

CLINICAL TRIALS-RELATED ADMINISTRATIVE WORKLOAD

Clinical Trials-Related Administrative Workload and the Methods Used to Assess It

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Abstract

The 2012 Faculty Research Survey Research Report conducted by the Federal Demonstration Partnership (Survey) found that clinical trials were one of the 22 most common administrative workload burden activity areas. This Project was launched from that finding and makes the case for a greater recognition of clinical trials as a clinical research subspecialty impacted by clinical trials-related workload problems. The clinical trials findings from the Survey were compared to available measurement tools on workload and clinical trials to determine whether the same and/or other workload administrative variables would be found. The researcher found that each measurement tool contained some of the variables that had been identified in the Survey. Those variables that were identified in the Survey and other measurement tools included: 1) Difficulty negotiating acceptable protocol; 2) Redundancy in reporting data; 3) Concerns about informed consent; 4) Working with boards such as the Institutional Review Board for the Protection of Human Subjects (IRB); 5) The requirement to post and update trials results; 6) The requirement to post and update trials progress; and 7) The degree of coordination required in managing clinical trials. Yet there were variables in the measurement tools that were not found in the Survey. For example, a single module in one of the measurement tools covered distinct workload activities pertaining to informed consent that included: more information on face to face contacts with patients and more telephone contacts to clarify trial participation, and also documented continuous psychological support to the subjects. None of the measurement tools captured the frustrations in the Survey that salaries were not keeping pace with the cost of living, and reporting requirements were not being uniformly enforced. In conclusion, the measurement tools other than the Survey were designed specifically to measure clinical trials workload and included

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an analysis that intentionally focused on multifaceted dimensions of workload. This focus specifically on clinical trials resulted in a more comprehensive examination of clinical trials workload. In an analysis of other measurement tools compared to the survey results, the researcher uncovered numerous areas that had not been addressed by the Survey. Furthermore, the measurement tools were not only designed to measure the workload burdens of the principal investigator, but those of the team who worked in clinical trials, thus allowing for a more comprehensive understanding of workload and administrative workload. The findings support the need identified by the Project.

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Introduction

There is consensus in the literature that administrative workload negatively impacts the amount of time scientists put into their scientific work and in the process of time their scientific achievements. Intentional efforts were initiated by the Federal Government to understand and address the problem such as the reports on the 2005 and 2012 Faculty Workload Surveys (hereinafter 2005 or 2012 Survey) conducted by the Federal Demonstration Partnership (FDP), (Schneider, Ness, Rockwell, Shaver, & Brutkiewicz, 2014) and the 2014 report on Reducing Investigators' Administrative Workload for Federally Funded Research (Board, 2014) (hereinafter NSF Board). The 2012 Survey found that clinical trials were one of the 22 most common Administrative Workload Types (i.e., administrative workload burden activity areas). This Survey garnered wide attention from the popular media, numerous professional associations, academia and continued Congressional interest. The connection of the FDP's report to Congress and implications regarding Congressional funding (taxpayers' money) put administrative workload in the spotlight. This reason alone would catapult any problem into a great societal concern. However, clinical trials have not been presented as a clinical research subspecialty impacted by clinical trials-related administrative workload problems.

(Sedwick, 2014) in her address to the U.S. House was asked to testify before Joint Subcommittees of the U.S. House of Representatives on the two Faculty Workload Surveys conducted by the Federal Demonstration Partnership in 2005 and 2012 (Sedwick, 2014). These Surveys assessed the impact of administrative workload in relation to federal regulations and requirements, on principal investigators' (PIs) with federally-funded projects. On both occasions, the researchers found that 42% of faculty workload allocated research time for conducting

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research was spent on duties related to administering the grant, such as proposal preparation, writing and evaluation (Sedwick, 2014).

The study by Sedwick, (2014) indicated that 32 percent of participants (N= 13,453) were from the biological and biomedical sciences, 16% from the physical sciences and mathematics, 14% from engineering and computer sciences, 12% from the behavior and social sciences, and 10 % from the clinical sciences and medicine. PIs spent 42% of faculty allocated research time for conducting research on duties related to administering the grant, such as managing regulatory requirements (Schneider et al., 2014). The 42% of their time was spent on tasks relevant to the following five areas: preparing proposals 15.4%, preparing reports 7.6%, pre-award administration 5.7%, post-award administration 13.6%. While time spent on actually conducting research was reported as 57.7% (Schneider et al, 2014). Within a one-year period, ten percent of participants reported clinical trials as their administrative workload responsibility. More than 50% of participants with responsibilities for running clinical trials reported that these responsibilities took up a substantial amount of their time (Schneider et al., 2014). Sixty-four percent (64%) of participants with clinical trials as the burdensome activity reported that these responsibilities consumed a substantial amount of their clinical research time (N=880). These statistics seem to make it plausible that clinical trials which were presented as one of the administrative burden responsibility areas were substantive enough to be studied as a clinical research subspecialty impacted by clinical trials-related administrative workload problems.

Schneider et al. (2014) indicated that substantial time was taken away from conducting science to work on, “Posting and updating trial progress to meet federal requirements;” “Completing training regarding federal requirements for clinical trials,” and “Posting and

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updating trials results to meet federal requirements” (p.56). Each of these responsibilities consisted of percentages in the 40’s. The 2012 Survey also included a qualitative research analysis on three frustration content themes for clinical trials, as it did for the other 22 administrative burden responsibility areas (Schneider et al., 2014). Frustration areas were “Challenges from dealing with multiple organizations;” “Problems related to Clinicaltrials.gov;” and “Lack of budget Flexibility.” (Schneider, et al, 2014). It seems worthwhile for this Project to unearth or highlight any further knowledge on problems associated with administrative workload with clinical trials.

The National Research Council (hereinafter Council) was asked to provide Congress with the top ten actions that should be taken for U.S. universities to remain competitive in the 21st century. In its reply to Congress the Council acknowledged that research productivity was slowed down because of regulatory workload burdens (Council, 2009). Administrative workload, therefore, has been an important problem that has authoritative support. In 2013, there was another government initiated study on administrative workload by the statutory Board of the National Science Foundation. They sent out a request for information (RFI) targeting principal investigators (PIs) “to identify which Federal agencies and institutions’ requirements contributed most to their administrative workload,” (Board, 2014, p.1). A series of roundtable discussions with faculty and administrators were also conducted. The goal was to make recommendations to address the Federal agency and Federal agency requirements that were most troubling and slowing down PIs’ ability to spend more time conducting science. Their results did not include an explicit section on clinical trials or clinical trials-related workload. However, the NSF Board reminded readers that it had a duty to ensure that taxpayers’ money was well spent and that

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research was conducted responsibly (Board, 2014). Finances would be one of the reasons readers would be interested in the Project's workload problem.

Defining Clinical Trials: Subspecialty and Workload Impact

There are many ways to describe clinical trials and their very description gave rise to the need for their recognition as suggested in this Project. They are a type of clinical research study (Medicine U. V., 2016) that cover a spectrum of biomedical and biotechnological trials. "Clinical trials are the furthest progression from the basic research lab... scientists apply their discoveries to humans, testing new drugs, devices, or innovative therapies in selected patients" (Center C. U., 2015, p. 2). They are "the way the medical field tests whether a new therapeutic product performs as expected and actually makes a difference in treating disease" (English, Lebovitz, & Griffin, 2010, p.ix).

Clinical trials are also "experiments designed to answer questions about possible new treatments or new ways of using existing (known) treatments" (Medicine U. V., 2016). "There are different types of clinical trials: "treatment, prevention, diagnostic, screening, and quality of life trials" (Center C. U., 2015, p. 2). The trials are conducted in phases, with each phase having a different purpose and answering a different research question (Administration U. F., 2016). When describing them in phases, they are experimental drugs or treatment that are tested in groups in Phases I-IV. In Phase I, small groups of people are tested for safety, dosage, range, and side effects (Center C. U., 2015, p. 4); In larger groups in Phase II trials are tested for effectiveness and further safety checks; In large groups in Phase III effectiveness is determined and side effects are evaluated and documentation occurs on how the trial compares with other treatment drugs. In Phase IV the treatment has approval from the Food and Drug Administration

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(FDA) and post-marketing studies provide more information about “risks, benefits, and optimal use” (Center C. U., 2015, p. 4). When the clinical trial has shown its potential worth as a treatment, the Food and Drug Administration (FDA) approves it to be used in medical treatment (Center, 2015). The term, experiments and phases, and the many different dimensions of clinical trials set them apart from the 22 other administrative burden responsibility areas in the 2012 Survey. Each of these topical points represent the breadth of clinical trials and add support to the Project’s call for their greater recognition.

Viewing clinical trials from another angle, the Food and Drug Administration created a separate set of guidelines for clinical trials (Administration U. S., 2015). Good (2014) noted that there are many challenges to be addressed in conducting clinical trials. Other authors focused on the negotiating of trial agreements stating that “agreements covering clinical trials must be carefully crafted” (Leibowitz & Sheckler, 2006, p.441). Workload metrics were also developed to measure clinical trials specifically in the area of cancer clinical trials. Greater recognition of these administrative burdens would go a long way in the ongoing intentional efforts to curb workload burdens but specifically for PIs, the clinical trials team, inclusive of research administrators who work in clinical trials.

Using Workload Measuring Tools in this Project

Since 2002, the Clinical Research Associates Committee of the National Cancer Institute of Canada Clinical Trials Group pointed out that measurement tools in other disciplines were inadequate for measuring clinical trials’ tasks, time, and effect (Roche et al., 2002, p. 546). They commented that pressure was being placed on the accountability of clinical trials activities, but

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no standards existed to measure time as a factor in clinical trials. They stated that “extra costs incurred in clinical trials [were] those of clinical research associates (CRAs), the individuals responsible for the management and administration of the study as well as data collection effort” (Ibid p. 545). They developed a Data Collection Form (measurement instrument) that measured four stages of trials activity and task categories, and used it to conduct clinical-trials related workload research. Their measurement led to the finding that the sponsor and the phases were effective in “determining clinical trials costs and resource use” (Ibid p. 545). Their work was regularly referenced in the literature which acknowledges the importance of understanding and assessing administrative workload. This Project brings together existing scholarship in the form of utilizing available measurement tools on workload and 2012 Survey results on clinical trials comparatively.

The Project and Addressing the Problem

There is a need for a greater recognition of clinical trials as a clinical research subspecialty impacted by clinical trials-related administrative workload problems, and for the integration of known knowledge on how administrative workload is measured. Briggs (2008) in commenting on her findings on workload research she conducted, recommended that “future work needed to link to and compliment other work being undertaken” (p. 23). Sedwick (2014) in an FDP 2014 hearing in the House of Representatives informed that “different types of research are subject to different types of administrative workload, suggesting that solutions may not be the same in all cases” (Sedwick, 2014, p.7). Further, she advised of a need for large scale solutions, inclusive of clinical trials.

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Since clinical trials were not a subspecialty in the 2012 Survey, this Project compares and contrasts the specific results section of this Survey to available clinical trials workload measurement tools, to explore whether Survey findings and other administrative workload variables (negative or positive) were identified in these measures. It was decided beforehand that if their findings and other workload variables were found in validated measures they would support the need for greater recognition of clinical trials as a clinical research subspecialty impacted by clinical trials-related administrative workload problems. New found variables would be indicators that clinical trials as an administrative workload burden activity, are limited in capturing their multilayered levels and dimensions. These findings are expected to complement current literature and to be helpful to advisory panels such as FDP in making decisions about clinical trials. Greater recognition for clinical trials subspecialty should make room for discussions in federally initiated studies on the role of other professionals who work with clinical trials such as research administrators.

Application of the Problem to Research Administration

The problem has implications for research administration (RA). Clinical trials offices have become common place in “the academic health center research infrastructure to consolidate administrative activities related to clinical trials” (Rubin & Lazar, 2009, p. 1). There were 213,639 clinical trials studies” with locations in all 50 states and in 193 countries” (Clinicaltrials.gov, 2016). Some research administrators work in universities with as many as 12 different clinical trials units, including one in the School of Medicine, (Medicine J. H., 2016). The greater recognition that the Project seeks would spotlight the work of research administrators, because the burden on the clinical research team along with the PI could become

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the focus of federal initiatives on clinical trials-related administrative workload. Research administrators' professional duties are tied into those of researchers with whom they work.

The responsibilities and duties of RAs span the disease areas of all clinical trials research. Duties and responsibilities connected to an office of sponsored projects such as pre and post award, the office of research compliance, and the grants accounting department at a minimum also spread across these disease areas in research. McDowell (2014) advised that "It is the role of research administration to understand the administrative infrastructure that supports and is part of the research enterprise and to administer that infrastructure." Rubin & Lazar (2009) commented that numerous regulatory requirements affected how these centers operate before, during, and after a clinical trial takes place. Clinical trials, those connected to their operations, and the workload problems associated with clinical trials, including RAs, are part to this same infrastructure.

The role of research administrators is entangled with those of PIs and their clinical studies in terms of fulfilling different regulatory and university requirements. RAs are bearers of information of laws, regulations, and policies which are enforced in the pre and post grants administration processes. RAs are responsible for adherence to FDA's regulations related to Good Clinical Practice and Clinical Trials. RAs report on alleged misconduct in science. Misconduct has different procedural connotations for clinical trials. RAs work in the specific area of budgets and finance, as (Benson & Levine, 2015) clearly demonstrated in their power point presentation. This Project, therefore, has numerous applications for RAs, and in particular those who work in clinical trials.

Literature Review

Why the Two Major Reports Not Compared in this Project

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The NSF Board expressed that “many of the issues raised have been highlighted in previous surveys and reports for more than a decade” (Board, 2014). Queries in the NSF Board’s request for information (RFI) survey were based largely on the 2012 Survey. Some questions were prefaced with these words “Principal investigators responding to the FDP’s 2012 Faculty Workload Survey identified the following sources of administrative work ...” (p.28) and proceeded to list seven of the burden activity areas of the 2012 Survey. Their responses echoed the list from the 2012 Survey results and their recommendations were comprehensive and surpassed those of the 2012 Survey.

The same question also asked if the burdensome requirement produced for them an increasingly significant amount of administrative work (Board, 2014); to specify whether the source of the extra work was from the requirement, their institution or another source (Board, 2014); and for their recommendations to help reduce the level of work (Board, 2014). Another reason was that while the NSF Board gave rich qualitative findings on the “top burdens from the RFI,” regarding “perceived source of burden” “agency specific issues,” (Board, 2014, p32), (an invaluable policy contribution), clinical trials or clinical trials-related administrative workload, the focus of this Project were not a part of its scope. Since the Board comparatively expanded on the 2012 Survey, this Project does not seek to reinvent the wheel by comparing the two government initiated reports. It can be said that the report by the NSF Board supports the existence of the problem identified by the Project.

Administrative Workload vs. Workload

For both the 2012 Survey and the NSF Board, administrative workload referred to the types of responsibilities of funded research performed by PIs that encroached upon their time to conduct science. In the 2012 Survey, administrative workload referred to the time PIs with

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federally funded research spent on activities related to pre-award proposal preparation such as writing and budget preparation; Post-award administration such as applying for approvals; Other post-award activities such as supervising budgets and personnel; and preparing post-award reports such as progress and final stage reporting (Schneider et al., 2014). Workload was also presented in terms of responsibilities associated with a particular administrative workload burden activity area or areas. Administrative burden responsibility areas were as follows: “Financial management (Non ARRA), Personnel, Effort Reporting, “COI, RCR, General Lab Safety/Security, Data Sharing, Subcontracts, IRB, Chemical Safety, Intellectual Property, Biosafety, HIPPA, ARRA, IACUC, Recombinant DNA, Radiation Safety, Cross-Agency Differences, Export Controls, Control Substances/Narcotics, Clinical Trials, Select Agents, and (PCII for DHS)” (p. 41).

The NSF Board used the term burden in place of administrative workload problems and explicitly described burden “as excessive regulations and requirements that slow the pace of research and do not improve either scientific or regulatory outcomes” (Board, 2014, p.6). Seven of the burden areas found in the 2012 Survey were also similar to the findings of the NSF Board, and these were “Finances; Personnel management; Effort reporting; Conflict of interest; Lab/safety security; Data sharing, and subcontracts” (p.28). Therefore, the regulations were the burden and the activities revealed the symptoms.

The clinical trials-related workload measurement tools used in this Project were independent of the focus of the two federally initiated reports. Smuck et al., (2011), part of the Clinical Trials Network (CTN), a group comprised of the Ontario Institute for Cancer Research (OICR) and the Ontario Cancer Research sites defined and developed a pyramid-shaped workload complexity rating scale called the Ontario Protocol Assessment Level (OPAL). They

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presented workload in terms of standard core routine tasks, and incremental procedures that were unique to each clinical trial. Core tasks “included protocol review; Informed consent form review; Research ethics board submission during the active study; Ongoing protocol administration; Sponsor-related safety reporting; and Query completion during follow-up” (p.81). Incremental procedures unique to each trial or the complexity triggers included: “pre-study site visit, investigator meeting, equipment needs (e.g., storage or computer checks during activation; review of pathology, biomarker studies, radiology, and patient diaries during the active study; and additional assessment of quality of life or length of follow-up during follow-up” (p.81). Workload pertained to the tasks, how long it took, and its complexity.

Berridge & Coffey (2008) in presenting their workload measurement in Canada with the European Organization for Research and Treatment of Cancer (EORTC), defined workload as “the measurement of the length of time it takes to complete a series of tasks and how frequently they are performed in order to objectively determine staffing requirements for this series of staff” (p. 98). Good, Lubejko, Humphries, and Medders (2013) as part of the Wichita Community Clinical Oncology Program (WCCOP) developed and implemented the WCCOP Protocol Acuity Tool (WPAT). They presented workload as determined by the “complexity of treatment, trial specific laboratory, testing requirements, treatment toxicity potential, complexity and number of data forms required, degree of coordination required (i.e., involvement of ancillary departments, outside offices/sites, and/or disciplines); and number of trial random assignments or step (p.211). The measures, therefore, did not vary in their view that tasks, procedures and complexity were critical to an understanding of workload for clinical trials.

Workload needs to be defined within matrices and according to organization types and settings. This would allow placing concepts from different dimensions of workload into a

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multiplicity of slots within complicated organizational structures. The 2012 Survey looked at PIs workload within the context of organizations that were federally funded, and reported on fields of study, Carnegie classifications, whether or not the university had a School of Medicine, whether funding was received from the National Institutes of Health (NIH) or NSF, and the level of funding and the number of grants/contracts held. Each one of these factors make it the more relevant to note that PIs work within structures that define workload and administrative workload in particular ways. There are different methods of categorizing workload across universities, industry, and states. All of the descriptions of workload in this Project are valid within specific organizational contexts.

Background and Description of Workload Measurement Tools

The 2012 Survey provided results for the administrative workload burden activity area clinical trials, but corresponding questions were not provided and could not be located. Instead, only the responses were given. Further description on the 2012 Survey is provided in the measurement section where it is compared with the measurement tools.

Briggs (2008) advised that the “measurement of workload is a complex multifaceted area and an important but difficult subject” (Briggs, 2008, p.22). Briggs shared that ‘patient group’ was recently added to the variables usually used to measure trials complexity. Briggs commented on the existence of only one known comprehensive study that was developing a workload measurement and it was at EORTC. Briggs developed a Complexity Scoring Tool to assess “problems and requirements related to clinical research management at a cancer center center within a clinical trials unit in the UK” (p.23). It scored complexity in five areas horizontally. The entire first vertical column was labelled “Category/ Section” and was constructed with three labels “Section 1 Set up,” “Section 2 Recruitment,” and “Section 3 Follow-up.” The

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Category/Sections were the rows and they were labeled categories 1-5. Each section had five categories respectively that started by measuring fewer duties and gradually increasing in responsibilities at category 5. An example from Section 2 Recruitment and its Category 1 was “1 or 2 contacts required, e.g., “single blood sample, no treatment.” (p. 23). Its Section 2 Recruitment Category 5 was “trial coordinated from department either local in total or in partnership with company Novel 1V agent” (p.23). Briggs (2008) recommended that future work needed “to link and complement other work being undertaken” (p.23). Briggs reported on the results of the testing of the tool with “volunteers throughout the U.K. who were asked to review validity, reliability, and repeatability by undertaking three different exercises” (Briggs, 2008, p. 23). Briggs later co-authored with Lyddiardc, Briggs, Berridge, and Coffey (2010) in the four EORTC Modules the Workload Measurement Instrument (WMI).

Berridge and Coffey (2008) reported on the progress of testing their Workload Measurement Instrument that was in its sixth of seven stages of its development at EORTC. By 2008, their efforts resulted in the WMI which broke new ground. It was comprised of four separate Modules that facilitated indentifying main and subtasks, time, and resources for clinical trials, instead of the long-standing main tasks only and single events (Berridge & Coffey, 2008). Each module was developed with a separate purpose in the WMI. The recommendation by Roche et al., (2002) that new workload measurement tools should be developed with more specificity on tasks, and subtasks influenced the development of their modules for the WMI tool (Berridge & Coffey, 2008).

Module 1: “The Planning Stage,” dealt with the four subheadings 1) “Protocol evaluation and preparation of submissions” (For example, “Reading the Protocol,” and “Preparation of trial document and submission to Research and Development Department).” 2) “Meetings and

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Training.” 3) “Financial Agreements/Clinical Trials Agreement (CTA)”. and 4) “Administration and IT preparation.” “Module 2: “The Implementation Stage” focused on the subheadings 1) “Identify potential trials subjects and screen for eligibility.” (For example, “Document eligibility/noneligibility in screening log, notes and database,” and “Contact trial center/chief investigator to check eligibility).” 2) “Informed consent procedures.” 3) “Randomization/registration.” 4) “Subject Care.” “Module 3: “Trial Data Management” focused on the subheadings 1) “Monitoring/audit visits,” and 2) “Protocol Amendments,” (For example, “Participate in external/internal auditing and audit visit,” and “Resolve queries postmonitoring and postaudit visit).” 3) “Financial management.” “Module 4: The Closure/final Stage” focused on the single subheading “Procedures for the closure of the study.” (For example, “Inform the national authorities,” and “Organize drug return and drug destruction)” (p.100).

Lyddiardc et al. (2010) and Coffey, Berridge, Lyddiard, and Briggs (2011) reported on the same research and findings, so this was a duplication. The latter had the stamp of being peer reviewed. They advised that the first six stages of the modules’ development, piloting, and revisions “of a draft checklist of trial related activities, drafting of the WMI, a feasibility study, and analysis and revision of the trial related tasks incorporated into the four modules previously outlined in an Applied Clinical Trials article that appeared in June 2008” (Coffey et al., 2011). They shared that at the same time they were developing the WMI, Briggs, (2008) developed the Complexity Scoring Tool and through collaboration they agreed that “in the longer term, a joint workload and complexity project would aim to independently validate and link together the Workload Measurement Instrument (WMI) and the complexity tools” (Lyddiardc, et al., (2010); and (Coffey et al, (2011). Both authors did not provide the final WMI. They stated that “Modules

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1, 2, and 3 of the WMI [were] validated and completed” (Lyddiardc et al. 2010, p.4; and Coffey et al., 2011, p.40).

Lyddiardc et al., (2010) advised that the WMI was available from authors. Both expressed that they piloted the four modules for six months to test their validity, and 414 measurement tools were completed and returned. They informed that “workload was only recorded for research staff working on the trials and excluded Principal Investigators, pharmacists and daycare staff, etc.” (Lyddiardc et al., 2010); and (Coffey et al., 2011). They found that in the module “the section ‘other’ consistently included administration and communication main tasks and subtasks activities. Based on their findings, minor changes were made to each of the Modules.

The Clinical Trials Network (CTN), a group comprised of the Ontario Institute for Cancer Research (OICR) and the Ontario Cancer Research sites defined and developed a pyramid-shaped workload complexity rating scale called the Ontario Protocol Assessment Level (OPAL), to evaluate workload for their sites (Smuck et al., 2011). They shared that the literature search confirmed “a gap for capturing workload complexity in clinical research confirming the issues identified by their CTN members” (p.80). The literature did not cover the many dimensions of conducting clinical trials even though there had been increased protocols requirements and resulting increased workload (Smuck et al., 2011). OPAL was tested for validity and reliability via a three-month pilot study (Smuck et al., 2011). In a pre-study decision, a variance of 1.5 was deemed proof of success as a measurement tool (Smuck et al., 2011). They found that differences in the score for this measurement ranged from 0 – 1.5. The OPAL score [was] determined by the type of intervention being studied and the number of

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incremental procedures included.” They also found that “The assigned OPAL score represents the protocol workload for the administrative component of managing a protocol” (p.81).

Rating for OPAL ranked from Score 1 – Score 8. Less complex, non-treatment trials were at the top of the pyramid (Smuck et al., 2011). The type of intervention being studied and the number of incremental procedures included determined the score. Starting at the top of the pyramid: A “Single contact Score” of one (1) represented a non-treatment trial, and included “quality of life, survey, and blood samples.” A “multiple contact Score” of two (2) represented a non-treatment trial with multiple contact events that included “quality of life, survey, and blood samples.” A “Phase II, III, IV Interventional Nondrug score” was given a score of three (3) and represented “In-house investigator initiated, imaging, and exercise studies.” A “single special procedures (SP) and/or single central processes” (CP) were given a score of four (4) and represented “A treatment trial Phase II, III, or IV.” This included any “SP and/or CP with one (1) occurrences. A “multiple SP or multiple CP” was given a score of four (5) and represented “A treatment trial phase II, III, or IV.” This included “any SP/CP with (2) or more occurrences.” A “single SP plus a multiple CP or single CP plus multiple SP” were given a score of six (6) and represented “A treatment phase II, III, IV.” This included “any SP/CP with one or more occurrence, and any SP/CP with two (2) or more occurrences.” A “multiple SP plus a multiple CP” were given a score of seven (7) and represented “A treatment trial phase of II, III, or IV.” This included “any SP with two (2) or more occurrences and CP with two (2) or more occurrences.” A “Phase I trial” (the widest point on the pyramid was given a score of eight (8), and represented “Any Phase I trial” (p.82).

Consistent specific tasks for each segment of any clinical trial regardless of complexity were regarded as core tasks and included: “Protocol review, informed consent form review,

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research ethics board submission during the activation segment, source documentation completion, adverse event monitoring, safety reports, and visit monitoring during the active study; Ongoing protocol administration, sponsor related safety reporting, and query completion during follow-up” sessions. In addition to core tasks, “many protocols require incremental procedures that are unique to each trial.” Incremental procedures were positively correlated with “increased complexity which leads to increased workload.” A “pre-study site visit, investigator meeting, equipment needs (e.g., storage or computer checks) during activation; review of pathology, biomarker studies, radiology, and patient diaries during the active study; and additional assessment of quality of life or length of follow-up during follow-up” fit into this category. Smuck et al., (2011) determined that “all cancer clinical trials can be rated with OPAL,” (p.81), and described it as an effective tool even without patient enrollment (Smuck et al., 2011).

Good et al. (2013) reported that there was a need for a quantifiable, valid and reliable method of measuring clinical trials-related workload. They informed that cancer trials in the twenty-first century “require involvement of multiple disciplines and intensive recruitment planning” (p.211). They shared that the National Cancer Institute (NCI) used “an algorithm of 1.5 full time equivalents (FTEs) per 40 credits or registrations” (p.211). They noted that this was inadequate as it was incapable of assessing all of the work efforts in the different trials complexities. The solution was an objective measurement tool. Good et al. (2013), as part of the Wichita Community Clinical Oncology Program (WCCOP) developed and implemented the WCCOP Protocol Acuity Tool (WPAT) and ran it as a trial for 11 years 1999-2010, the years covering the grant. They registered 850 patients yearly. Their aim was to find the best way to balance workload among their clinical trials research nursing staff (Good et al., 2013, p.213).

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They emphasized the importance of the work of the clinical research nurses and the non-nurse clinical research associates in clinical trials.

Good et al. (2013) categorized patients according to their status in the clinical trials. The categories are “On-study vs Off study.” In the “On-study” participants are either receiving treatment and being observed or only being observed. In “Off study,” there was neither treatment nor observation for “patients whose disease had progressed” (p.212). The authors used “Six workload-related determinants” for “the treatment or cancer-focused trial” (p.211). These were “complexity of treatment; trial specific laboratory and testing requirements; treatment toxicity potential; complexity and number of data forms required; degree of coordination required (involvement of ancillary departments, outside offices/sites, and/or disciplines); and number of trial random assignments or steps” (p. 211). Trials were then scored according to estimated workload using 1- 4 which pertained to observing a trial, the toxicity of oral agents, a regimen of chemotherapy, and high toxicity multi-drug regimens. (Information for this tool had to be taken from the description in the article since no actual tool was provided). Good et al. (2013) reported that their tool “validated subjective feedback from staff about the need for additional staff.” In the eleven years of calculating acuity scores, the scores increased in the predicted direction, and there was “per research nurse FTE reductions in workload” (p.213).

Methodology

Process of Arriving at the Problem and the Selection of Articles

One issue from a list of many that kept spawning each course taken in the MS Research Administration Program was the emphasis by grant funders to have proposals and reports submitted on time by principal investigators conducting sponsored clinical research. This issue represented one of the many areas in which research administrators perform their duties within universities, hospitals, medical centers and industry in general. It was hypothesized that there

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was a relationship between workload and submitting a grant on time. Based on that hunch, the literature search began by exploring ‘principal investigators’ using Google as the search engine. An article in the Principal Investigator Advisor (Advisor, 2010) that described grant writing, time management, writing papers, and grant administration as the first four top challenges for PIs shifted the researcher’s focus on principal investigators’ workload to the broader topic of administrative workload in clinical research. The concept workload was discussed in terms of the complexities of clinical trials workload (complexities meaning the extent to which effort is needed in managing the impact of treatment). When the 2012 Survey report was located it provided a roadmap back to the hypothesis mentioned earlier. A path that was grounded in the literature became wider. Clinical trials were listed among the Administrative burden responsibility areas in 2012 Survey but not in the 2005 report; Ten percent (10%) of participants were from the clinical sciences and medicine and 32% from the biological and biomedical sciences. The thought was triggered that clinical trials and its related administrative workload problems needed to be studied separately within clinical research.

The path started to become narrower. Knowledge that the Project would have to connect its problem to research administration was considered. Research administrators “balance facilitating sponsored program activities of project directors, principal investigators, co-principal investigators, the academic or nonprofit community while accommodating the priorities and stewardship expectations of the institution, governmental entities, sponsors and the public” (Woods, 2014). The MS Research Administration at Johns Hopkins University was launched from a background of science and medical research and this thought cemented the focus of the problem for the Project. The process continued with the selecting of articles.

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Based on the assumption that articles and reports dealing directly with a subject matter should surface in the first forty articles, articles with key words like ‘workload,’ ‘administrative workload,’ and ‘clinical trials’ in the title were reviewed (i.e., mainly the abstract and otherwise skimming in the first round) and chosen or not chosen for full review. A search in Google, Google Scholar, PubMed, Medline, Cochrane Library, and CINAHL databases using multiple combination of the key words identified (see Table 1). Many articles on workload and clinical trials focused on the clinical research nurse, clinical research associate, clinical research coordinators and data manager. Except for the two major government-related reports there was a dearth in the literature on administrative workload and clinical trials. Since the two major studies focused on the PI, to resolve this matter a decision had to be made about exactly on what the Project would focus. This Project, a secondary analysis had to be driven by the literature. An article by Roche et al. (2002) which was set aside because it was written over ten years ago added to an already aroused interest in focusing on measurement tools as a part of assessing administrative workload. The earlier concern about clinical trials being placed among the other Administrative burden responsibility areas in the 2012 Survey was chosen as a jump-start to explore the literature on measurement tools and workload in clinical trials and then let the literature direct the actual Project. That path led to becoming focused and resolute resulting in the actual problem for this Project.

The articles on workload measurement and clinical trials indicated the need for administrative workload measurement tools for clinical trials-related workload and administrative workload. Noteworthy was the observation that when the references listings within articles used in this Project were checked, they were already selected for inclusion in the Project. When the same set of articles kept surfacing with different keyword combinations, a

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decision was made to stop searching for articles for the literature review section. Numerous articles were used for different purposes throughout this Project and each one was selected by the planned method for selecting articles.

Design

A secondary review and analysis on the specific problem was used in this Project. The design consisted of the use of all articles and reports secured via the methods described earlier. However, the problem of the Project was launched from one of the two major administrative workload reports, the 2012 Survey. The other report was presented as an example to support the need presented in the problem of the Project as explained earlier. The articles used in the literature review section to discuss the problem were authored by Roche et al. (2002); Berridge & Coffey (2008); Briggs (2008); Lyddiardc et al. (2010); Smuck et al. (2011); Good et al. (2013); and Schneider et al. (2014). These were the available articles in the literature that presented workload measurement tools for clinical trials that could be found. Each article was synthesized, its findings compared, and discussed in relation to recognizing clinical trials as a clinical research subspecialty impacted by clinical trials-related administrative workload problems. The content of each of their measurements was presented without paraphrase in order not to misinterpret. This was done for the same reason that in research, interviewers are asked not to interpret the question as is expected for the consent form. Except for the 2012 Survey, the remaining article, reports and other sources were used to support, inform, define, or explain some elements or statements relevant to a particular discussion of the problem, and the proposed way of addressing it. Many sources were used in defining and exploring the multiple dimensions of clinical trials, and the dynamics of workload and administrative workload.

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Results on the 2012 Survey and the Workload Measurement Tools

In this section, the 2012 Survey's responses specific to clinical trials as an administrative workload burden activity area are compared and contrasted in accordance with the proposed method of the Project for addressing the problem. The variables in each measurement tool are described and matching variables on the 2012 Survey and each measurement tool are presented in the results. If there are no matches, that is also noted. A general discussion on the findings of the literature is provided at the end of presenting the last comparative results.

Table 2 shows that participants in the 2012 Survey expressed that they had difficulty negotiating acceptable protocol. The Complexity Scoring Tool (Briggs, 2008) included a category that sought findings on any activity that needed approval. Approval was measured from "few with no resource implications" to complex with a moderate degree of complication. This type of activity was recorded as a category 3 out of 5 increasing intensity levels (p.23). Administrative responsibilities were recorded for all sections of the measurement tool for Category 5, and these were not part of the 2012 Survey findings. "Problems related to Clinicaltrials.gov" and "Lack of budget flexibility" (Schneider et al, 2014, p. 57) were not captured because the Complexity Scoring Tool focused on activities. The authors informed of the validation of the measurement tool and it provided additional workload variables, therefore, there is support for the Project's identified need.

Table 3 shows that the scope the WMI (Berridge & Coffey) transcended the findings of 2012 Survey but there were some similarities. The 2012 Survey's findings on posting and updating progress and results, and completing training requirements (federal requirements not specifically mentioned) matched the variables this measurement tool (Berridge & Coffey, 2008).

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WMI sought to measure “activities carried out from the time of receiving the protocol to subject recruitment,” “the time involved in all tasks following the identification of potential clinical trial subjects,” and “time spend on administrative issues related to the data management of a specific trial” (p.100). The 2012 Survey did not indicate that it had the capacity to measure such dimensions. There is the possibility that the need for the update of a software, a problem reported by the 2012 Survey in Clinicaltrials.gov could have been included in responses for the WMI (Berridge & Coffey) in its section on “Administration and IT Preparation.” However, Clinical trials.gov has workload variables pertaining to the care of patients that were not captured in the WMI. Modules 1, 2, and 3 of the WMI were validated and they provide additional workload variables, therefore, there is support for the Project’s identified need of recognizing clinical trials as a clinical research subspecialty, and administrative workload problems as impacting variables. Based on the information given in Lyddiardc et al. (2010); and Coffey et al. (2011), it is important to note here that the same findings for the WMI (Berridge and Coffey) and presented in Table 3 apply to measurement tool of Lyddiardc et al. (2010).

Table 4 shows that variables OPAL sought to measure issues on “Informed consent form review,” and “Research ethics board submission during the activation segment.” Similarly, the 2012 Survey’s reported difficulties in getting consent which would have been tied into the consent form. OPAL introduced levels of measurement according to clinical trials phases, another area not covered by the 2012 Survey. OPAL revealed numerous variables that were not found in the FDP survey responses. OPAL itemized its variables as routine or core tasks for each segment of any clinical trial regardless of the complexity, thus accounting for a multilevel and cross dimensional understanding of clinical trials and its related trials-workload. Such variables were missing in the 2012 Survey findings. Smuck et al. (2011) informed of the validation of the

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measurement tool and it provides additional workload variables, therefore, there is support for the Project's identified need.

Table 5 shows there are findings in the 2012 Survey that could reasonably be compared to those WPAT sought to measure. WPAT's "Trial specific laboratory and testing requirements" can be interpreted as requirements from the federal government and other sources. WPAT captured the Clinicaltrials.gov finding on the problem of many data forms being required, but the FDP specifically found that this was time consuming. WPAT sought to measure the "degree of coordination required" internally and externally to get the job done, and the Survey found that participants had difficulty dealing with multiple organizations. WPAT included additional dimensions for examining clinical trials workload in its measurement of On Study and Off Treatment, and Off Study variables and these were not addressed in the Survey. The authors informed of the validation of the measurement tool and it provides additional workload variables, therefore, there is support for the Project's identified need.

Discussion on the Results of the Measurement Tools vs. the 2012 Survey

The aims of the 2012 Survey were not the same as the measures but they shared the common element of the administrative workload burden activity. The 2012 Survey was initiated to explore workload burdens of PIs with federally funded research, and clinical trials surfaced as one of these burdens. The measures were developed for clinical trials settings and to measure the complexities of the science of the trials and/or the tasks, procedures, and time involved in conducting clinical trials.

All of the tools introduced new dimensions for assessing workload. Some sought to measure more workload administrative tasks than others but in all instances there were many variables not found in the 2012 Survey. Since all of the authors specified that their measurement

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tools were validated, they are indicators that clinical trials viewed as an administrative workload burden activity area limits capturing their multilayered levels and dimensions. It can be argued that the validation time is limited for these measurement tools and this is an implied concern of Good et al. (2013) that had 11 years of tool validation.

Category 5 in the Complexity Scoring Tool by Briggs, (2008) was comprised of administrative workload activities but there are no attempts to determine whether they fall outside of the normal range of duty and are burdensome. The latter applies to all of the measures. The WMI provided by Berridge and Coffey (2008) which is applicable to Coffey et al. (2011), and Lyddiardc et al. (2010) has tasks and subtasks and widely cover areas that a researcher with experience in clinical trials can verify or state that they do not apply to his/her setting. The WMI modules present numerous additions to the 2012 Survey and, as is true for all of the measurement tools this is better understood with a review of their descriptions (in the literature review). Of all the measurement tools, the WMI contained the most administrative workload variables.

The OPAL gathered more information than is presented in the 2012 Survey. For example, this measure rated the entire activities and phases of clinical trials, and tasks related to biomarkers. It provided “the total workload per staff member,” “the means of capturing how workload is distributed,” and “objective data to assess the need for additional or reallcoated resources” (p.83). It is more comprehensive than the 2012 Survey results in what it seeks and how the scores are determined. The contents of the instruments are also proof that there are other variables to be considered in assessing clinical trials administrative workload burden.

The workload-related determinants presented in the WCCPP Protocol Acuity Tool (WPAT) indicate the type of direct data that can be obtained on workload when the recognition

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the Project seeks is applied. They combined actual treatment variables with tasks variables. They distinguished between On study with treatment and without treatment, and Off study with no treatment at all. This is an addition to the findings in the 2012 Survey. Like the other authors their measurement tool was reported as successful for the purpose that it was designed. They do not make any claims to generalizability.

Good et al. (2013) described the work of Berridge and Coffey (2008), and Smuck et al. (2011) as authors “who have begun the process of developing measurement tools,” (p.213) emphasizing WPAT’s 11 years of workload assessment data history. The other measurement tools testing time ranged from three months to six months and broader claims of generalizability were made. Discussion surrounding the need for this article raised the question of integrating known knowledge and the need for those who researched workload and administrative workload in clinical trials to collaborate and/or network. Finally, in their discussion of the workload measurement tools all of the authors implied the importance of the teamwork in clinical trials.

Conclusions

This Project began with the important observation that there is a need for recognizing clinical trials as a subspecialty impacted by clinical trials-related workload problems, and then allowing the literature to showcase the multifaceted its dimensions (see Table 6). Despite the different purposes for the 2012 Survey and for each measurement tool respectively there were comparable findings. This result was in the expected direction and the need identified by the Project was supported. The measurement tools were designed to capture the actual workload and/or administrative workload in practical clinical trials settings and so the findings can be applied to practice.

Validated measurement tools sought to measure many of the variables on the 2012 Survey. There were variables in the survey that could not be measured in the measurement tools

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unless open-ended questions were included. The Survey's aim and focus was to research workload burdens and its style facilitated that purpose. The measurement tools provided information on the vast dimensions of clinical trials that transcended the knowledge provided by the 2012 Survey. Schneider et al. (2014) acknowledged that their study was a fraction of a broader issue of workload and there was an implicit theme across the literature that administrative workload and workload should be assessed in relation to the team that conducts the clinical trials because of the important roles they play in the success of the trials. Schneider, et al. (2014) added that "without comparable information about workload among administrative staff, it is not possible to get a complete picture of costs of administrative requirements, or the potential of enhancing efficiency" (p.104).

The need for further discussion in the literature on workload and administrative workload in relation to clinical-trials also became evident. It was also observed that there needs to be a clear standard definition of complexity for clinical trials since it is often used in clinical trials. This Project adds to current literature on how administrative workload in clinical trials is measured. Support for the need identified by the Project is important for research administrators who work with clinical trials because the administrative workload could mean increased work for them that may be continually added without any recognition or compensation. This Project is a new resource when researching administrative workload, the 2012 Survey, the NSF Board, and the measures to assess it.

What was Learned from the Project?

1. The importance of team science in today's global society. This Project revealed a need for parties with the same interest in clinical trials to connect and build on their knowledge and scholarship.

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2. Observing that the discussion about piloting the measurement tools did not include the protection of human subjects reinforced my knowledge of the importance of ethics in conducting research. HIPPA was not mentioned in the WPAT, a U.S. study. Berridge & Coffey (2008) included working with an ethics committee as a statement to be checked off on their measurement tool.
3. Briggs (2008) described workload measurement as difficult and she was correct because choosing an article for research based on the keywords in the title will not work in every situation as workload is not adequately defined.

The Limitations of the Project

1. There were several limitations that emerged through the Project.
2. The 2012 Survey and the NBF Board specifically studied PIs who were federally funded. The literature available for this Project was limited and presented workload in clinical trials without necessarily focusing on PIs.
3. Most of the measurements tools were designed internationally. However, three of the international authors who developed measurement tools identified regulatory burdens as part of the reason for the need to create a workload measurement Berridge & Coffey (2008); Smuck et al. (2011), and Good et al. (2013).
4. Only one measurement tool (i.e., the WPAT, Good et al., (2013) was constructed in the U.S. However, Lyddiardc et al., (2010), authors who shared the WMI Berridge and Coffey (2008) measurement tool, expressed that the “increasing use and complexities of multi-modality treatment regimes, the rising costs of trials, the emphasis on the efficient use of available resources and adherence to good clinical practice (GCP), increasing regulatory requirements and demand for high quality

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- assurance control have resulted in an increased focus on workload issues” (p.1). It seemed, therefore, that the background for the measurement tools discussed had many similarities with the U.S. The use of these articles, therefore, was appropriate, but may also be viewed as a limitation.
5. The 2012 Survey was quoted very often about the burdensome federal requirements on PIs and this was understandable because PIs are accountable for administering the grant even though it is granted to the institution. PIs were not the center of the measurement tools instead it was the other professionals who did the actual administering of the research protocols. One international study noted in its limitation that it did not include PIs in piloting its measure. The measurement tools were constructed from the perspective of the importance of the role of the team that conducts clinical trials. The 2012 Survey was launched from a base of seeking the consequences of burdensome regulations on PIs who received Federal grants. The measurement tools also did not focus on PIs as their foci for measuring workload, it was on the clinical trial and the clinical trials’ team (i.e., the clinical research nurse, the clinical research coordinator who were supervised by the research physician).
 6. Despite an extensive search it was difficult to find articles that researched PIs and their workload problems.

How Conclusions were Formed

The conclusions for this Project were determined by the overall literature. The findings for the literature were arrived at by checking the 2012 Survey results and the NSF Board and using face validity for comparable features. Face validity is “a type of content validity

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determining the suitability of a given instrument as a source of data on the subject under investigation, using common sense criteria” (Saunders, 2003). Addressing the problem depended on whether or not the FDP findings and other administrative workload variables were found in measurement tools that were tested for validity and reliability. Smuck et al. (2011) was tested for validity and reliability. Briggs, (2008) was tested for reliability. Berridge and Coffey (2008) and Lyddiardc et al. (2010) conducted validity tests at all of the stages. Good et al. (2013) reported positive results after validating the measurement tool for over 11 years. Without going into the details about validity and reliability (which are beyond the scope of this Project) based on the results after the authors tested the measurements, the Project supported the need for a greater recognition of clinical trials as a clinical research subspecialty impacted by clinical trials-related administrative workload problems. The integration of known knowledge of how administrative workload and workload are measured was implied. It is surmised that the authors presented in this Project would approve of the findings. This Project also only focused on a small area affecting clinical research.

Recommendations

There are several recommendations the author sets forth.

1. Clinical trials should be studied as a separate clinical research subspecialty with clinical trials-related administrative workload problems.
2. Both workload and administrative workload should be studied when researching clinical trials.
3. The drive to produce valid and reliable measurement tools for the complexities and workload in clinical trials should continue but with the collaboration of the few authors who have done a tremendous amount of work on the measurement tools.

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Table 1

Searches Conducted by the Researcher for the Project

- Google Key Words – 1. Administrative Workload and Clinical Research; 2. Clinical Studies and Workload; 3. Research Administration and Workload;
- Google Scholar: 1. Administrative Workload and Clinical Research; 2. Clinical Studies and Workload; 3. Research Administration and Workload; Workload Clinical Trials and PPI 2008; Clinical Trials and workload measures; workload measures and research administration; clinical trials workload; Administrative Workload and Clinical Trials; Workload and clinical Research Scientist
- PubMed – Workload Clinical Trials and PPI 2008; Clinical Trials and workload measures; workload measures and research administration; clinical trials workload; Administrative Workload and Clinical Trials; Workload and clinical Research Scientist
- Medline – Clinical Trial Sciences and Workload; Clinical Research Clinical Trials; Clinical Studies and Administrative Workload.
- CINAHL – Administrative Workload and Clinical Research

References from topics in the articles were selected for use in this Project

PI's Workload and Clinical Trials

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Table 2

Results of the 2012 Survey and the Complexity Scoring Tool

2012 Survey Found	Complexity Scoring Tool Sought to Measure
“Participants said it was “difficult to deal with discrepancies negotiating acceptable protocol that will be acceptable by all parties involved” “Getting consent and approval more than once”	“Local approvals. Few or no resource implications; Some resources implications; “Complex approvals possibly commercial moderate resource implications”
Numerous Variables Missing	Numerous variables across 3 Sections and 5 Categories. Using Category 5 as an example: Section I: “Coordination of the Multi-Research Ethic submission in total or in partnership.” Section 2. “Trial coordinated from department, either local in total or in partnership with company.” Section 3. “Complex moderate to long-term follow-up.”
"Problems related to Clinicaltrials.gov" “Non- clinical trials are being posted.” “The design and organization are not intuitive.” “Reporting requirements for the websites are: Time consuming, complicated to complete, and do not seem to be uniformly enforced (e.g., university versus industry).” “The software needs to be updated to facilitate reporting.”	Variables Missing
“ Lack of budget flexibility: ” “Salaries do not necessarily change as cost of living changes.” “It is especially consuming to complete extra reporting for changes that cannot be predicted.”	Variables Missing

Note. On the left, are quotations from the Survey on Responsibilities associated specifically with conducting clinical trials from the “2012 Faculty Workload Survey Research Report,” by Schneider, S. L., Ness, K. K., Rockwell, S., Shaver, K., & Brutkiewicz, R. (2014). Retrieved from: <http://www.researchadministrationdigest.com/fdp-faculty-workload-survey> pp. 56-57.

Note. On the right, are quotations from The Complexity Scoring Tool in “Real-world workload needs” by Briggs, J. (2008, May). “Oncology and clinical trials for in the 21st Century” *Applied Clinical Trials Supplement*. actmagazine.com, p.98-101.

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Table 3

2012 Survey and the WMI (Berridge & Coffey)

2012 Survey Found	WMI Sought to Measure
“Completing training regarding federal requirements for clinical trials” “Posting and updating trials results to meet federal requirements” “Posting and updating trials progress to meet federal requirements”	“In-house meeting for information and training.” “Prepare and submit protocol amendments” “Update study document following amendments” “Participate in in-house meetings to discuss amendments” “Subsequent training following study amendments.”
Numerous Variables Missing - Module 1 Planning Stage Numerous Variables Missing- Module 2 The Implementation Stage Numerous Variables Missing - Module 3 Trial Data Management	“Completed for each new protocol in the planning stage” – administrative activities from receiving protocol to subject recruitment, e.g., “Financial agreements/clinical trial agreement (CTA)” “Completed for every subject considered eligible to enter into a trial”- from enrollment and continuing until closure: Time involved in all tasks after identifying potential clinical trial subjects,” e.g., “Document eligibility/non eligibility in screening log, notes, and database.” “Completed for each protocol during the trial data management stage” - “document the time spent on administrative issues related to the data management of a specific trial.” Start “during the implementation stage, continuing during follow-up, and ending at the trial closure,” e.g., “Resolve queries post monitoring and post audit visit” Module 4 was Not Validated
“Problems related to Clinicaltrials.gov”	“Administration and IT preparation”
“Lack of budget flexibility”	Variables Missing

Note. On the left, missing items and quotations from the Survey on Responsibilities associated specifically with conducting clinical trials from the “2012 Faculty Workload Survey Research Report,” by Schneider, S. L., Ness, K. K., Rockwell, S., Shaver, K., & Brutkiewicz, R. (2014). Retrieved from: <http://www.researchadministrationdigest.com/fdp-faculty-workload-survey> pp. 56-57.

Note. On the right are quotations from Workload Measurement by J. Berridge and M. Coffey, 2008, *Applied Clinical Trial*, 17 p. 98.

Table 4

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2012 Survey and the OPAL

2012 Survey Found	The OPAL Sought to Measure
“Getting consent and approval more than once;” “Dealing with multiple organizations involved in clinical trials such as compliance organizations, Agencies and Local IRBs”	Variables that are core tasks or consistent specific tasks for each segment of any clinical trial regardless of complexity such as: “Informed consent form review,” “Research ethics board submission during the activation segment.”
Numerous Variables Missing	<p>Numerous variables in the multidimensional OPAL as described in the Literature Review:</p> <p>A “Single contact Score” of one (1) represented a non-treatment trial ...”</p> <p>A “multiple contact Score” of two (2) represented a non-treatment trial with multiple contact events ...”</p> <p>A “Phase II, III, IV Interventional Nondrug score” was given a score of three (3) ...”</p> <p>A “single special procedures (SP) and/or single central processes” (CP) were given a score of four (4) ...”</p> <p>A “multiple SP or multiple CP” was given a score of four (5) ...”</p> <p>A “single SP plus a multiple CP or single CP plus multiple SP” were given a score of six (6) ...”</p> <p>A “multiple SP plus a multiple CP” were given a score of seven (7) ...”</p> <p>A “Phase I trial” (the widest point on the pyramid was given a score of eight (8) ...”</p> <p>E.g., “pre-study site visit, investigator meeting, equipment needs (e.g., storage or computer checks) during activation; review of pathology, biomarker studies, radiology, and patient diaries during the active study; and additional assessment of quality of life or length of follow-up during follow-up”</p>
Problems related to clinicaltrials.gov	Variables Missing
Lack of budget flexibility	Variables Missing

Note. On the left, are quotations from the Survey on Responsibilities associated specifically with conducting clinical trials from the “2012 Faculty Workload Survey Research Report,” by Schneider, S. L., Ness, K. K., Rockwell, S., Shaver, K., & Brutkiewicz, R. (2014). Retrieved from: <http://www.researchadministrationdigest.com/fdp-faculty-workload-survey> pp.56-57.

Note. On the right are quotations taken from OPAL, the “Ontario protocol assessment level: Clinical trials complexity rating tool for workload planning in oncology clinical trials,” by Smuck et al., 2011, *Journal of Oncology Practice*, 7, p. 80-84.

CLINICAL TRIALS-RELATED ADMINISTRATIVE WORKLOAD

Table 5

2012 Survey and the WPAT

2012 Survey Found		The WPAT Sought to Measure	
“Posting and updating trials progress to meet federal requirements” “Posting and updating trials results to meet federal requirements”		“Trial specific laboratory and testing requirements” “Trial specific laboratory, testing requirements” “Complexity and number of data forms required,”	
“Dealing with multiple organizations involved in clinical trials such as ...Agencies and Local IRBs”		“Degree of coordination required (involvement of ancillary departments, outside offices/sites, and/or disciplines)”	
Missing Variables			
	On Study		Off Study
	Active Treatment	Off Treatment (being observed)	No observation, No Treatment Cancer Control Focused Trial based on 6 workload determinants
<p>Determinants:</p> <p>“Complexity of treatment”</p> <p>“Treatment toxicity potential”</p> <p>“Number of trial random assignments or steps.”</p> <p>Scored according to estimated workload using 1- 4:</p> <p>“Observation/Registry trial”</p> <p>“Oral agents with minimal toxicity”</p> <p>“Chemotherapy and/or radiation therapy regimen, increased toxicity potential when compared with a trial rated as 2”</p> <p>“Complex multiple drug regimens, high degree of toxicity potential, involve multiple standards of care research test/procedures etc.”</p>			
“Lack of Budget Flexibility”		Variable Missing	

Note. On the left, are quotations from the Survey on Responsibilities associated specifically with conducting clinical trials from the “2012 Faculty Workload Survey Research Report,” by Schneider, S. L., Ness, K. K., Rockwell, S., Shaver, K., & Brutkiewicz, R. (2014). Retrieved from: <http://www.researchadministrationdigest.com/fdp-faculty-workload-survey> pp.56-57

Note. On the right are quotations that describe the measurement tool WPAT in the article, or summary descriptions, Measuring Clinical Trial-associated Workload in a community clinical oncology program, by Good, et al., 2013 *Journal of Oncology Practice*, 9, p. 211-216.

CLINICAL TRIALS-RELATED ADMINISTRATIVE WORKLOAD

Table 6

The Impact of the Project

Started	What Accomplished
<p>The 2012 Survey finding that clinical trials were one of 22 other faculty workload burden areas</p> <p>The search for Survey findings and other workload variables in validated measures.</p>	<p>The need for recognizing clinical trials as a subspecialty impacted by clinical trials-related workload problems was supported.</p> <p>The Project's findings can be applied to practice settings because the measurement tools were designed for that purpose.</p> <p>Many of the findings of the 2012 Survey were variables on validated measures.</p> <p>All of the measurement tools introduced new and multifaceted dimensions that stand in support of the need identified by the Project.</p> <p>The Project contributes to the ongoing discussion on a definition of workload.</p> <p>The Project identified an implicit theme across the literature about the importance of teamwork in assessing clinical trials.</p> <p>The two major government initiated studies, the 2012 Survey and the NSF Board could not be used comparatively for the purposes of this Project, and that observation was not in the expected direction.</p> <p>The Project is accessible to professionals such as research administrators and to future planners like sponsoring agencies, foundations, FDP, and other think-tank bodies.</p>

CLINICAL TRIALS-RELATED ADMINISTRATIVE WORKLOAD

Biographical Statement

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Dr. Woodroffe has extensive experience as a university faculty member, and as a principal investigator/program director (PI/P) in the private sector, and nonprofits in sponsored research. She chaired departmental, university-wide, statewide and national committees. She has wide knowledge and experience with the Human Subjects Internal Review Board and has written proposals and received grant funding. Her newest addition from the MS Program at JHU is in the area of contract negotiations.