Implementation of a drug-use and disease-state management program

SUSAN J. SKLEDAR AND MARY M. HESS

Over the past decade, the health care environment increasingly has focused on efficiency and productivity, with emphasis on improved outcomes. As part of this, each year at the University of Pittsburgh Medical Center-Presbyterian (UPMC-Presbyterian), the pharmacy department was faced with making multimillion dollar decreases in its budget. Drug-acquisition costs account for roughly 80% of the department budget. In an effort to decrease drug costs and fulfill the department’s mission to provide optimal pharmacotherapy and promote patient safety, we developed a drug-use and disease-state management (DUDSM) program in 1996. This clinical program provided a systematic, population-based approach for identifying persons at risk, intervening with specific programs of care, and measuring clinical and economic outcomes. This article describes the development of the program, as well as how it has changed over the past four years.

Abstract: A drug-use and disease-state management (DUDSM) program was instituted in 1996 at a teaching hospital associated with a large nonprofit health care system. The program’s goals are to optimize pharmacotherapeutic regimens, evaluate health outcomes of identified disease states, and evaluate the economic impact of pharmacotherapeutic options for given disease states by developing practice guidelines. Through a re-engineering process, resources within the pharmacy department were identified that could be devoted to the DUDSM program, including the use of clinical pharmacy specialists, promotion of staff pharmacists into the DUDSM program, a pharmacy technician, and information systems support. A strength of the program is its systematic approach for developing and implementing new initiatives, as well as monitoring compliance with all initiatives on an ongoing basis. The initiative-design process incorporates continuous quality improvement principles, outcome design and evaluation, competency assessment for all pharmacists, multidisciplinary collaboration, and sophisticated information systems. Seventy-five initiatives have been implemented, ranging from simple dose-optimization strategies for specific drugs to complicated practice guidelines for managing specific disease states. Improved patient outcomes have been documented, including reduced length of stay, postsurgical wound infection, adverse drug reactions, and medication errors. Documented cost savings exceeded $4 million annually for fiscal years 1996–97 through 1999–2000. Overall compliance with DUDSM initiatives exceeds 80%, and physician service profiling has been initiated to monitor variant prescribing. The DUDSM program has successfully integrated practice guidelines into therapeutics decision-making, resulting in improved patient-care outcomes and cost savings.

Index terms: Administration; Clinical pharmacists; Compliance; Computers; Costs; Disease management; Drug use; Drugs, adverse reactions; Errors, medication; Guidelines; Hospitals; Pharmaceutical services; Pharmacists, hospital; Pharmacy, institutional; hospital; Physicians; Prescribing; Professional competence; Protocols; Quality assurance; Surgical wound infection

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Description of health system

The University of Pittsburgh Medical Center Health System (UPMCHS) is one of the largest nonprofit integrated health care systems in the United States, and it is the leading integrated health system in western Pennsylvania. The hospitals of UPMCHS are a comprehensive network of tertiary, specialty, and community hospitals. UPMCHS health-related services include same-day surgery, primary-care and specialist physician practices, long-term care and home care, retirement living options, community-based programs, and a managed-care insurance company.

Affiliated with the University of Pittsburgh Schools of the Health Sciences, UPMCHS is a site of ongoing research and teaching programs. UPMC-C-Presbyterian is a medical and surgical facility on the Oakland campus of UPMCHS. It is a level 1 regional resource trauma center; its specialties include solid organ and bone marrow transplantation, cardiology, cardiothoracic surgery, critical care, sports medicine, trauma, and neurosurgery. The UPMC-C-Presbyterian pharmacy department offers many varied services, including an investigational drug service, drug information and pharmacoepidemiology center, DUDSM program, fully computerized unit-dose and i.v. admixture service, automated dispensing systems, and anesthesiology and operating room satellite pharmacies. Clinical pharmacy services are provided in the areas of critical care, general medicine, infectious diseases, nutrition support, neurosurgery, cardiology, geriatrics, and ambulatory care.

Development of the program

In 1996, the executive administration of UPMC-C-Presbyterian, while feeling the continued pressure to decrease costs, increased emphasis on improving the quality of health care provided. The pharmacy department was charged with reducing the budget from $21 million to $15 million through a combination of operational and clinical initiatives. In conjunction with this, the pharmacy department adopted a continuous quality improvement (CQI) philosophy to guide reduction efforts and improve patient-care services.

While the hospital was in the process of creating physician-directed clinical pathways, emphasis on drug selection and optimal therapeutic regimens was limited. The department of pharmacy thus began a pharmacy-based DUDSM program, originally known as the “target drug program.” Operational initiatives, including decentralization and automation, identified positions that could be redirected into the DUDSM program.

Through this re-engineering effort, resources were allocated to the DUDSM program. Pharmacy leaders and the original members of the DUDSM team defined the program’s goals, which were as follows:

- Optimize pharmacotherapeutic regimens,
- Evaluate health outcomes of identified disease states, and
- Evaluate economic impact of pharmacotherapeutic options for given disease states.

While cost reduction was important, provision of optimal patient care was the first priority. As an additional benefit, we hoped that the program’s vision would enhance the role of pharmacists on the health care team. Financial targets for reducing drug costs were set by the hospital’s clinical administrators with pharmacy leaders’ input.

Since the program began in 1996, these goals have remained the program’s focus, with increased emphasis on clinical decision-making, evaluation of new literature, progression toward practice guidelines, integration of CQI indicators, enhanced modeling of economic outcomes, and increased patient safety.

During the first five months of program planning, the executive director of pharmacy services spent much time promoting the concept of the DUDSM program to the hospital’s clinical administrators and medical staff, including the medical executive committee, nursing leadership council, and pharmacy and therapeutics (P&T) committee. It was essential to obtain the medical staff’s support for the program and to promote it as a collaborative effort since patient care is a multidisciplinary process.

Also during this time, drug expenses were analyzed to identify opportunities to improve pharmacotherapy and reduce costs. This was done through computer reports indicating the top diagnosis-related groups (DRGs), their associated drug expenditures, and pharmacy drug acquisitions (dollars and volume). These reports were evaluated during a series of meetings with DUDSM staff, clinical pharmacy specialists, and medical staff leaders. This focused our efforts and provided a framework for designing guidelines. We called each guideline for a specific drug, therapeutic drug class, or disease state an “initiative.”

A very important step in program design was dedicating resources to the DUDSM program. At its inception, the program had 2.0 full-time-equivalent (FTE) clinical pharmacists, 1.8 FTE staff pharmacists, and 0.5 FTE pharmacy technician. Information systems support also was designated for the program. Responsibilities of the DUDSM team included the identification, design, implementation, and evaluation of initiatives, as well as patient monitoring, outcome reporting, and initiative assessment.

Developing proposals for new initiatives

At the beginning of the program, initiatives targeted drugs with high volume, high cost, or association with disease states consuming sub-
stantial resources. Over the years, the initiative-identification process has become more systematic. It now also includes a review of pharmacy purchase reports for drug products with the highest percentage change in use from the previous 12 months, adverse drug reaction reports, and drug costs by DRG category. Information systems reports also rank aggregate drug use at UPMC-Presbyterian, as well as prescribing trends for different physician services. In addition, information systems reports are used to estimate the potential impact of therapy changes and help us determine baseline prescribing practices for new initiatives.

Clinical pharmacy specialists help generate ideas for new initiatives by discussing prescribing trends seen in clinical work rounds. Published literature also drives new initiative opportunities. Consensus papers, literature reviews, and the primary literature are periodically reviewed for new approaches to disease management or definition of therapeutic niches for new agents.

Therapeutic initiatives can be classified into four major categories: disease-state practice guidelines, patient safety programs, therapeutic dose optimization, and therapeutic interchanges. A fifth category of operational initiatives includes generic substitutions, compounding changes, and waste reduction efforts. Table 1 shows examples of initiatives in each of these categories.

A systematic approach for developing proposals for new initiatives is critical to the success of the DUDSM program (appendix). For each new initiative, clinical specialists and DUDSM pharmacists prepare a proposal in a review-paper format. The steps of proposal development parallel the plan-do-check-act cycle. All initiative proposals are formally presented to the P&T committee and medical executive committee for approval.

Implementing initiatives

As the DUDSM program was being designed, we reviewed previous efforts to change prescribing practices. From this review, we found two points to be linked directly to project success: communication of the initiatives must reach all health care practitioners, particularly prescribers, and follow-up regarding initiative impact and variant prescribing must be consistent. As a result, we designed an intensive five-step implementation approach that encompasses communication, education, information systems support, operational design, and monitoring strategies. While implementation is often the most time-consuming and resource-intensive step in rolling out DUDSM program initiatives, it is essential to provide a thorough, consistent approach for each topic.

Communication. Information regarding new initiatives is communicated to practitioners in three ways: written, oral, and electronic. This multifaceted, multidisciplinary process is vital to increasing awareness of recommendations for new initiatives.

Written materials, including memoranda and newsletters, are disseminated to physicians, nurses, pharmacy staff, and other disciplines when applicable. Oral presentations of information are given at multidisciplinary committees and conferences, during rounds, and by pharmacists individually on the patient-care units. Information is also transmitted electronically to individual practitioners, and we post each new initiative and complete proposal to the pharmacy department’s intranet web page and via electronic mail to health care staff. The DUDSM program has an entire section of the electronic formulary devoted to practice guidelines and reviews.

Education. We also take a multidisciplinary, multifaceted approach to educating practitioners about initiatives. At inservice-education programs, each participant receives a training packet that includes background about the drug or disease state (epidemiology, incidence, and treatment options), as well as DUDSM guidelines, estimated impact, and strategy for intervention. In addition, one-page fact sheets are prepared for insertion into the medical chart and for distribution upon request. Each pharmacy area has a

Table 1.
Examples of Initiatives in Each Category

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease-state practice guidelines</td>
<td>Community-acquired pneumonia, Fluid resuscitation guidelines, Heparin-induced thrombocytopenia, Invasive fungal infection, Prevention of pneumococcal disease, Surgical antimicrobial prophylaxis, Insulin medication error-reduction project, Ketorolac practice guidelines, Meperidine practice guidelines</td>
</tr>
<tr>
<td>Patient safety</td>
<td>Dosing of ceftriaxone, Dosing of piperacillin, Dosing of metronidazole</td>
</tr>
<tr>
<td>Therapeutic dose optimization</td>
<td>Benzodiazepines, Fluoroquinolones, H₂-receptor antagonists</td>
</tr>
<tr>
<td>Therapeutic interchange</td>
<td>Generic substitutions, Oral vancomycin product selection, Propofol line extension</td>
</tr>
</tbody>
</table>

*This is not a complete list; as of August 2000, 75 initiatives were approved.
DUDSM reference binder that includes a copy of the initiative proposal, as well as literature support for the recommendation.

To close the educational loop, pharmacists are required to complete a Web-based program and pass a clinical competency exam on implemented initiatives through the pharmacy department's Web page.

Information systems support: The usefulness of information systems goes beyond identifying ideas for new initiatives; computer programs are also essential to implementing initiatives. Intelligent computer reports are designed to screen patients for potential interventions, gather postimplementation compliance data, and monitor prescribing trends. In addition, reports are designed to facilitate the intervention process, enhance the assessment process, and monitor compliance with CQI indicators.

Financial reports are used for monthly budget analysis and justification, as well as to determine internal-use benchmarks. Online screen prompts on the pharmacy computer system assist pharmacists with information retrieval and learning.

Operational design. Careful thought is given to designing the implementation strategy for initiatives. Essential to the success of each new intervention are a comprehensive knowledge of pharmacotherapy and consistent and complete patient evaluation. Therapeutic interventions are made one of three ways. Automatic interchanges include conventional therapeutic interchanges, such as for H2-receptor antagonists and fluoroquinolones, as well as more sophisticated automatic interchanges, such as for i.v.-to-oral switches and renal dose-adjustment programs. Traditional interventions include recommendations for treatment of acute insomnia, enforcement of meperidine practice guidelines, and selection of antifungal agents. A third type of therapeutic intervention involves chart flag notes with traditional follow-up. Examples include i.v.-to-oral switch for agents not on the automatic interchange program, promotion of pneumococcal vaccination, and efforts to reduce medication errors associated with insulin use.

We use information systems reports to identify and screen patients for inclusion in various initiatives. The screening process includes review of patient profiles, archived patient clinical progress information, laboratory and hemodynamic data, and nutritional status. Patient laboratory data, microbiology results, dictated progress notes, and hemodynamic data are accessible through the clinical information system. The data analyst pharmacy technician assigned to the DUDSM program facilitates the screening process for 15 of the 60 initiatives now used at UPMC-Presbyterian. Examples of technician-facilitated screenings include pneumococcal vaccination, i.v.-to-oral switch, and surgical antimicrobial prophylaxis. Potential interventions are passed on to the DUDSM pharmacist or clinical specialist for detailed patient evaluation and subsequent intervention in care.

Careful thought is given to who will enforce the initiative. Many initiatives are enforced at the point of pharmacist order entry via therapeutic interchange or traditional intervention following pharmacist-physician discussion. Interventions are documented in the pharmacy computer system for later retrieval and analysis. DUDSM pharmacists perform interventions that require a more time-consuming evaluation, such as streamlining a patient's antimicrobial therapy on the basis of culture and sensitivity reporting or evaluating a patient's eligibility for pneumococcal vaccination.

Select initiatives are focused on daily if the targeted drug or disease state occurs in large numbers or potentially has a large financial impact on the institution. Examples are i.v.-to-oral switch, pneumococcal vaccination, and antifungal practice guidelines.

Clinical pharmacy specialists are expected to apply all initiatives to patients on their clinical services.

Monitoring. As initiatives are implemented, they are monitored with high intensity until assessment confirms greater than 80% compliance. Once this is achieved, some initiatives continue to be identified prospectively and followed, such as guidelines for heparin-induced thrombocytopenia (HIT) and treatment recommendations for enterococcal infections. Most initiatives, however, are shifted into a unit-based monitoring program in which patient-care units not covered by clinical specialists are set up on a rotating basis, and, for each patient on the unit, a DUDSM pharmacist monitors that patient's pharmacotherapy for compliance with all DUDSM-approved initiatives. The clinical specialists do the same for their services. In doing so, pharmacists are encouraged to promote the DUDSM program and interact directly with practitioners. As part of monitoring, they also give educational feedback on interventions to order-entry pharmacists, who perform a substantial number of interventions daily.

Data have been compiled on overall initiative success, prescribing trends per service, prescribing trends per intervention, and intervention workload per unit. Besides documenting interventions in the pharmacy computer system, we track detailed clinical parameters on data-collection sheets that can be scanned and downloaded into a comprehensive database.

A key aspect of monitoring is the design of outcomes, which is incorporated into the initiative development process. The identification of baseline data for selected outcomes is an integral component of the CQI approach to our program. The major types of outcomes for DUDSM initiatives are economic, clinical,
and process outcomes. Economic outcomes may include financial impact assessment, such as cost savings and cost avoidance. Clinical outcomes may include renal function and number of adverse drug events, wound infections, bleeding episodes, readmissions, and therapy switchbacks. Process outcomes may include guideline compliance, interchange conversion success, and appropriate consultations obtained. As outcomes modeling is further enhanced over the next phase of the program, humanistic outcomes will be integrated into outcome measurement.

A more global approach to monitoring includes quarterly assessment of implemented initiatives. The quarterly assessments look at the impact of each initiative over time, detailing compliance and variant prescribing by service and physician, including investigation into outliers. Reviewing the initiatives on an ongoing basis for comparison with newly published literature also is a component of DUDSM program monitoring; this completes the CQI cycle.

Finally, providing feedback to major stakeholders and multidisciplinary committees is an expected part of the DUDSM program. Selected initiatives are showcased as “dashboard indicators” for the pharmacy, and compliance and outliers for these are reported monthly.

All initiatives are monitored monthly for financial impact and drug dispensing trends; these are compiled into fiscal year spreadsheets. Quarterly clinical assessments are performed on a rotating basis to keep up with initiative impact, compliance, and new literature. This compliance information is now being collated into a searchable physician profiling database for peer-review-protected discussions.

**Personnel and student investment**

Over the four years of the DUDSM program, the pharmacy department’s investment in the program has increased. Completely dedicated to the program’s operation now are 4.1 FTE pharmacists and 1.0 FTE pharmacy technician. Not included is time spent by clinical faculty members. In addition, formal director and assistant director roles have been defined.

The data analyst pharmacy technician has been integral to the program’s success. The technician performs monthly financial impact analyses, prepares CQI indicator reports and graphs, maintains the physician profiling database, and serves as our link with the medical records department and pharmacy purchasing group regarding patient information and purchase acquisition data, respectively. The technician also screens patients for various interventions and conducts retrospective analyses of initiatives and select quarterly assessments. Through this pharmacist–technician approach to patient assessment, the number of interventions in therapy and patients evaluated per day has dramatically increased.

The pharmacy department has created pharmacy student learning experiences in the DUDSM program, including clerkship rotations and advanced institutional practice experiences. Through a longitudinal experience in DUDSM, pharmacy residents have been integrated into the program; residents also are exposed to it as a component of the practice management rotation.

A unique student learning experience offered by the DUDSM program is a one-year internship for Pharm.D. students in their last didactic year before clerkship. The Pharm.D. internship began in 1997, roughly one year after the DUDSM program began. The concept was to enable Pharm.D. students to apply principles of DUDSM to proposal design, implementation, and evaluation in a real practice setting. In addition, students learn clinical thinking skills by evaluating patients, and they have an opportunity to improve their oral and written communication skills. This better prepares them for residency programs, while providing the DUDSM program with additional resources. A range of three to six interns work in the DUDSM program per year; each averages 10–12 hours weekly. As of August 2000, 13 Pharm.D. students have completed the DUDSM internship.

**Challenges**

Barriers to programs like ours can include, for example, perception of cookbook medicine, inertia of previous practice, and lack of confidence in the guidelines. At UPMC-Presbyterian, our biggest challenge was generating physician awareness and support of the program. This continues to be an important emphasis of the program. Key to this is involving practitioners, specifically the major stakeholders of the initiative, in the development and approval of the practice guidelines so that they feel partial ownership. For example, when developing antimicrobial dose-optimization initiatives, we involved the infectious disease department.

The P&T committee has also played an important role in promoting the DUDSM program through its rigorous review and discussions of pharmacotherapy and disease management as part of the approval process for initiative proposals. Highlighting successful multidisciplinary projects and showcasing them via different means, such as by submitting CQI projects in the annual UPMC-Presbyterian Performance Improvement Award and by making presentations at grand rounds, have similarly promoted collaboration and medical staff support.

Another challenge for the DUDSM program is ensuring that pharmacists are properly trained so that they can apply the initiatives consistently in the institution. Training programs for DUDSM and
staff pharmacists continue to be a priority as initiatives are implemented and developed. Both clinical specialists and DUDSM pharmacists serve as mentors for staff pharmacists to enable them to become familiar with the supporting literature so that they are comfortable making interventions, when necessary.

The biggest challenges for many institutions may be allocation of resources and the availability of sophisticated information systems. When the DUDSM program was being designed, resources were allocated from other areas within the department with defined financial targets. As these targets were achieved and exceeded, resources were reinvested into the program for further growth. Also, while our information system is integral to an efficient program, many initiatives can be designed with manual data collection and collation. The time commitment for manual chart abstraction, however, should be incorporated in the timetable for initiative design.

Evaluation of the program

Table 2 shows the evolution of the program’s original target drug focus to the comprehensive disease-management program it is today. In the first year of the program, 27 initiatives were developed, approved, and implemented; an average of 16 new ones have been implemented each year since then. Combining calculations of cost savings and cost avoidance, the DUDSM program has documented savings exceeding $4 million dollars annually to UPMC-Presbyterian for the past three years (Table 3).

Research has become a focus of the DUDSM program, and initiatives often drive research opportunities. There are now four research projects underway, including practice surveys, cost-benefit analyses, and enhanced outcome design models. In addition, the DUDSM program has received local and national recognition. It has provided a unique and challenging opportunity for pharmacists, pharmacy technicians, pharmacy students, pharmacy residents, and providers from other health care disciplines to experience a comprehensive patient-care program.

Most importantly, DUDSM program initiatives have had positive patient care outcomes and improved the “bottom line”. Practice guidelines have led to improved quality of care, fewer infections, streamlined agent selection, fewer adverse events, cost savings, and generation of revenue. For example, the guidelines for surgical antimicrobial prophylaxis have led to reduced costs of prophylaxis, optimized timing of presurgical doses, narrowed therapeutic spectrums of agents chosen, reduced durations of prophylaxis (thus helping to reduce resistance), and decreased or unchanged occurrence of postoperative wound infection. Recommendations for empiric treatment for community-acquired pneumonia have led to a decrease in mean antibiotic cost per patient while readmission rates and discharge disposition remained the same. (Length of stay decreased but could not be solely linked to our initiative.) Guidelines for serum vancomycin concentrations and dosing resulted in reduced vancomycin use and fewer laboratory serum concentration determinations.

Future plans

Given the success of the drug-use and disease-state management program at UPMC-Presbyterian, it is now being implemented across the entire UPMCHS. In 1999, a UPMCHS P&T committee was developed to serve as the primary committee to review and approve systemwide clinical initiatives. Pharmacists from the UPMC-Presbyterian DUDSM program will provide the leadership for the systemwide program, both in operational function and in identifying system initiatives to be developed. So far, 22 UPMCHS initiatives have been approved, all of which have been implemented at UPMC-Presbyterian as the template.
The current agenda for the UPMC-Presbyterian program includes working with the medical executive committee, which has just been requested by the chief executive officer to create a pharmaceutical-use subcommittee. Through this subcommittee, we hope that current initiatives can be enhanced and that new ones larger in scope than those spearheaded by any one department will be developed.

Conclusion

Through a comprehensive drug-use and disease-state management program, we have successfully integrated practice guidelines into the therapeutic decision-making in our institution, resulting in improved patient-care outcomes and cost savings. A key to the success of the program is a thorough implementation plan involving medical and nursing staffs, as well as consistent monitoring of compliance with the guidelines and follow-up with practitioners.

References


Appendix—Steps in developing a proposal for a new initiative

A. Identify opportunity
   1. High-volume drug use or occurrence of disease state
   2. High cost of drug therapy or disease state
   3. New pharmacologic entity with narrow therapeutic niche or limited clinical support
   4. Publication of new consensus paper or other recommendations
B. Enlist multidisciplinary involvement
   1. Identify and address concerns of major stakeholders, such as physicians and specialists
   2. Identify physician champion, if possible
   3. Evaluate and discuss the published literature (see C2)
   4. Incorporate local expertise as appropriate
C. Write initiative proposal
   1. Description of initiative, including recommendations prominently displayed on page 1
   2. Background literature support
      a. Primary literature
      b. Consensus papers
      c. Pharmacoeconomic studies
     d. Society and organization recommendations (e.g., University Health System Consortium, Agency for Healthcare Research and Quality, American College of Chest Physicians, ASHP)
   3. Review practices in similar institutions
      a. Review from pharmacy journals
      b. Phone survey
      c. Worldwide Web
      d. Consult pharmaceutical industry
   4. Assess current University of Pittsburgh (UPMC) experience
      a. Annual drug-use evaluation
      b. Information systems reports
      c. Chart review
      d. Point prevalence study
   5. Determine current UPMC drug costs associated with the initiative
      a. Purchasing information
      b. Archived data
      c. Pharmacy information systems data
   6. Approximate projected annual savings
      a. Cost analysis of new therapy versus current therapy
      b. Quantify other costs, such as reduced length of stay, avoidance of adverse drug reactions if possible, and decreased laboratory monitoring
   7. Include references
   8. Design implementation plan
      a. Pharmacist enforcement (drug-use and disease-state management pharmacist or order-entry pharmacist or both)
      b. Automatic interchange or traditional intervention
      c. Determine frequency of monitoring (focused initiative versus unit-based monitoring)
   9. Design outcomes
      a. Identify indicators for clinical, process, and economic outcomes; potentially identify humanistic outcomes
      b. Design outcome monitoring tools
      c. Have at least one clinical, process, and economic indicator for each initiative
      d. Goal for compliance ≥ 80%
D. Present proposal at committee meetings
   1. Pertinent multidisciplinary committees
   2. Pharmacy and therapeutics committee
   3. Formulary subcommittee
   4. Total quality council
   5. Medical executive committee