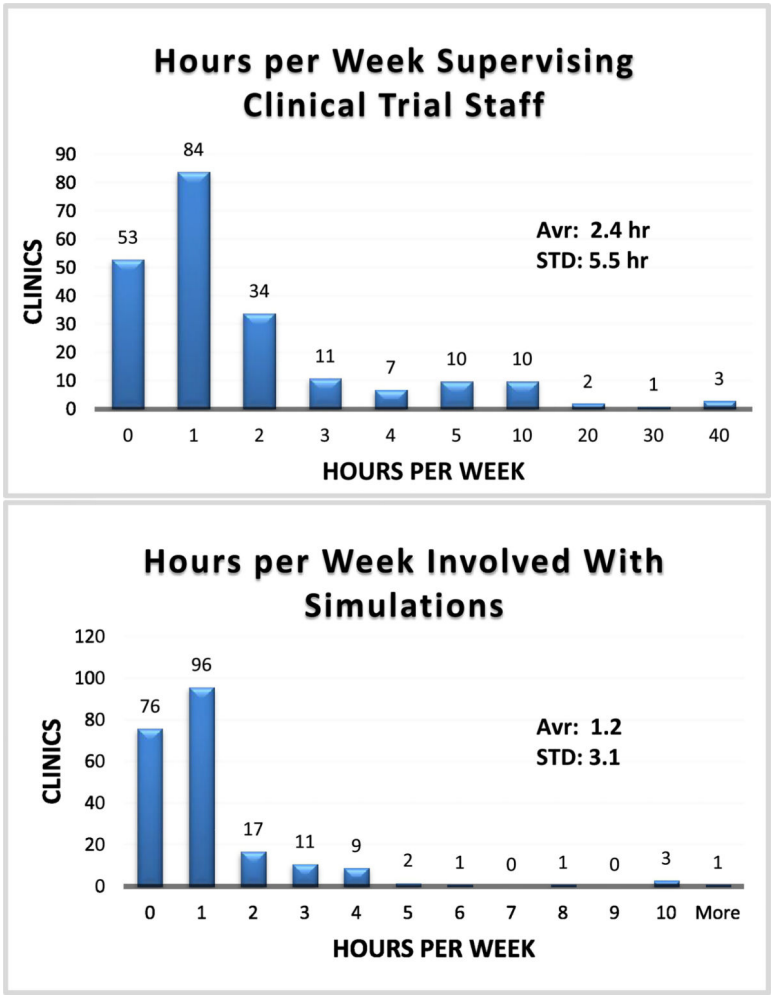

Figure 1.

Top: Question #7 data showing the distribution of supervision hours spent by the protocol physicist. Bottom: Question #9 data showing the hours per week spent by the trial physicist during the simulation process for protocol patients.

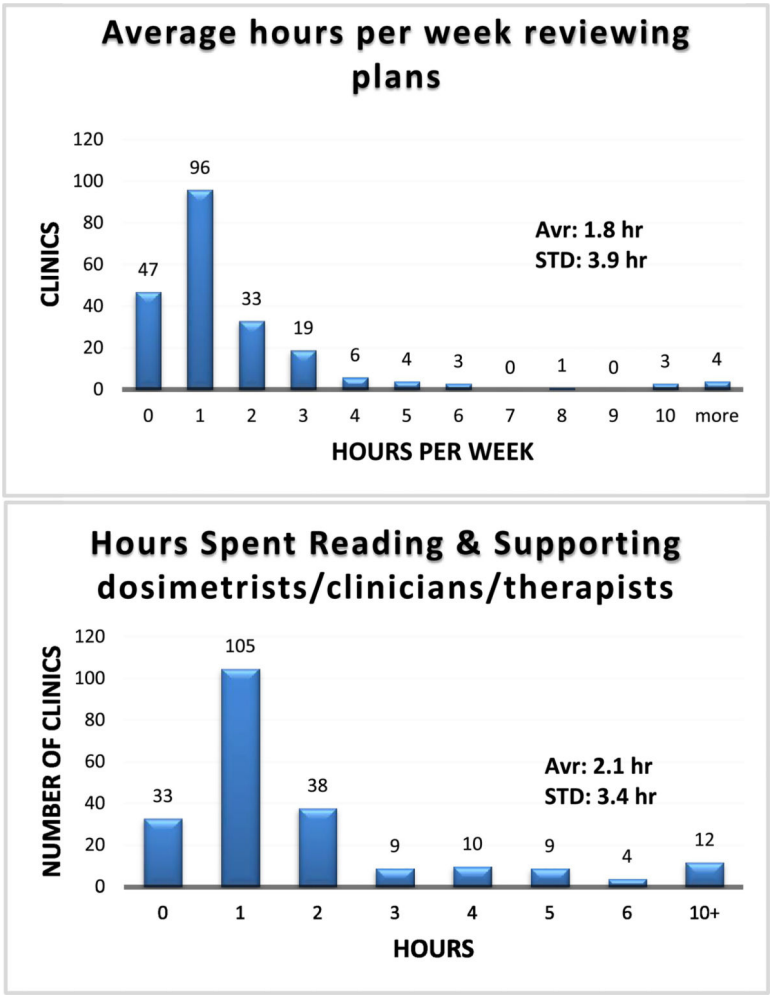

Figure 2.

Top (Question #10): Frequency graph of data describing the hours per week spent by protocol physicist reviewing treatment plans. Bottom (Question #15): Data showing physicists assistance for protocols in the form of support research.

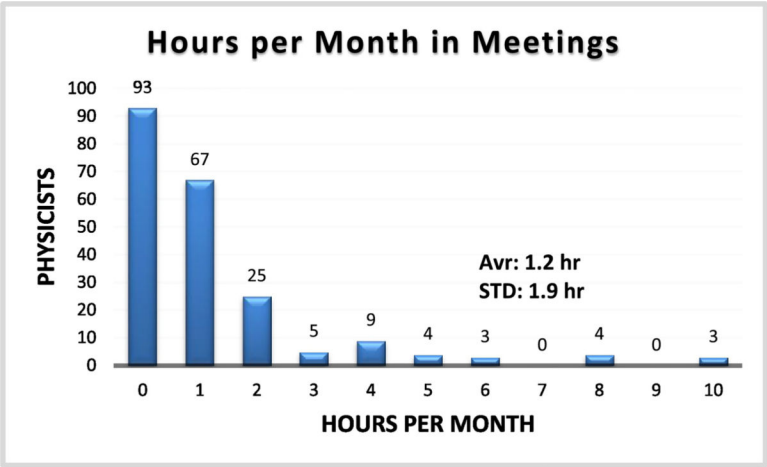

Figure 3.
Data showing how much time is spent each month attending clinical research meetings.

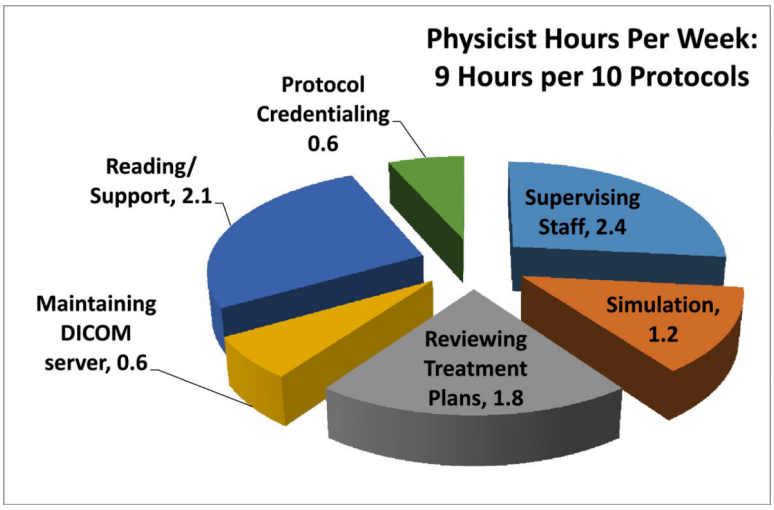

Figure 4.

Summary of averaged physicist hours per week supporting an average of 10 Clinical Protocols.

Table 1.

Survey Questions

#	Question
1,2,3	Institution name, RTF number, name of Physicist.
4	How many clinical trials that include radiotherapy does your institution participate in?
5	How many patients have been enrolled in the above trials?
6	How many dedicated clinical trial staff does your department or institutions have?
7	How many hours per week do you spend supervising or interacting with the clinical trial staff?
8	Who performs the electronic data submission for each protocol patient?
9	On average, how many hours per week do you get involved in the simulation process for protocol patients?
10	On average, how many hours per week do you spend reviewing treatment plans for protocol patients?
11	On average, how many hours per week do you spend maintaining your DICOM server?
12	Are you credentialed in the Continuing Research Education Credit Program (CREC)?
13	If yes, how many hours per year are required of you to become credentialed and maintain the CREC?
14	How many hours per year do you or your physics group spend for Protocol credentialing process?
15	On average, how many hours per week do you spend reading clinical trial protocols and supporting dosimetrists/clinicians/therapists?
16	On average, how many hours per month do you spend attending clinical research meetings in your department/institution?

Table 2.

Responses to Question #8.

Q8. Who performs the electronic data submission for each protocol patient? (check all that apply)		
Answer Options	**Response Percent**	**Response Count**
Dosimetrist	24.2%	79
Clinical study staff	17.8%	55
Physicist	52.6%	172
Other (please specify)	6.4%	21