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Drug Interaction Screening in SWOG Clinical Trials

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Abstract

Purpose—Polypharmacy in cancer patients can lead to drug interactions that cause unsafe or ineffective treatment. A recent recommendation for pharmacist-led drug interactions (DI) screening during oncology clinical trial eligibility assessment was published, but little is known about the current "real-time" processes. The objective of this survey was to understand the frequency and process for DI screening at sites enrolling patients onto SWOG clinical trials.

Methods—Qualtrics survey invitations were emailed to 180 SWOG head clinical research associates to inquire on the frequency of and personnel involved in DI assessment in subjects who were screened for and enrolled in clinical trials at their sites. Descriptive statistics were performed to evaluate the data.

Results—Responses were collected from 83 (46%) surveys. The majority of sites (51%) reported that DI screening only occurred during eligibility assessment when a drug interaction was included in the protocol exclusion criteria. The pharmacist was "always" involved in DI screening during eligibility assessment at 17% of sites. Clinical research coordinators (56%) and research nurses (45%) were the predominant personnel who performed DI screening to assess eligibility for trial enrollment. A subset of sites (3%−6%) reported not having access to a pharmacist.

Conclusion—DI screening for SWOG trials is highly variable. A pharmacist-led service may improve the quality of this critical task, but may be restricted by the lack of involvement or access to pharmacists at some sites.

Keywords

oncology; clinical trial; drug interactions; pharmacist; survey

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Introduction

Cancer patients often receive multiple medications, [1, 2] particularly when they reach end of life care.[3] Polypharmacy in geriatric cancer patients manifests with high rates of clinically relevant drug interactions (DI),[4–6] causing medications that are safe and effective when taken separately to be unsafe or ineffective when taken concomitantly.[7] DI screening is critically important in oncology clinical trials for both the treatment outcomes of trial subjects and the accuracy of the research findings; undetected DI put subjects at greater risk of toxicity or ineffective treatment, and threaten the validity of comparisons between the tested treatments.

Eligibility criteria in clinical trial protocols may include warnings or restrictions against enrolling patients taking medications that interact with the study drug. DI screening during eligibility assessment for early phase oncology clinical trials identifies clinically relevant DI in more than half of patients, but the majority of patients can be enrolled by discontinuing or changing the interacting medication, with less than 5% of patients requiring trial exclusion due to unresolvable DI.[8] To assist with DI screening, protocols often include lists of interacting drugs, but the location within the protocol, comprehensiveness, and frequency of updating of these lists are highly heterogeneous.[9] In addition, the availability of easy to use and up-to-date DI screening tools is scarce. An alternative approach would be for a pharmacist to perform DI screening within a comprehensive medication review.[10] A recent publication within the American Journal of Health-System Pharmacy proposed a standardized process for pharmacist-led DI screening for all patients enrolling on oncology clinical trials.[11]

Development of a standardized process for DI screening for oncology clinical trials, potentially conducted by a pharmacist, may be a worthwhile initiative. However, limited information is available on the current processes for DI screening. This lack of information was identified in SWOG (formerly known as Southwest Oncology Group), one of 5 federally funded clinical trials research groups comprising the National Clinical Trials Network (NCTN) under the aegis of the National Cancer Institute (NCI). SWOG has nearly 6,000 physician researchers at more than 950 institutions nationwide and in six other countries. It includes 32 NCI-designated cancer centers, as well as community hospitals, private practices, and physician group networks. SWOG sites are highly diverse in their operations for prescribing, processing, and dispensing medications, including study drugs, depending on resources available at the site. In addition, treatment may be given in an inpatient or outpatient setting and medications administered via different routes based on patient specific disease factors. The objective of this survey was to describe the current process for screening DI within SWOG clinical trials, including the frequency of screening, the staff responsible, and the resources that are available and used to make DI decisions. Evaluation of the current process has the potential to justify the need for standardization of DI assessment.

Methods

Sample Selection and Survey Distribution

In total, there are about 950 SWOG or NCI Community Oncology Research Program (NCORP) sites (or institutions) that enroll patients onto SWOG clinical trials. These sites are represented by a group of 180 Head Clinical Research Associates (CRA), each of whom is associated with multiple sites. This survey attempted to collect a single response from each of the 180 Head CRAs. The response rate is calculated to be the number of surveys with a single question completed out of the 180 invited CRAs.

A description of the survey and a direct, though not unique, link to online survey software (Qualtrics, Provo, UT) were e-mailed to each Head CRA. The e-mail invitation included instructions to complete the survey or forward to one individual to complete the survey on behalf of their sites. The instructions explained that the survey was anonymous and was not for the purposes of SWOG oversight or auditing. It was also specified that the purpose of the survey was to understand how DI screening was being performed at SWOG sites in order to guide potential development of a standard system. All CRAs were requested to answer based on their actual process and not their understanding of SWOG or institutional policy. The initial invitation was sent via e-mail on October 12, 2016, with e-mail reminders sent on October 26 and November 14 of the same year. This study was determined to be non-regulated by the University of Michigan Institutional Review Board (IRB) and as such did not require IRB approval. Participant consent was assumed based on their willingness to complete the survey.

Survey Development and Analysis

The survey was developed by the SWOG Pharmaceutical Sciences Committee, composed primarily of pharmacists representing different SWOG sites. Survey topics were selected based on the objective of understanding whether DI screening was occurring within SWOG clinical trials, who was performing it, and using what resources. One member of the committee drafted the survey questions and response options to develop the initial structure of the survey. Four members of the Pharmaceutical Sciences Committee and five clinical research coordinators performed pre-testing by completing the survey in Qualtrics and providing written feedback. The survey was updated based on this feedback, followed by review of the revised survey by Pharmaceutical Sciences Committee members to finalize questions, response options, and confirm congruency of questions with responses.

The final survey instrument, which can be obtained by contacting the corresponding author, includes ten questions and is divided into two main sections. The first section collects general demographic information about the individual completing the survey, the SWOG site they represent, and the availability of staff and resources at the site. The second section asks about DI screening at two time points: 1) during subject eligibility assessment for trial enrollment and 2) during treatment at the time of medication changes in currently enrolled study subjects. For each time point of data collection, the survey asks how frequently and by whom DI screening is performed. The final question asks about the availability of drug information resources and the frequency that each resource is used at the institution for DI

screening. The questions are a mixture of single-response multiple choice, select all that apply, or grids with several options for each choice. Finally, the respondent was provided an opportunity to make general comments regarding the DI screening process or the challenges with DI screening at their institution via an open text box. The objective of this study was to provide descriptive information regarding the process for DI screening for SWOG clinical trials. For that reason, only descriptive analyses were performed. Textual responses to the final question were not coded for analysis, but were manually reviewed by the study team.

Results

Demographics of Individual and Site Respondents

Invitations were sent to 180 SWOG Head CRAs, the survey was opened 92 times, and 83 surveys recorded a response to at least one question, for an overall response rate of 46.1%. At least 72 completed surveys were submitted, for a completion rate of 40%. The individual completing the survey most often self-identified as a clinical research coordinator (34%) or a research/study nurse (31%) (Table 1). Responding sites were most often identified as “Community hospital cancer center/specialty outpatient cancer care site” (52%) or “Academic teaching institution/hospital” (30%) (Table 1).

Drug Interaction Screening During Trial Eligibility Assessment

In regards to screening potential subjects for SWOG trial eligibility, the greatest number of sites reported that screening is “always” conducted by clinical research coordinators (65%) and research/study nurses (53%) (Table 2). Alternatively, the vast majority of sites (91%) reported that pharmacists are “never” responsible for enrollment eligibility screening (data not shown). Regarding screening of DI during trial eligibility assessment, only 38% of sites reported that DI screening “always” occurs. The majority of sites (51%) reported that DI screening “only occurs if a DI is specified within the protocol exclusion criteria,” while the remaining 10% of sites reported that DI screening “sometimes” occurs, and no sites reporting that it “never” occurs. The individuals performing DI screening during enrollment eligibility assessment also vary site to site; most sites reported that a clinical research coordinator (56%), research/study nurse (45%), or site principal investigator (PI)/Medical Doctor (MD) (35%) performs this task, whereas only 17% of sites reported that a pharmacist is always responsible for DI screening during enrollment eligibility assessment (Table 2).

Drug Interaction Screening for Medication Changes in Study Subjects

The frequency of screening DI for enrolled study subjects that have medication changes is similar to that reported at baseline, including 44% of sites that perform this task “only when dictated by the protocol.” Again, most of the remaining sites reported that screening always occurs (40%), none reporting it “never” occurs, and the remaining 16% reporting it “sometimes” occurs. DI screening for enrolled study subjects is most commonly performed by the site PI/MD (59%) or the research/study nurse (48%) (Table 2). Interestingly, as seen in Table 2, pharmacists are more frequently involved in DI screening for enrolled subjects (43%) than they are during eligibility assessment (17%).

Staff and Drug Information Resource Availability and Use

Every site responding to the survey reported having reliable internet access. Greater than 90% of sites reported access to an electronic medical record (98%), clinical research associate/study coordinator/research nurse (98%), or pharmacist (94%). Fewer sites reported access to a drug information service (73%) or drug information resources online (78%) or in textbooks (55%). When asked which resources were used for DI screening, and how often, the resources that were most frequently cited as being used "always" included the site PI (24%), a pharmacist at the practice site (23%), or the electronic medical record/clinical decision support system (21%). Less than 10% of sites reported that they "always" use drug information services, websites, resources, or literature searches, although many tools were used "often" or "sometimes" by more than 20% of sites. When asked about the availability and use of pharmacists as DI resource, the plurality of sites reported using pharmacists "often" (36%) or "sometimes" (29%). 23% reported using pharmacists "always," while a small minority of sites reported that pharmacists were "rarely used" (5%), "never used but available" (4%) or "not available" (3%).

Discussion

High rates of clinically relevant DI in cancer patients[4–6] preclude enrollment of some patients onto clinical trials.[8] Ideally, clinical trial enrollment screening would include a DI assessment within a comprehensive medication review performed by a pharmacist.[10, 11] The objective of this survey was to describe the current state of DI screening for potential and enrolled subjects within SWOG clinical trials. As expected, we found that the process and staff responsible for DI screening was highly variable across SWOG sites. A majority of sites reported that DI screening only occurred for eligibility assessment when the clinical trial protocol required it as an exclusion criterion (51%) and a plurality only perform DI screening for enrolled subjects at the time of a medication change when dictated by the protocol (44%).

Contrary to recent calls for pharmacists to conduct DI screening as part of oncology trial eligibility screening,[11] only 17% of the SWOG sites in our survey reported that pharmacists always conduct DI screening during eligibility assessment. This task was most often completed by clinical research coordinators and nurses. Recent surveys of oncology nurses document a lack of familiarity with DI for drugs their patients commonly use[12] and a self-described need for further DI training.[13] The local PI/MD was often involved in DI screening at eligibility assessment (35%) and for enrolled subjects (59%). Lack of knowledge of DI has also been documented in surveys of prescribers,[14, 15] though we are unaware of data from medical oncologists in particular. Integration of clinical pharmacists into hematology/oncology service has been reported to enhance identification of DI, with high rates (>97%) of acceptance of treatment recommendations.[16–18] While this supports the value of pharmacist involvement in DI screening, up to 6% of SWOG sites reported not having access to pharmacists in our survey. Therefore, a standard pharmacist-conducted DI screening system within SWOG is not feasible at this time, and the benefit of such a system would have to be considered within the context of its additional cost.

It may be possible to overcome the limited availability of pharmacists by integrating electronic DI screening tools that enable clinical research coordinators and research/study nurses to perform first-pass DI screening. Potential DI identified by this platform could then be elevated to an off-site pharmacist or local PI/MD for evaluation and decisions about enrollment and treatment. Several sites provided comments supporting the usefulness of electronic clinical decision support systems, and one specifically stated they “Would love an electronic medical record system that associates the patient with a specific protocol and ultimately warns the provider when a potential prohibited medication is ordered.” A previous survey of oncology nurses found that 65% endorsed the usefulness of a system for detecting DI within clinical care.[13] A prospective study of pharmacists screening oncology patients using DI software detected previously unrecognized DI in 14% of patients, all leading to treatment modifications.[19] Further research is needed to determine whether DI screening performed by other practitioners is similarly effective.

There are several challenges to developing and implementing a DI screening tool. Not all SWOG institutions in our survey reported access to clinical decision support tools including electronic medical records, and even fewer reported access to, or use of, drug information services and resources. Additionally, concordance studies of DI checkers have found unacceptably high rates of discordance between systems,[20, 21] necessitating development of best practices[22] and integrated informational systems [23–25] to ensure uniformity of decision making. This problem is exacerbated in trials of investigational agents, for which DI information (i.e. metabolic pathway, inhibition/induction potential, mechanism of action, etc.) is not publicly available or included in standard DI software. A tool populated with protocol-specific investigational drug information for DI screening in clinical trial subjects could ameliorate these challenges.

This survey should be interpreted in the context of several limitations. The response rate (46%) is below thresholds typically used for high-quality surveys (>60% or 80%),[26] creating concerns for non-response bias and lack of generalizability.[27] This could bias results in one of many hypothetical ways if, for example, head CRAs at sites that did not respond are less vigilant in overseeing operations or are more overworked. We attempted to minimize non-response rates by making the survey brief (10 questions, median completion time 250 seconds (4:10)), sending two follow-up invitations, and sending invitations from the SWOG Operations office, which we believed would enhance the credibility and maximize site compliance. As a consequence of this low response, and our decision to survey Head CRAs representing multiple sites instead of surveying individual sites, we did not have sufficient data to make within-study comparisons, such as between types of SWOG sites. An unplanned post-hoc review of responses from academic teaching hospitals and community hospitals did not identify any overt differences.

Another limitation of this new survey is that it has not undergone testing of validity and reliability, and it is possible that critical questions were not asked or responses and scales were not optimal. Furthermore, survey completion via the internet introduces the possibility that survey invitations were not received, respondents were not the ideal person to answer questions, or that multiple responses from a single institution were submitted. The survey was sent to a single head CRA representing a group of sites, with instructions to complete

once on behalf of the group. Therefore, responses do not actually represent single institutions and, depending on the size of the group for which a head CRA responded, the estimates reported may not accurately represent the SWOG network. Finally, the instructions explained that the survey was for use by the Pharmaceutical Sciences Committee, and was not being used by SWOG Operations for oversight or auditing; however, it is possible that respondents were not completely honest out of concern that the survey was being used for oversight purposes.

Despite these limitations, this survey represents a unique dataset characterizing the current practice of DI screening during SWOG clinical trials. Similar research on the frequency and process for DI screening during clinical trials is needed to determine the generalizability of our findings to non-SWOG sites that enroll patients to NCI National Clinical Trials Network trials, sites that enroll patients on industry oncology trials, and sites that enroll patients to non-oncology trials. Our findings indicate that pharmacists are not typically involved in DI screening during SWOG trial enrollment, which is instead conducted by research staff including research coordinators and nurses. A system that relies exclusively on pharmacists to perform screening may not be possible given the lack of pharmacy staff at some sites, and may be challenging based on the lack of pharmacist involvement at others. Approaches that utilize electronic tools optimized for use by research staff should also be considered, though challenges exist. Further research is needed to develop and test a tool to determine whether this approach could enhance the uniformity, efficiency, and effectiveness of clinical trial DI screening to ensure patient safety and accurate assessment of the benefits and harms of drugs within clinical trials.

Conclusion

DI screening is not being systematically conducted within SWOG clinical trials. When DI screening does occur, it is primarily conducted by clinical research coordinators or study nurses. Pharmacist-led DI screening is not the current practice within SWOG and is precluded by a lack of pharmacists' availability at some sites or involvement at many others.

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Key Points

1. Pharmacist-led drug interaction screening has been recommended for all patients enrolling on oncology clinical trials, who often have drug interactions due to polypharmacy.
2. A survey of SWOG sites indicates that drug interaction screening is not uniformly conducted during enrollment eligibility screening for potential oncology clinical trial subjects.
3. Drug interaction screening during eligibility assessment is typically performed by the clinical research coordinators or research nurses, whose knowledge and training of drug interactions varies.

Table 1:

Demographics of Respondents and Sites[a]

Category	Option	n (%)
Survey Respondent (n=83)	Clinical Research Coordinator	28 (34%)
	Research/study nurse	26 (31%)
	Clinical Research Associate (CRA)	6 (7%)
	Nurse/NP/PA/APRN	6 (7%)
	Pharmacist	4 (5%)
	Physician	1 (1%)
	Other[b]	12 (14%)
Practice Setting of SWOG Site (n=82)	Community hospital cancer center/specialty outpatient cancer care site	43 (52%)
	Academic teaching institution/hospital	25 (30%)
	VA Hospital	4 (5%)
	Non-academic hospital	3 (4%)
	Private practice office infusion center	1 (1%)
	Other[c]	6 (7%)

[a]NP = nurse practitioner, PA = physician's assistant, APRN = advanced practice registered nurse

[b]Manager, Manager of Research Office, Clinical Research Manager, Research Manager, Director of Clinical Research Operations, Director (2), Research Director, National Cancer Institute Community Oncology Research Program (NCORP) Administrator (2), Supervisor, Lead CRA

[c]NCORP Office-answer for our group, Multi Site NCORP, HMO style healthcare provider, Outpatient cancer center-Military, Military hospital/ academic teaching institution

Table 2:

Staff Involved in Screening Subjects for Eligibility and DI[a]

	Screen Potential Subjects for Clinical Trial Eligibility (n=83)[b]	**Screen DI During Eligibility Assessment (n=78)[c]**	**Screen DI for Medication Changes in Current Subjects (n=75)[d]**
Clinical Research Coordinator	54 (65%)	44 (56%)	31 (41%)
Research/study nurse	44 (53%)	35 (45%)	36 (48%)
Clinical Research Associate	23 (28%)	17 (22%)	13 (17%)
Principal Investigator/MD	22 (27%)	27 (35%)	44 (59%)
Staff nurse	4 (5%)	4 (5%)	11 (15%)
Pharmacist	1 (1%)	13 (17%)	32 (43%)
Other	2 (2%)	2 (3%)	1 (1%)

[a] DI = drug interactions, MD = medical doctor

[b] Number of sites that reported this staff person is “always” involved in this process (Q4). Percentages out of 83 (number of institutions that answered Q4). Note that more than one person could have been selected.

[c] Sum of those reported to “always” screen for eligibility (Q4) at institutions where this person also screened DI (Q6) plus those reported to screen DI at institutions where this person was different from the individual who screened for eligibility (Q6B). Percentages out of 78 (number of institutions that reported screening at enrollment (Q5)). Note that more than one person could have been selected.

[d] Number of sites that reported this staff person is involved in this process (Q7B). Percentages out of 75 (number of institutions that reported screening drug interactions in trial subjects who had medication changes (Q7)). Note that more than one person could have been selected.