

ASHP

Restricted Drug Distribution System Survey

March 2007

The American Society of Health-System Pharmacists (ASHP) recently administered an online survey to pharmacy department directors to learn more about their experiences with restricted drug distribution systems (RDDS). Members of the ASHP Pharmacy Practice Managers Section and the Informatics Section were invited to participate via an email invitation. Five hundred and twenty-one responses were received. Responses were received from 49 states.¹ Overall, survey findings indicate that access and continuity of care problems do exist with RDDS drugs in hospitals and health-systems. The findings also indicate that respondents believe that it is possible to improve these programs. Survey results are summarized below:

Respondents were asked to indicate which RDDS drugs are prescribed for patients seen at their hospital or health-system. The top 10 drugs and RDDS programs identified by respondents included:	
Clozaril (<i>clozapine</i>): Clozaril National Registry Program	66%
Thalomid (<i>thalidomide</i>): S.T.E.P.S. Program	46%
Tikosyn (<i>dofetilide</i>): T.I.P.S. Program	45%
Accutane, Amnesteem, Claravis, Sotret (<i>isotretinoin</i>): iPLEDGE Program	30%
Aralast, Prolastin, Zemaira (<i>alpha-1-proteinase inhibitor</i>)	29%
Fosamax (<i>alendronate</i>): Paget's Patient Support Program	29%
Tysabri (<i>nataluzimab</i>): TOUCH Prescribing Program	26%
Tracleer (<i>bosentan</i>): Tracleer Access Program (TAP)	25%
Suboxone (<i>buprenorphine</i>)	17%
Iressa (<i>gefitinib</i>): Iressa Access Program	16%
Total Responses: 521	

Continuity of Care Respondents were asked to indicate whether RDDS programs compromise continuity of care. Of responses, 82% indicated that continuity of care is compromised either occasionally (62%) or frequently (20%). Respondents were asked to provide more details regarding their answer:

"Patients are ready to be infused but the drug is not here. Patients have to read a pamphlet on tysabri each time before we start preparation of the product. It takes 1-2 months to enroll patients in some of these programs." **(Tennessee Member)**

"Programs that restrict distribution through specialty pharmacies frequently cause interruptions in drug therapy when a patient changes level of care (from outpatient to nursing home or hospital). These programs are typically focused on outpatients only and have given little or no consideration to what happens when the patient becomes an inpatient. We recently had an Exjade patient entering a nursing home go without medication for over a week because of the poor RDDS program". **(Ohio Member)**

If I need it, I need it now. With a short stay, getting the drug in a reasonable time is critical. May cause the patient to miss an important medication or require us to transfer to a major hospital when it could have been easily done at our hospital. **(North Carolina Member)**

¹ Invitations were sent to 3,389 ASHP members. The survey was fielded February 27, 2007 through March 5, 2007 (with one reminder to nonrespondents).

Timely Access Respondents were asked whether or not RDDS programs they encounter compromise timely access to the drug. Of those responding, 90% stated that RDDS programs either occasionally (67%) or frequently (23%) compromise timely access.

Improving Programs The survey also asked members to indicate whether or not they think it is possible to simplify and improve RDDS programs. Of respondents, 56% indicated 'Yes', 4% indicated 'No', and 40% indicated 'Don't Know'.

Respondents were asked to provide details regarding their answer:

"Standardize process/procedures for obtaining approvals - 1 website, 1 phone number. Allow purchase through standard wholesaler if basic criteria are provided (like IPledge)."

(Illinois Member)

"Would prefer to work with one agency that handled all RDDS drugs rather than go through the hassle of enrolling with each one separately. Can be confusing, especially for pharmacy/nursing/medical with multiple sources for these medications and different processes."

(New Hampshire Member)

"It would be nice to have one central contact for these items instead of having to call multiple places to even find out where to order them."

(Washington Member)

Respondents were also asked to indicate whether or not it is possible to standardize some aspects of RDDS programs in order to reduce burden and simplify administration of such programs. Of respondents, 67% indicated 'Yes', 5% indicated 'No' and 28% indicated 'Don't Know'.

Respondents were asked to provide their thoughts regarding how standardization could work. Some respondents stated:

"Universal patient enrollment forms (or website) would be a good start."

(Georgia Member)

"Single reporting form and standardized reporting intervals to a centralized agency would be an improvement. It is a paperwork nightmare to have a different program for every drug, with different rules and a different file and a different place to report."

(Ohio Member)

"Much as ADR & Medication Error Reporting has moved toward improved standardization, the FDA could preside over this with each manufacturer in order to govern standardization to the extent possible. This could result in several "models" or formats, not to exceed TEN, that the RDDS should need to fall into."

(New York Member)

Additional Findings

- Sixty-eight percent of respondents believe that RDDS programs are necessary in some circumstances in order to protect patients from risk.
- Seventy-five percent of respondents indicated that their hospital or health-system is registered to dispense products for one or more RDDS programs.

- Twenty-two percent of respondents indicated that RDDS drugs are prescribed in their setting one time a week or more, and 36% indicated that these drugs are prescribed at least two times a month.
- Seventy-nine percent of respondents believe that practicing hospital and health-system pharmacists' input into the development of RDDS programs would yield better programs.

Conclusion Pharmacy department managers responding to this survey generally support the need for RDDS programs when necessary to protect patients from heightened risk associated with a particular drug. These programs however do present challenges in the hospital and health-system setting that must be considered. Timely access to drugs for patients and care continuity are just two areas that are either frequently or occasionally a problem. Most respondents believe that RDDS programs can be improved and standardized, and that pharmacists' input into the development of such programs would improve them.