ISSUES IN CLINICAL RESEARCH

Clinical research: National survey of U.S. pharmacy-based investigational drug services—1997

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Abstract: The results of a survey on the status of pharmacy-based investigational drug services and ways in which some institutions have adapted to recent changes that may affect research are presented.

A 99-item survey on investigational drug services was sent in February 1997 to pharmacy directors at 1495 hospitals affiliated with teaching institutions throughout the United States. The survey covered workload, inpatient and outpatient pharmaceutical services, marketing of services, quality assurance, committee involvement, funding sources, computerization, and educational activities.

The response rate was 21%; 68% of the respondents were from sites involved in dispensing drugs used for clinical research, with pharmacies at larger hospitals being more likely to dispense investigational drugs than pharmacies at smaller hospitals. The pharmacies participated in a mean 51 active protocols for every full-time-equivalent employee budgeted to research protocols. The correlation between staffing level and number of protocols was high. The service provided most often was the maintenance of drug accountability records for study drugs dispensed to inpatients and outpatients. There was wide variation in the types of services provided to researchers by the pharmacies. Basic services, such as dispensing and inventory control, were provided by nearly all the pharmacies, whereas more-specialized services tended to be provided more often at institutions more heavily committed to research.

Pharmacy-based investigational drug services at hospitals affiliated with teaching institutions offered basic services, such as dispensing and inventory control, the most often was the maintenance of drug accountability records for study drugs dispensed to inpatients and outpatients. There was wide variation in the types of services provided to researchers by the pharmacies. Basic services, such as dispensing and inventory control, were provided by nearly all the pharmacies, whereas more-specialized services tended to be provided more often at institutions more heavily committed to research.

Index terms: Administration; Clinical studies; Computers; Data collection; Documentation; Drugs, investigational; Economics; Marketing; Personnel, pharmacy; Pharmaceutical services; Pharmacists, hospital; Pharmacy, institutional, hospital; Quality assurance; Workload

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Pharmacy-based investigational drug services traditionally have been established in institutions that participate heavily in medical research so that pharmacy and the institution can manage the dispensing and use of investigational drugs. This allows for proper control and documentation of medication use and distribution and adequate dissemination of important information to physicians, nurses, pharmacists, and other members of the health care team. In the 1990s, in large part because of the many new drugs discovered or created through biotechnology, investment in medical research expanded, and many more institutions and private practitioners now participate in medical research. At the same time, study designs have become more complex, in the hopes of producing results in a shorter time and bringing new drugs to market faster, to maximize the return from the time and dollars invested in research.

Because federal regulation assigns responsibility for managing investigational drugs and devices to the in-
Investigational drug services

The Issues in Clinical Research series is edited by Maurice C. Lunik, M.S., Clinical Research Administrator, U.S. Affiliate Medical Division, Eli Lilly and Company, Indianapolis, IN, and former Investigational Drug Studies Coordinator, Pharmacy Service, SLU Care, The Health Service Division of Saint Louis University, St. Louis, MO. Articles in the series were originally presented at the ASHP Annual Meeting, Minneapolis, MN, June 3, 1997.

The practice of investigational drug services has evolved from that presented at the ASHP Annual Meeting, Minneapolis, MN, June 3, 1997. This evolution has been driven by the recognition and the development of pharmacy practice. The terms biotechnology, recombinant DNA technology, gene therapy, molecular biology, and cloning were originally presented at the ASHP Annual Meeting, Minneapolis, MN, June 3, 1997.

Since then, numerous developments in pharmaceutical services, clinical research, new drug development, and regulations have influenced the way pharmacy practice is practiced. The terms biotechnology, recombinant DNA technology, gene therapy, molecular biology, and cloning were foreign to most pharmacists only a few years ago.

The trend toward shorter hospital stays and the shift of patient care to alternative settings have reduced the number of days a patient might be available to a hospital to participate in clinical research. Third-party payers’ policies on reimbursement for research-related costs have made recruitment of research subjects more complex. It is usually not permissible to charge third-party payers for administering and monitoring investigational therapies.

A new survey of investigational drug services was undertaken in 1997 to provide a picture of the current status of pharmacy-based investigational drug services and to determine ways in which some institutions have adapted to recent changes that may affect the way research is conducted.

Methods

A survey containing 99 items, divided into 10 sections, was formulated. Drugs in research protocols were defined as drugs supplied specifically for research and not paid for by patients or insurance. Pharmacy participation in studies was defined as pharmacy or the investigational drug service handling the dispensing of drugs in research protocols, inventory control, ordering, and other such activities.

The survey was sent in February 1997 to the attention of the pharmacy director at 1495 institutions by using a mailing list obtained through Medical Marketing Service Incorporated of Wooddale, Illinois. The mailing list included the results of a search of an American Hospital Association membership database for all U.S. hospitals affiliated with a teaching institution as of January 1997. No follow-up mailing was sent.

The data were originally entered into a spreadsheet (Lotus 1-2-3 Release 4 for Windows, Lotus Development Corp., Cambridge, MA) for administrative purposes. Later, these data were transformed into SPSS database format for statistical analysis. The reliability and accuracy of the data were checked at the end of transformation. A simple statistical check for outliers yielded no unusual values.

Means are reported with standard deviations whenever appropriate. In addition, a 95% confidence interval is provided for every estimate of population mean. The Pearson correlation statistic, along with p value, is used to describe the degree of relationship between two continuous variables. When appropriate, data obtained in this survey were compared with data obtained in 1991.

Results

Of the 1495 surveys sent, 320 (21%) were returned with usable responses. This response rate is substantially lower than that for the survey conducted in 1991, although the total number of responses was similar.

Workload. Out of 312 respondents, 211 (68%) reported that their sites were involved in dispensing drugs used for clinical research. Respondents were equally distributed among small, medium-sized, and large hospitals: 100–108 respondents apiece. Among small institutions (fewer than 200 beds), 30 sites (30%) dispensed investigational drugs; these sites participated in an average of 28 (range, 0–150) studies. Among medium-sized institutions (200–400 beds), 68 sites (63%) dispensed investigational drugs, participating in an average of 39 (1–200) studies. Among large institutions (more than 400 beds), 88 sites (86%) dispensed investigational drugs and participated in an average of 69 (2–750) studies. Out of the 211 sites involved in dispensing investigational drugs, 14% were small hospitals, 32% were medium-sized hospitals, and 42% were large hospitals. Hospital size was not reported for 25 (12%) of the sites involved in dispensing drugs for research protocols.

The mean number of protocols was greater in the medium-sized and large hospitals, compared with the 1991 survey (28 and 54, respectively). In general, study openings and closings per year (based on 1996 figures) and investigational drug doses prepared per month (for the most recent three months) tended to increase with hospital size and number of active studies. Overall workload related to the dispensing of investigational drugs is reported in Table 1. At the 107 sites that budgeted for pharmacist hours in support of research protocols, the pharmacist worked a mean 37.8 hr/wk; at the 45 sites that budgeted for technician hours, the technician worked a mean 34.1 hr/wk; at the 9 sites that budgeted for secretarial support, the secretary worked a
mean 22.8 hr/wk; and at the 13 sites that budgeted for other support, the person worked a mean 24.5 hr/wk.

A starting point for determining staffing levels is the average number of protocols that can be managed by one full-time-equivalent (FTE) employee. On the basis of the 120 respondents who provided sufficient information, pharmacies that dispense investigational drugs in hospitals affiliated with teaching institutions participated in a mean 51 active protocols for every FTE employee budgeted to research protocols, a level in line with the average of 52 protocols per FTE suggested in 1987 by Ryan et al. The correlation of staffing level to number of protocols was high ($r = 0.791$, $p < 0.01$). The actual number of protocols that can be managed by an FTE may vary according to many factors, including the complexity of the protocols, the degree of pharmacy involvement in the protocols, the types of staff that the pharmacy uses to manage these protocols, and how experienced those staff members are in handling research protocols.

**Inpatient and outpatient pharmaceutical services.** The service provided most often was the maintenance of drug accountability records for study medications dispensed to inpatients and outpatients (Table 2). Out of 197 respondents, 162 (82%) always used a satellite location, not the primary area where the drug was originally received, for the maintenance of these records on inpatients. A majority (85%) of the respondents reported that inpatient pharmacists at their institution are always supplied with dispensing procedures, and 13% reported that the dispensing procedures are sometimes supplied. A drug monograph or drug data sheet on drugs not available on the U.S. market were the least used method for distributing drug information on inpatient study drugs (Table 3).

Some 70% of investigational drugs for inpatient studies were dispensed from a centralized pharmacy, 10% from a satellite pharmacy, 18% directly from an investigational drug service area, and 2% from stock stored on a unit (including automated dispensing machines). At three hospitals, physicians dispensed directly to the patient or inpatient unit. A majority (68%) of investigational drugs for inpatient studies were dispensed by staff pharmacists, 30% by the investigational drug service staff, and 2% by other staff members (research nurses, clinical pharmacists, and inpatient nursing staff). According to the survey, 84% of institutions reported always dispensing an outpatient investigational drug pursuant to a written prescription. On the basis of 158 responses, 27% of investigational drugs for outpatient studies were picked up by the patient at an outpatient pharmacy, 16% were prepared and dispensed by a physician in a clinic, 13% were dispensed directly from the investigational drug service area, 40% were prepared by the investigational drug service but dispensed by a physician or a nurse directly to the patient, and 3% were dispensed by other means, including through an inpatient pharmacy, mail order, or a home care agency.

**Pharmacy Workload**

Inpatient pharmacists at 98% of institutions reported that inpatient pharmacists at their institution are always supplied with dispensing procedures, and 13% reported that the dispensing procedures are sometimes supplied. A drug monograph or drug data sheet on drugs not available on the U.S. market were the least used method for distributing drug information on inpatient study drugs (Table 3).

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Outpatient pharmacists at 98% of institutions reported that inpatient pharmacists at their institution are always supplied with dispensing procedures, and 13% reported that the dispensing procedures are sometimes supplied. A drug monograph or drug data sheet on drugs not available on the U.S. market were the least used method for distributing drug information on inpatient study drugs (Table 3).

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Pharmacies were the initial dispensing site for 98% of outpatient investigational drugs and 81% of outpatient investigational drugs. In the 1991 survey, 83% of the institutions reported that they require that the dispensing of investigational drugs be controlled by the pharmacy department; however, that survey did not distinguish between inpatient and outpatient dispensing.

Table 4 shows the percentage of sites that reportedly offer special investigational drug services and the frequency of these services on the basis of the number of respondents whose institution provides the service.

### Table 1.

**Workload at Hospital Pharmacies That Dispense Investigational Drugs**

<table>
<thead>
<tr>
<th>Workload Measure</th>
<th>Pharmacy Workload</th>
<th>Mean ± S.D.</th>
<th>Minimum/Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study activity in 1996</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study openings</td>
<td>183</td>
<td>17 ± 22</td>
<td>0/750</td>
</tr>
<tr>
<td>Study closings</td>
<td>182</td>
<td>13 ± 21</td>
<td>0/165</td>
</tr>
<tr>
<td>Inpatient doses prepared per month*</td>
<td>175</td>
<td>24 ± 67</td>
<td>0/700</td>
</tr>
<tr>
<td>Cancer chemotherapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drugs for injection, not for chemotherapy</td>
<td>175</td>
<td>40 ± 97</td>
<td>0/910</td>
</tr>
<tr>
<td>Drugs not for injection, not for chemotherapy</td>
<td>175</td>
<td>82 ± 505</td>
<td>0/6,000</td>
</tr>
<tr>
<td>Total</td>
<td>175</td>
<td>146 ± 584</td>
<td>0/7,000</td>
</tr>
<tr>
<td>Outpatient doses prepared per month*</td>
<td>175</td>
<td>19 ± 51</td>
<td>0/400</td>
</tr>
<tr>
<td>Cancer chemotherapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drugs for injection, not for chemotherapy</td>
<td>175</td>
<td>11 ± 44</td>
<td>0/500</td>
</tr>
<tr>
<td>Drugs not for injection, not for chemotherapy</td>
<td>175</td>
<td>127 ± 474</td>
<td>0/5,000</td>
</tr>
<tr>
<td>Total</td>
<td>175</td>
<td>157 ± 514</td>
<td>0/5,470</td>
</tr>
<tr>
<td>Total investigational drug doses prepared per month*</td>
<td>175</td>
<td>303 ± 1040</td>
<td>0/12,470</td>
</tr>
<tr>
<td>Staff hours budgeted to be worked per weekb</td>
<td>36.6 ± 159.5</td>
<td>0/220</td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technician</td>
<td></td>
<td>18.1 ± 99.7</td>
<td>0/120</td>
</tr>
<tr>
<td>Secretarial</td>
<td></td>
<td>1.4 ± 10.7</td>
<td>0/120</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>2.2 ± 11.3</td>
<td>0/100</td>
</tr>
</tbody>
</table>

*On the basis of the most recent three months.

bThe survey asked for a breakdown by dispensing versus clinical hours; however, this was inconsistently completed by respondents. "Other" reflects residents and fellows, nurses, or other personnel working for the investigational drug service. Mean hours reflect overall mean across all sites reporting the use of designated staff for investigational drugs.
Out of 211 respondents, 149 (71%) reported at least one of the special services listed in the table. Other special services reported include budget consulting, chemical analysis of drugs, laboratory monitoring and dosage adjustments, design of study-specific computer order-entry screens, investigational new drug applications, pharmacokinetic studies, and matching of potential investigators with studies. According to the survey data, 35 (17%) of the 211 sites had instituted a protocol for gene therapy. Pharmacy was involved at 10 (29%) of the 35 sites, and 3 of these sites had purchased special equipment for handling products used in gene therapy.

**Marketing of services.** Respondents from 132 sites reported some form of marketing, representing about 63% of the sites involved in dispensing investigational drugs. This is up from 31% of respondents in the 1991 survey, although this change could partly reflect differences in how the question was presented in the survey rather than a change in practice.

Among the sites with some method of promoting the service to investigators, the most common method (85% of these sites) was a policy that required the pharmacy to be contacted before submission of the protocol to the institutional review board (IRB) or during its deliberation. The next most popular form of marketing was a brochure or informational pamphlet or mailing about the service, as reported for 26% of sites (compared with 25% in the 1991 survey). Respondents at several sites (26%) also reported having made contact with sponsors or other sources for the purpose of recruiting new studies to the institution (this question was not asked in the 1991 survey). Lectures, presentations, or grand rounds having to do with investigational drug services were conducted at 17% of these sites (compared with 10% in the 1991 survey). Some 7% of sites used other forms of marketing, such as a newsletter or a column in a newsletter, or assistance in the recruitment of study subjects through commercial advertising.

**Quality assurance.** One method for monitoring compliance with hospital policy and federal regulations as well as assessing quality of service is to implement quality assurance (QA) activities. Some 128 (67%) of the 191 respondents reported that the pharmacy perform routine QAs covering study drug dispensing or related activities, an increase from the 1991 survey (59%). A physical count of the drug compared with the documented balance on the drug accountability record was reportedly performed regularly at 93% of the sites, with 42% monitoring the record monthly (the most frequent interval reported). Also, 93% reported regularly checking the storage temperature of the drugs, with 66% monitoring it daily (the most frequent interval reported). Prescription accuracy was monitored at...
72% of the sites, with 65% monitoring it daily (the survey item did not differentiate random checks of prescriptions from routine pharmacist check before dispensing). Half the sites had someone check the consent form for the patient’s signature, with a majority of those sites checking the form with every new enrollment; 5% of the respondents reported that the investigational drug service administers user-satisfaction surveys.

The survey inquired about which committees receive reports on the QA monitors; 67% of the respondents said their site’s internal pharmacy committee received the reports, 48% that a hospital or multidisciplinary QA committee received the reports, 31% that the pharmacy and therapeutics (P&T) committee received the reports, and 25% that the IRB or human subjects committee received the reports. A majority of sites reported the QA results at least monthly, except for the hospital or multidisciplinary QA committee, to which QA results were most often reported quarterly.

A limited number of additional QA activities were described by respondents. These activities included verifying drug information in the patient’s chart, monitoring the log of returned doses, and quizzing pharmacists to ensure that they understand the study.

**Committee involvement.** The respondents were asked whether a pharmacist serves on the IRB; out of 202 total responses, 169 (84%) were yes. During 1996, respondents’ IRBs reviewed a mean ± S.D. 178 ± 256 protocols (range, 0–1739; 95% confidence interval [CI], 135–221), with 89 ± 117 of the protocols involving drugs (range, 0–602; 95% CI, 69–108).

The role of the P&T committee as it applies to investigational drugs is not clear, although many have taken the stance that the committee should at least be aware of which investigational drugs are used within the institution. At the 139 institutions where respondents reported that the P&T committee received information about investigational drugs, the most common information reported was adverse reactions involving study medications, followed by general information about protocols being conducted (Table 5).

A total of 61 respondents (31% out of 199 who answered the question) reported having a general clinical research center (GCRC; sponsored by the National Institutes of Health) or similar unit in their institutions; out of these, 25 (41%) reported having a pharmacist involved in the center’s scientific advisory committee, which reviews protocols on the basis of their scientific merit and may be responsible for allocation of resources as well. In addition, because of the intensive research that commonly goes on in a GCRC, the respondents were asked how study medications were most commonly dispensed to the patients in the GCRC. The most common source was the hospital’s inpatient pharmacy (55% of responses), while 16% of the respondents reported that a satellite pharmacy handled this function. Other sources, such as an investigational drug service or a nonpharmacy source, were the most common points of dispensing at 28% of these institutions.

### Funding sources. The survey respondents were given several choices for possible sources of revenue and were asked to what extent each was used to fund...
pharmacy costs associated with research. The “average” pharmacy participating in the survey received half its study-related revenues through fees charged to investigators (usually reimbursed through the fund the investigator receives from the sponsor) (Table 6). Approximately one third of costs were labeled as “absorbed,” meaning that they were not reimbursed and instead were covered by the institution as part of the cost of participating in a research program. Each of the choices, aside from “other” (a miscellaneous category for other income sources), was used as the single source of revenue for at least one institution in the survey. Of note, about 10% of funding came from core grants, which generally are written to cover the overall expenses of a research institute such as a comprehensive cancer center (sponsored by the National Cancer Institute) or a GCRC and include the costs of personnel and materials dedicated to carrying out research. In general, these core grants have limited discretionary funds; most costs must be budgeted in advance and are not earmarked for a specific research protocol.

Respondents from institutions that receive funds through fees charged to investigators or departments were asked to estimate what portion of those fees were actually received as payments (e.g., through cost transfers, actual checks received). Of fees charged to investigators, a mean ± S.D. 86 ± 27% of the fees were actually received as payments (range, 0–100; 95% CI, 81–91%); of fees charged to departments within the institution, a mean 67 ± 42% was actually received as payments (range, 0–100; 95% CI, 54–80%).

Last, respondents were asked which, if any, of three measures were taken to ensure that pharmacy costs were written into study budgets. On the basis of these responses, 23% of sites had an institutional policy that requires pharmacy reimbursement, 47% of sites required contact with the pharmacy as part of protocol submissions to the IRB, and at 14% of sites the accounting department, Office of Clinical Trials, or another department or office outside of pharmacy helped in this effort. At 35% of sites, respondents reported that pharmacy costs were not routinely budgeted or did not need to be budgeted; this may apply to situations in which pharmacy costs for research are absorbed by the institution or are covered by other means, such as a core grant or school or university funding. Information on other methods was collected; however, the responses to this survey item varied widely, and no other single method was reported with any consistency.

**Computerization.** The survey inquired whether sites had computerized inventory control or accountability and billing and, if so, what software program they used. Respondents not using computers for these functions and not planning to use computers in the next 12 months were instructed not to provide answers. Out of 59 responses, 28 respondents reported that their sites were currently using a computer program for inventory control and accountability and 33 that their sites were considering implementing such a program in the next 12 months (2 respondents selected both options). The software programs used varied so widely, including both purchased software and systems developed inhouse, that no program could be reported with any meaningful frequency.

Of the 73 responses received about computer programs used for billing or invoicing, 56 respondents reported having their billing computerized and 19 reported that they were considering implementing a computerized billing program in the next 12 months. Again, many different software programs were used, including business-accounting packages, spreadsheets, and databases; no single program was reported with any meaningful frequency.

**Educational activities.** Out of 211 respondents, 6% reported that their institutions offer pharmacy student clerkships in investigational drugs and 14% that they offer pharmacy resident rotations. The mean ± S.D. duration of a student clerkship was 4.1 ± 1.8 weeks.

### Table 6.
**Sources of Funding Used To Support Investigational Drug Services**

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>% Funding Provided by Source</th>
<th>Mean ± S.D.</th>
<th>Minimum/Maximum</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fees charged to investigators</td>
<td>50 ± 39</td>
<td>0/100</td>
<td>45–56</td>
<td></td>
</tr>
<tr>
<td>Hospital support provided or costs absorbed</td>
<td>31 ± 38</td>
<td>0/100</td>
<td>25–37</td>
<td></td>
</tr>
<tr>
<td>Salary support provided through a core grant</td>
<td>7 ± 17</td>
<td>0/100</td>
<td>4–9</td>
<td></td>
</tr>
<tr>
<td>Fees charged to departments</td>
<td>5 ± 14</td>
<td>0/100</td>
<td>3–7</td>
<td></td>
</tr>
<tr>
<td>Block funding provided through a core grant</td>
<td>4 ± 17</td>
<td>0/100</td>
<td>1–6</td>
<td></td>
</tr>
<tr>
<td>Salary support obtained from a school or university</td>
<td>2 ± 11</td>
<td>0/100</td>
<td>1–6</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1 ± 10</td>
<td>0/90</td>
<td>0–3</td>
<td></td>
</tr>
</tbody>
</table>

*Fees charged to investigators are fees actually billed to the investigator, whether they are paid or not. Salary support through a core grant reflects monies designated in an NIH core grant or a similar grant. Fees charged to departments are fees billed to whole departments and often may represent a cost transfer from one department to another rather than an actual exchange of money. Block funding from a core grant differs from salary support only in that funds may be designated in the grant to pay for a full research satellite pharmacy; in some cases an entire institution may be dedicated to research and the bulk of funds supporting the pharmacy may come from a core grant. Salary support from a school or university generally refers to school faculty or positions partly funded by a school or university, whereas the investigational drug service performs both a teaching role and a research role.

*bCI = confidence interval.*
(range, 1–6; 95% CI, 3.1–5.3) and of a resident rotation, 3.6 ± 1.7 weeks (range, 0–8; 95% CI, 2.7–4.5).

Discussion

The development in recent years of new classes of drugs and new methods of creating drugs, as well as new regulations and guidelines related to research, has produced an evolution in the way in which research is performed in the United States and in the role pharmacists play in carrying out research. There is still wide variation in the types of services that pharmacies provide or are able to provide for researchers, although the basic services of dispensing and drug accountability are provided uniformly by nearly all institutions that participate in research. As more therapies that once required a hospital stay are able to be administered in alternate-site settings, more research will flow to these settings, possibly involving clinicians who are unfamiliar with the requirements for carrying out research. Assisting with research in the alternate-site setting is an important role for pharmacists and is likely to continue to expand in the years ahead. The setting for drug dispensing in outpatient studies may be one factor that affects whether outpatients receive supplies of investigational drugs pursuant to a written prescription. Supplies may be dispensed from an inpatient or outpatient pharmacy, a physician’s office, or an ambulatory care clinic for ambulatory use, or from any of these settings for administration directly to the patient onsite; these were not distinguished in the survey responses, and thus responses to the outpatient section of the survey may reflect all these settings. Computer systems that allow for recording, transmission, and monitoring of study data have been developed for investigators and study coordinators and are already being used by some groups; however, such systems are far from standard in pharmacies, where there is wide variation in the types of systems used and the functions these systems perform. This is another area for growth, although the timetable for availability of such systems cannot be predicted yet. Some investigational drug services are using an intranet9 or the Internet10 to disseminate information.

At institutions where medical research is conducted, there may be several committees that evaluate the merits of this research, approve the use of the institution’s resources, or protect the subjects who participate in the research. Some of these committees play key roles in the conduct of research; thus, pharmacists who dispense investigational drugs should be aware of the committees and become involved when possible. The survey did not cover the extent to which the P&T committee can influence which studies are conducted; however, this topic should be addressed in future research. Because some research protocols use products available on the U.S. market for indications in the FDA-approved labeling, a P&T committee might interpret those protocols as marketing plans for introducing the drugs into institutions at which the drugs have not yet been added to the formulary.

The survey was not worded in a way that could enable specific determination of the effect of a policy requiring that pharmacy be contacted before or while the IRB considers approval of a protocol. Such a policy might result in more investigators turning over control of outpatient-study drugs to the pharmacy or might simply allow the pharmacy to better prepare itself for assisting with new studies. This survey item was phrased differently in the 1991 survey, in which 77% of the sites reported that the pharmacy learned of new protocols through referrals by an office or committee (e.g., budget office, IRB).

A less common QA activity that was not specifically included in the survey but has been described elsewhere11 is the monitoring of investigational drugs not dispensed from the pharmacy. This activity will become more common as medical centers continue to become parts of expanding health systems and institutional pharmacies take on expanded roles in the management of ambulatory patients.

With cost containment being a critical activity at health care institutions, it is more important than ever for pharmacists to justify the time they spend managing research protocols. In some research-intensive institutions, dispensing investigational drugs may be considered an integral part of the pharmacy’s function. Alternatively, many institutions expect the pharmacy to generate revenues to cover the costs associated with dispensing investigational drugs. Revenue may be generated through, for example, salary support for pharmacy staff or funds written into individual study budgets. Most privately sponsored research allows for at least some pharmacy costs to be written into the budget that is part of the contract between the private sponsor and the investigator or institution.

There are several possible reasons for the low response rate to our survey:

- The length of the survey may have been prohibitive for some recipients;
- The survey was sent only to the attention of pharmacy directors, whereas the 1991 survey was addressed to specific pharmacists whenever possible;
- Organizational structures are changing in ways that might affect how hospitals are classified compared with 1991 (e.g., mergers and affiliations with teaching institutions), and thus institutions that would not have been included in the 1991 survey may have been included in the current survey; and
- Directors of pharmacies not involved in dispensing investigational drugs might not have bothered sending in only demographic information.

Conclusion

Pharmacy-based investigational drug services at hospitals affiliated with teaching institutions offered basic services, such as dispensing and inventory control,
almost universally and offered specialized services to varying degrees.

References