Therapeutic selection during an emergency response

MICHAEL J. MONTELLO AND TIMOTHY AMES

Abstract: Therapeutic selection in a postdisaster setting is described.

Therapeutic selection is the process of assessing a patient's pharmaceutical requirements and selecting the appropriate therapy. Although the primary criteria for drug selection during a disaster response are the same as in usual pharmacy practice, there is a shift in emphasis created by communication and transportation limitations and by changes in the patient's general living environment. The cost of agents

is no longer viewed in terms of dollars but in the context of limited inventories. A disaster may exacerbate health problems or make adverse drug effects more common and problematic. Drug administration and patient compliance will be hampered. Pre-established guidelines for appropriate patient care should be reviewed and approved by a group of representative health care providers. General policies for pharmaceutical care should include guidelines for a formulary, prescription refills,

dispensing limitations, and prescriber approval. Therapeutic selection should involve obtaining a medical history, selecting a drug regimen, educating and counseling the patient, and documenting the process. Pharmacists should use familiar procedures that they are comfortable with to minimize stress and optimize outcomes. Procedures should be flexible to adjust to circumstances and individual patient needs.

Therapeutic selection during a disaster response, although based on the same principles as traditional therapeutic selection, is more complex. Pharmacists will need to tailor their approach to the circumstances and to individual patient needs.

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CDR MICHAEL J. MONTELLO, M.S., is Deputy-Chief Pharmacy Officer, Disaster Medical Assistance Team-1, U.S. Public Health Service, Bethesda, MD. CPT TIMOTHY AMES, M.P.H., is Chief Pharmacy Officer, Disaster Medical Assistance Team-1, U.S. Public Health Service, Rockville, MD.

Address reprint requests to CDR Montello at the Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, Executive Plaza North, Room 707, Bethesda, MD 20892, or to montellom@ctep.nci.nih.gov. he U.S. federal disaster response plan for health and medical services includes provisions for the overall public health response, preventive medicine, and the triage, treatment, transportation, and evacuation of patients.^{1,2} Pharmacists in the Public Health Service (PHS) have participated in a number of emergency responses. Pharmacists have a variety of important administrative and clinical skills that are vital in these situations.³ One of the most important clinical functions a pharmacist can perform during a disaster response is therapeutic selection.

Definition of therapeutic selection

Therapeutic selection is the process of assessing a patient's medication requirements and selecting the appropriate therapy to address the patient's needs. One must consider the therapeutic intent, patient characteristics, and the health care environment when selecting an agent. Simplified, the criteria for selecting a therapeutic regimen can be summarized by the following equation⁴:

Benefit of regimen + Danger of not treating the condition – Adverse events = Value of regimen

No matter the setting, a considerable amount of detail is required to adequately assess the value of a treatment regimen. The patient's comorbidities, concomitant medications, living environment, and finances must be considered. What is the cost of the agent? Does the patient have insurance? Questions about the health care environment should be addressed. Does the institution have a formulary?

Therapeutic selection during a disaster response

Although the primary criteria for selecting an agent in the traditional practice setting and during a disaster response are the same, there is typically a shift in emphasis during a disaster response. This shift is created by communication and transportation limitations and by alterations in the patient's general living environment. Road closures, power outages, and downed telephone lines can make consultation with other health care providers and replenishment of pharmaceutical supplies impractical or impossible. Inventory limitations create a restrictive environment. Given that patients are not charged for agents dispensed by federal response teams during a disaster, the cost of an agent is no longer measured in dollars but in terms of the current inventory. All things being equal, selection will likely be based on the quantity of an agent on hand rather than on the dollar value of the agent.

The patient's access to food, clean water, and shelter also affects therapeutic selection. Consider the following scenario: A pediatric patient has an earache. Augmentin (amoxicillin–clavulanic acid, SmithKline Beecham) and Bactrim (trimethoprim–sulfamethoxazole, Roche) are currently on formulary. The patient has limited access to food, potable water, and refrigeration, and no shelter. Both formulary options are problematic. The pharmacist must weigh the potential risks and benefits of both agents when selecting which product to dispense.

The altered living environment can also exacerbate health problems or make potential adverse effects more common and burdensome during a disaster. Consider the patient with well-controlled diabetes. Significant variations in blood glucose levels may result from dietary changes, dehydration, stress, exposure, and increased physical activity. Health care workers must consider the patient within both the predisaster and the postdisaster environment when making a therapeutic selection.

Ease of administration and compliance should be considered. Many patients will be too busy to remember to take a medication four times daily. Therefore, medications that have long half-lives or require less frequent administration are preferable. For example, for the treatment of sexually transmitted diseases or other infections, a single i.m. injection of an appropriate antimicrobial would be preferable to long-term oral antimicrobials. On the other hand, agents with a prolonged duration of action could be associated with adverse effects that persist for an extended period.

Pre-established policies for therapeutic selection

To ensure effective patient care and adequate control of the pharmaceutical inventory, pre-established guidelines for appropriate patient care during a disaster response should be reviewed and approved by a group of representative health care providers. Providers should review all policies before deployment of the response and periodically during deployment. The health care team should assess whether any of the policies should be modified. In general, policies should be flexible and should allow for adaptation to the unique circumstances of each disaster. General policies for pharmaceutical care should include guidelines for a pharmacy formulary, prescription refills, dispensing limitations, and prescriber approval.

Formulary. Identification of a standard pharmacy formulary is essential to ensuring quality patient care. The formulary should include representative agents for treating the major chronic diseases found in the United States (e.g., hypertension, diabetes mellitus, asthma). Appropriate acute care medications (e.g., analgesics, antimicrobials, cough and cold remedies) should also be included. Because of logistic concerns, the formulary should be limited. The inclusion of "me too" drugs should be minimized. Agents with multiple indications (e.g., ibuprofen, diphenhydramine) are ideal. The standard formulary may be supplemented according to the nature of the disaster or the demographics of the expected patient population. Based on prior experience, it can be expected that, once deployed, the formulary will be in constant transition. Pharmaceutical companies, hospitals, government agencies, and charities often donate medications to disaster victims. There is frequently little control over the acquisition of medical supplies. Boxes of drugs, often short dated, will appear mysteriously. On the other hand, the pharmacist will often be unable to procure a specific antiepileptic or antiarrhythmic agent. Continuous monitoring of the formulary is of vital importance to therapeutic selection. Other prescribers should be notified as often as possible about any changes to the formulary.

Refills. Prescription refills are often the number one reason for patient visits to field clinics during a disaster and account for a substantial portion of a pharmacist's workload. Guidelines on the type of evaluation required for each refill should be established. For example, must all patients receive a complete physical evaluation (e.g., vital signs, laboratory work) before receiving a prescription refill, or can the pharmacist simply take a patient history before dispensing a refill? It should be clear who is responsible for performing any required physical evaluations.

Dispensing limitations. The quantity of medications dispensed will depend on the circumstances. Pharmacists should consider the agent's indication, the current inventory, and the anticipated re-establishment of the local health care system.

Prescriber approval. Authorized substitution of a therapeutically equivalent agent for the drug prescribed is considered to be therapeutic interchange. Given inventory limitations, the prescribed agent will often not be available. Must a pharmacist consult a physician before substituting a therapeutic alternative? If other prescribers are not available, often the only practical option is to make an unauthorized substitution of a therapeutically equivalent agent (i.e., therapeutic substitution).

Whether physician consultation is required may depend on the nature of the prescription and the agent prescribed. Most pharmacists would probably feel comfortable making a substitution with agents such as nonsteroidal anti-inflammatory drugs, cold preparations, and antilipemics but very uncomfortable making a substitution with drug classes such as antiarrhythmics and anticonvulsants. The pharmacist's comfort level will often depend on his or her prior experience. The health care team should establish general guidelines regarding which drug classes would require consultation and which classes would not.

A step-by-step approach to therapeutic selection

Therapeutic selection during a disaster response is not part of the average pharmacist's training, and literature on the subject is virtually nonexistent. A standard approach cannot be developed because of the volatile nature of disasters. During a disaster response it is important to remember that, although the surroundings may be unusual, pharmacists should use procedures they are comfortable with. Special "disaster procedures" should not be developed unless absolutely necessary. Performing familiar functions will minimize stress and optimize performance. The following practical step-by-step guidelines for therapeutic selection have been developed on the basis of prior experience.

Therapeutic selection in both the disaster setting and the traditional setting involves obtaining a patient history, making a therapeutic selection, providing patient education, and documenting the process. Depending on the circumstances, a physical assessment and prescriber consultation may also be obtained.

Patient history and assessment. The first step when making a therapeutic selection in a disaster setting is to obtain an in-depth and detailed patient history. In addition to the patient's medical history and information on drug allergies, a pharmacist should obtain information on the patient's current living conditions and determine the potential for patient education and compliance. The patient's medical chart or notes, if available, should be carefully reviewed for additional information.

During a disaster, patients' medications may be lost or destroyed. Often patients will approach the pharmacist with a handful of empty vials or a list of their current medications. The pharmacist should determine the indication, dosage, route, duration, efficacy, and toxicity for each medication. It is important to ask about other drugs (e.g., nonprescription drugs, illegal drugs) the patient may be taking. Most patients are somewhat reluctant to reveal any details about illegal drugs they are using, especially to a uniformed health care provider, but it does not hurt to ask.

Many drugs have multiple indications (e.g., propranolol, diazepam). The selection of a suitable alternative will depend on the indication of the agent in a particular setting. In most circumstances the alternative will be another agent in the same therapeutic class (e.g., atenolol instead of propranolol). Occasionally an agent in a different pharmacologic class might be an appropriate substitute. For example, diphenhydramine may be a suitable alternative to diazepam for sedation. Whenever possible, agents with similar mechanisms of action, toxicity profiles, and schedules should be selected.

The length of drug therapy should be considered. A patient who has been receiving a short course of prednisone after exposure to poison ivy would be treated differently from someone receiving long-term steroids for asthma. The prior effectiveness of a medication and any adverse effects should also be evaluated during therapeutic selection. The pharmacist should determine the patient's general medical condition before and after the disaster.

When assessing the patient's pharmaceutical needs, it is important to determine the patient's current living environment. A pharmacist must assess the patient's diet and access to shelter, clean water, refrigeration, and transport. Security of medications should also be considered. The loss of childproof locks on medicine cabinets could increase the risk of an accidental overdose and the propensity for vandalism. Unscrupulous individuals may seek prescription medications, especially narcotics, after a disaster. If possible, provisions should be made to minimize the risk of such events to patients and their families.

During the patient interview, the pharmacist should assess the potential for patient education. The pharmacist should consider any language barriers and the patient's mental capacity (e.g., age, whether mentally retarded). Substitution of a therapeutic alternative for a previously prescribed agent is dangerous if patients cannot be educated about potential changes in therapy. If family members are available, they should be involved in the conversation. Most patients will be under extreme stress, so it would not be unusual for someone to forget something important. The more individuals involved, the greater the likelihood that the proper information will be conveyed and retained.

Although there is no effective way to prospectively determine whether a patient will be compliant with therapy, the patient's chart or prescription vials will provide some clues. The date the last prescription was dispensed and the number of days' supply should be verified. It is important to keep in mind that some patients may have been noncompliant because of the disaster.

An appropriate physical assessment of the patient's condition should be made. If possible, laboratory data (e.g., blood glucose concentrations, electrolytes) should also be obtained. The level and complexity of the physical assessment and laboratory data will often depend on the workload, the size and composition of the health care team, and the patient's chief complaint.

Therapeutic selection. Whether the patient requires new pharmacologic therapy or continuation of therapy, the pharmacist must use whatever tools are available in making the appropriate selection. Medical charts or notes, if available, should be reviewed for potential contraindications. Pharmacists should also review available medical references, consult with other team members, and use their own clinical judgment. Of course, all decisions must be based on the current formulary.

A disaster does not lend itself to literature searches. It is not practical and is often quite difficult to maintain even a limited selection of medical references. Handbooks are very practical. Some personal recommendations include *Handbook of Clinical Drug Data* (Drug Intelligence Publications, Hamilton, IL), Drug Information Handbook for the Allied Health Professional (Lexi-Comp, Hudson, OH), Harriet Lane Pediatric Handbook, (Year Book Medical Publishers, Chicago, IL) and Guide to Antimicrobial Therapy (Antimicrobial Therapy, Dallas, TX). Photocopies of drug class reviews from Drug Facts and Comparisons (Facts and Comparisons, St. Louis, MO) are often very useful. Martindale: The Extra Pharmacopoeia (Pharmaceutical Press, London) may be a useful resource for foreign deployments. Consultation with other pharmacists or health care practitioners is advised whenever possible. However, there is no substitute for a pharmacist's practical experience in selecting an agent.

In most circumstances the choice of agent will be limited to what is currently available on formulary. If no suitable alternative is available, every attempt should be made to find a source of the item. Procurement of a nonformulary item will probably require considerable time and effort and in many circumstances may be impossible. If unable to obtain a specific agent, the pharmacist or health care team may have to decide whether to treat the patient with a less suitable alternative or provide no treatment. The decision will depend, among other things, on the severity of the illness. Pharmacists should remember the axiom "First do no harm."

Prescriber approval. How and when to seek prescriber approval for therapeutic selection will vary with the situation. The availability of prescribers, the state of communications, and the nature of the exchange should be considered. Workload and communication limitations may make consultation impractical in many circumstances. Ultimately the decision to solicit prescriber approval is going to be a judgment call.

Patient education and documentation. Substitution of an alternative therapeutic agent requires careful patient counseling. Failure to appropriately counsel a patient could have severe consequences. Patients have to be aware that an exchange has been made and have to know the reason. It should be made clear that this is only a temporary change and that only the minimum supply of medication is being dispensed to maintain the patient's care during the disaster. Patients should be instructed to return to their usual caregivers as soon as possible to resume their predisaster regimen. The pharmacist should outline what medications were originally prescribed, what medications are being used as alternatives, and why the new agent is a suitable alternative. All new instructions and warnings should be clarified. Any changes in schedule, frequency, or storage should be identified, and potential adverse effects should be clearly described.

Counseling skills are extremely important. The pharmacist should use open-ended questions and have patients repeat the directions to ensure that they fully understand all new instructions. It is important to provide as much documentation as possible and encourage patients to ask questions.

Pharmacists should be aware that patients may take the opportunity to obtain free medication even though they may have ample supplies at home. Unless supplies are especially tight, it is often simpler to dispense the medication without being concerned about what drugs the patient may or may not already have. It is virtually impossible to police this situation, and dispensing free medication to a patient is inconsequential compared with the losses many people may have experienced. However, it is important to explain in a nonaccusatory manner what patients should do if they happen to find a supply of their old medication. Patients must be instructed not to take their old and new drugs together. The pharmacist should explain in simple terms that this would result in therapeutic duplication and could potentially be harmful. Whenever possible, patients should be encouraged to continue with their predisaster regimens and to discard their new medications once they have located the old ones.

The process of therapeutic selection must be documented on the patient's chart or record, including what medications were originally prescribed, what medication is being used as an alternative, and both the old and new instructions. There should be a brief explanation of why the alternative was selected. References should be included if appropriate. There should be a record of whether prescriber approval was obtained. If a prescriber was not available for approval, a reason should be stated briefly. The patient counseling session should also be documented.

The prescription label should include a brief statement clarifying that a therapeutic selection was made. The following wording is suggested: "As a result of the recent emergency, a therapeutic selection has been made. When possible, please return to your local pharmacy to continue with your previously prescribed medication."

Conclusion

Therapeutic selection during a disaster, although based on the same principles as traditional therapeutic selection, is more complex. Pharmacists will frequently be relied on to select appropriate drug therapy for a patient on the basis of the person's unique characteristics. Selection may not include physician consultation, and pharmacists should be prepared to apply their unique skills and clinical experience after a disaster.

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