ABSTRACT In March 2001, a survey of more than 85 academic health centers was conducted to investigate the activities, staffing, and financing of investigational drug services (IDSs). The results were presented in summary form at the University HealthSystem Consortium Pharmacy Council Meeting in New Orleans, Louisiana, on December 1, 2001. The following trends were noted: (1) IDS activities continue to expand in academic health centers, with 87% of respondents indicating dedicated positions; (2) institutional investment is needed to subsidize IDS activities, because only 29% of institutions cover IDS salary expenses; (3) IDSs are understaffed at many institutions, with 62% of respondents indicating only one dedicated IDS full-time equivalent, despite an average of 100 ongoing study protocols; (4) improved communication linkages are needed between the P&T committee, the institutional review board (IRB), and IDS; and (5) systemwide computerization of IDS functions is not common (less than 29%).

INTRODUCTION

The University HealthSystem Consortium (UHC) is an alliance of more than 85 academic health centers dedicated to strengthening the market position of its members. The UHC’s objectives are to pool resources, create economies of scale, improve clinical and operating efficiencies, and influence the direction and delivery of health care (see www.uhc.edu). As such, several councils and committees study the efficient and appropriate use of clinical resources. The Pharmacy Research and Education Committee acts as a central coordinating body for the development of effective pharmacy-coordinated investigational drug services, promotes practice-based outcomes research, supports programs aimed at the professional education and development of pharmacy personnel, and facilitates institutional relationships with colleges of pharmacy. For the year 2001, one of the committee’s objectives was to examine investigational drug services (IDSs).

In light of the importance of pharmacy’s role in developing and staffing an IDS,1 the American Society of Health-System Pharmacists (ASHP) has published extensive guidelines on the role of the pharmacist in clinical drug research.2 With appropriate support and planning, the financial and informational barriers to the successful implementation of an IDS can be overcome,2–8 even in a rapidly changing pharmaceutical research environment.9,10 This report provides an update on IDS activities in U.S. academic health centers.

Descriptive studies of pharmacy-based IDSs have been published.11,12 In 1993, Rockwell et al. surveyed 765 teaching hospitals and received responses from 393. These investigators found that 37% of hospital pharmacies had formal IDS activities with an average of 46 ongoing studies. Investigational drug dispensing, storage, and labeling were major services provided (more than 70%). Only 23% of respondents reported funding self-sufficiency for the IDS, and 50% used computers.11

In 1997, the Rockwell group conducted a more ambitious survey (99 items of interest) and received responses from 320 of 1,495 teaching hospitals. Pharmacy participation in clinical research had increased to 68%, and an average of 46 ongoing studies. Investigational drug dispensing, storage, and labeling were major services provided (more than 70%). Only 23% of respondents reported funding self-sufficiency for the IDS, and 50% used computers.11

In March 2001, an electronic survey was sent to 85 UHC member hospitals; two email reminders were later sent to maximize the response rate. Overall, 46 usable responses were received (a 54% response rate) from a broad geographical distribution of academic health centers. Data from the 20-question survey were entered into an Excel spreadsheet for analysis.
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RESULTS

Most institutions have a dedicated position for IDS (87%), with space and facilities dedicated to a pharmacy department (89%). Pharmacy’s satisfaction with institutional support for IDS is substantial (67%). External IDS funding is used by 37% of respondents. One method that is used to generate support for IDS services, whether or not a dedicated position exists, is the use of fees, with almost universal acceptance (98%) of this strategy. Although these fees are intended to cover IDS salary expenses in most institutions (84%), they do so in only 29% (11 of 27 respondents). This percentage is comparable with previous survey results.

The following IDS activities have been performed most frequently at the 46 responding institutions:

- maintaining investigational drug inventory (98%
- storing drugs (96%)
- preparing and delivering drugs (93%)
- performing study randomization (93%)
- developing procedures with investigators (89%)
- preparing placebos (85%)
- developing drug information sheets (76%)
- consulting on study designs (72%)
- serving as a member of the institutional review board (72%)
- serving as a teaching and training resource (65%)
- developing consent forms (24%)
- acting as independent reviewers of clinical trials (22%)

Compared with the results of previous surveys, the present list shows a progression and an increase in commonly performed IDS activities. Although 30 pharmacy departments (65%) indicated that they participated in the review of institutional clinical trials, only six stated that their P&T committee also participated. In addition, only 13 of 45 (29%) institutions reported having a computerized record-keeping system to manage clinical trials. This low level of automation creates barriers for broader awareness among pharmacy clinicians and their participation in clinical research activities. Previous survey results that reported higher computerization levels may have captured basic pharmacy information systems functions that are not necessarily dedicated to IDS.

Pharmacist representation on the institutional review boards is high (91%), with a reported attendance at 72% of all scheduled meetings. Pharmacist FTEs dedicated to the investigational drug process were as follows: one FTE (62% of respondents), two to three FTEs (22%), no FTEs (9%), and four to five FTEs (7%); most institutions had more than 100 protocols under IDS management.

DISCUSSION

A pharmacy-supported, dedicated IDS provides many services that ensure patient safety and reduce the risk of adverse events during clinical drug trials. These services include:

- serving as the primary drug information resource for the research community and patient-care professionals.
- reviewing research protocols as a participant on the institutional review board.
- coordinating accurate protocol data collection and documentation, timely and accurate dispensing of drugs, and inventory management/accountability.
- ensuring that investigational drugs are used according to approved protocol guidelines.

In addition, the IDS should provide economic benefits to the sponsoring health care organization. These benefits include (1) cost avoidance through the use of free or alternative Investigational New Drugs (INDs) in place of commercially purchased medications, (2) an enhanced ability of investigators to attract research grants to the institution, and (3) supplementary service revenues to the pharmacy department to support IDS operations.

In large institutions, the IDS potentially enables cost avoidance in the range of hundreds to thousands to millions of dollars per year. At the University of Washington and at Harborview Medical Center, cost avoidance from IDS activity was estimated at more than $1.1 million and $1.77 million, respectively, in fiscal 1997.3

A well-run IDS can be beneficial in attracting new research to the institution. The IDS pharmacist, serving as an unblinded investigator in pivotal trials for new agents, ensures proper record-keeping and accurate dispensing and often plays a major role in the success of a complicated trial at the institutional level. In turn, a poorly run operation at the pharmacy level can sabotage trial results and cost sponsors millions of dollars as a result of:

- study subjects who have been disqualified or lost to follow-up.
- trial management inefficiency.
- expanded enrollment targets or additional new sites to meet enrollment.
- increased risk of legal liability.

In addition to enhancing the institution’s ability to attract industry-sponsored trials, a well-run IDS with a wide range of services also enhances the ability of investigators to attract private and government grants. For example, an IDS with experience and expertise in areas such as special packaging, compliance monitoring, IND submissions, formulation development, analysis of laboratory test results, and coordination of dispensing activities across multiple locations gives the investigator an edge over rivals at other institutions.

CONCLUSION

The IDS survey of academic health centers conducted in 2001 revealed the following:

- IDS activities continue to expand in a growing number of institutions.
- Further institutional investment is needed to subsidize IDS activities that generate considerable noneconomic value but that may never break even using fee structures alone.
- Understaffing of FTEs is common at many institutions; for example, an average of 100 protocols would suggest an average of at least two IDS-dedicated FTEs. (Most institutions have only one dedicated position.)
- Greater linkages are needed between P&T committees and institutional review boards to improve communications at most institutions.
- Systemwide computerization of IDS functions is not yet common.
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Finally, the UHC Pharmacy Research and Education Committee recommends more research to promote standards and relative weights for IDS activities to effectively compare IDS resources and needs in the future.

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