2. Allocation of Expensive Medications

Ethical Principles for the Purchase and Use of Expensive Medications

- Veterans receiving care in the VA health care system should receive medically appropriate medications. In determining the appropriateness of a medication, cost is a factor.
- In those instances in which it is necessary, on the basis of either scarcity or cost, to restrict medications from patients who may derive some benefit, it is incumbent on the VA health care system to develop processes that ensure that the restriction will be fair and equitable.
- Therefore, strategies should be employed that ensure that veteran patients with comparable needs be treated equally. The goal of such strategies is to minimize discrepancies between various medical centers, while recognizing that discrepancies may continue to exist.
- Veterans at VA facilities that have unusual and above average needs for expensive medications should not be penalized because they compete against other veterans at that facility for resources. Mechanisms should be in place to respond to special burdens and permit equity in resource availability.
- The greatest flexibility should be exerted to find ways to minimize drug rationing. However, when limiting of beneficial medical treatments is required, decisions should be based on the overall needs of the entire veteran community.

Definitions

Expensive Medications

Defining "expensive medications" is difficult. A medication could be expensive because it is:

1. a single agent that costs a lot of money, e.g., $8,500 per year for one patient;
2. a less expensive agent provided to many patients; or
3. a medication with a low success rate.

Another relevant factor would be the impact of distribution of a medication on a particular medical center's budget. Additionally, although some drugs may appear to be more expensive, a pharmacoeconomic analysis that includes factors such as reduced hospitalization and clinic visits may indicate that these advantages would offset the net cost of the drug. As an example, in Fall 1994, the Headquarters Executive Committee on Therapeutic Agents considered a drug a "high expense agent" when it costs $8,500 per patient per year, based upon the appearance of numerous new medications costing this amount.

Methods of Economic Analysis

Cost-Minimization Analysis - CMA

The research methodology called Cost-Minimization Analysis (CMA) is the easiest to understand and is widely used. The essence of CMA is that it compares the cost difference between alternative therapies that are known or assumed to result in identical outcomes. CMA is analogous to the kind of decision-making process one uses while shopping. If you compare two items and ultimately conclude, based upon all available information, that the two items are identical, price would be the only factor differentiating the two. So, you would choose the least expensive.

Cost-Effectiveness Analysis - CEA

When equivalence of performance is questionable, Cost-Effectiveness Analysis (CEA) should be used. CEA quantifies differences in both costs and consequences and is appropriate when the

consequences of therapies are different. It measures both the incremental cost between alternative therapies and the differences in the health benefits each produces. CEAs are widely used because of their ability to directly compare different forms of therapy. In addition, stating inputs in monetary terms and outcomes in natural units makes their findings useful to both payers and providers.

Cost-Benefit Analysis - CBA

Cost-Benefit Analysis (CBA) also evaluates both cost and consequences. All outcomes are monetarized, making it possible to express the findings as an easily understood ratio of dollars gained in benefits to dollars spent in costs. The problem with this analysis in medicine is that all outcomes (human life, pain, suffering) must be monetarized. Some variables are very difficult to monetarize, e.g., benign allergic reactions. It is difficult for human beings to make decisions based purely upon economic value: e.g., what is the dollar value of increasing the survival of a terminally ill person by an additional year? CBA is very helpful at a public policy level, because when funds are limited, it is reasonable to ask which program will achieve the maximum net social benefit.

Cost-Utility Analysis - CUA

Cost-Utility Analysis (CUA) calculates the price of inputs and uses non-monetary measures of outcomes. Outcomes reflect patient preferences for health states. For instance, consider a medication that produces a side effect in the form of an annoying but benign skin rash approximately 25% of the time. In CUA, this would be expressed as the cost per rash avoided compared with an alternative medication. The consequence would be expressed as a patient's preference, usually described by what percent decrement from ideal health this adverse event represents.

Guidelines

Headquarters Executive Committee on Therapeutic Agents

Ethical Responsibilities

As stated in the March 6, 1992, VA Memorandum No. 10-92-004 on the Executive Committee on Therapeutic Agents, it is the Department of Veterans Affairs' responsibility to assure that every effort is made to treat all patients with safe, efficacious, and cost-effective therapeutic agents. This requires a continuing review of drug utilization and prescribing practices to be conducted by the VA Headquarters Executive Committee on Therapeutic Agents (ECTA) and by the Pharmacy and Therapeutic Agents Committees (P&T committees) at each VA facility. Generic drug procurement is required whenever feasible.

The Headquarters ECTA is also responsible for developing a mechanism to review and evaluate the use of expensive drugs in the VA health care system. This information should then be distributed throughout the system to inform VA facilities about practice patterns when using expensive medications. Local facility policies and procedures that have been developed for making these difficult allocation decisions should be collected and distributed. If national data suggest the possibility of inequitable or inappropriate use, ECTA should bring this to the attention of local facilities and their P&T committees.

Ethical Situations

a. Problem: Limited Supply

The goal of equal access to expensive medications is an important imperative in the VA health care system. When the problem in achieving full access is shortage of supply of the expensive medications, the most equitable mechanism for distribution is a centralized mechanism that considers together all veterans who satisfy the selection criteria for the drug.

A suggested method for making this form of distribution operational would be for the ECTA to direct the development of patient clinical eligibility criteria. Local VA facilities would then

identify specific patients who meet the criteria and submit those names to ECTA. ECTA would then select recipients of the medication using a lottery. This method is an arguably just approach. For patients not selected through the VA lottery, VA staff should assist those patients to obtain medications through other than VA mechanisms.

b. Problem: New Ethical Dilemmas

New ethical dilemmas will periodically arise for ECTA. The VHA Bioethics Committee will identify members with expertise who can assist ECTA to evaluate the dilemma and look for solutions that are based upon generally accepted ethical principles. ECTA would also benefit from utilizing the considerations recommended below for local P&T committees. Additionally, utilization of an ethical decision-making process would assist the discussion.

Local VAMC Pharmacy and Therapeutics Committees

Ethical Responsibilities

a. Treat all patients with safe, efficacious, and cost-effective therapeutic agents.

In accordance with VA Memorandum No. 10-92-004, local Pharmacy and Therapeutics (P&T) Committees must adhere to the following guidelines:

- Consideration must be given to fluctuating drug prices.
- Generic drug procurement is required when available.
- The purchase of high cost drugs cannot be justified when equally safe and effective but less expensive preparations are available, except under unusual circumstances.

Each VA facility is forced to make difficult decisions regarding the purchase and prescription of both “less expensive” and “expensive” medications. With both of these categories of medications, the P&T Committee will have to consider issues of cost and perform a cost evaluation. The Committee should therefore have expertise in the areas of pharmacoeconomic analysis and ethics.

b. Develop a representative committee.

Headquarters is committed to supporting the P&T committees at individual VA facilities. The long standing policy of not rigidly restricting professional practice by administrative direction from Headquarters continues. Local P&T committees should include a broad based group of professionals with appropriate expertise. Members should represent individual characteristics of medical center and clinic populations. Policies will be reflective of professional clinical judgments from individual centers.

c. Establish an ethical process to guide allocation of expensive medications.

To provide patients with medically appropriate, expensive medications, it is recommended that the P&T committee create a process for handling expensive medication allocation decisions. The process should be based on the ethical principles presented at the beginning of this report. Decisions by the P&T committee concerning expensive medications should be consistent with the mission of the facility.

A clinical, ethical, and economic analysis should include at least the following considerations:

- Practice guidelines:

  The P&T committee should develop practice guidelines for the usage of expensive drugs, e.g., indications for when and when not to use, which populations will be treated, efficacy, safety, whether only certain physicians can prescribe or approve the use of such drugs, etc.

- Comprehensive cost evaluation:

  This consideration requires factoring in subjective variables such as quality of life, positive outcomes of the drug usage, and fewer admissions, rather than just looking at the absolute cost of the drug.

- Community standards of practice:

VA patients should receive care at least equal to that practiced in the general medical community.

- Local institutional needs:

  If a P&T Committee determines that patients will suffer serious harm by being deprived of an expensive medication, and no reasonable alternative treatment is available, and the facility is unable to provide the necessary funding, the committee is responsible to carry out the following steps. Every effort must be made to divert funds for the medication from discretionary items. If this cannot be accomplished, the facility may propose that there be a redistribution of funds in the VA health care system. This would apply when it could be demonstrated that an individual facility had an unpredictable number of patients whose clinical circumstances warranted the use of the expensive medication, e.g., a station with a high prevalence of persons with AIDS.

- Every decision made should be accompanied by a cost statement.

d. Monitor and evaluate.

The local P&T committee should have a mechanism to monitor and evaluate the use of expensive drugs. Data should be gathered on patients treated, their clinical outcomes, and costs to the facility. The committee should also perform an annual review of both new and old "expensive" drugs to evaluate whether the drugs are meeting their original purpose and whether more appropriate or effective therapies have become available. The committee should develop a list of "triggers" that would initiate a review of the use of medications, e.g., an abrupt increase in spending relative to a single drug or a class of drugs; changes of pharmacy costs; or twenty drugs constituting 80% of the pharmacy budget.

The committee should also be alert for discrimination against any subset of patients. The committee should be willing to share its materials so that practice patterns can be shared broadly

throughout the VA system, enabling medical centers and outpatient clinics to learn from each other.

e. Create an appeals process.

An appeals process should be developed to consider requests for a second review.

f. Assure continuity of service.

When patients transfer between medical centers, every effort should be made to provide continuity of care, including the use of expensive medications when appropriate.

g. Provide for fee-basis physician orders.

If a fee-basis physician orders an expensive medication that is not on the hospital's formulary, there should be a process for evaluating the request, based upon the individual's specific need. The VA facility would need to be primarily responsible for the patient. The order could then be approved by the facility. Subsequent medication orders would be written by the authorized fee-basis physician in conformance with all VA clinical guidelines.

Case Study

VHA and the Use of Erythropoietin: An Example of an Expensive Drug Distributed with Local Discretion and Central Guidelines

Human erythropoietin (trade name Epogen) is a naturally occurring protein that stimulates the bone marrow to synthesize red blood cells. Its appearance created an important therapeutic opportunity (and challenge) to develop priorities for usage. Providers needed to maximize its effectiveness while avoiding expenditures that would impose inappropriate limitations on other medical spending.

The drug was approved in 1989 for the treatment of anemia seen in patients undergoing chronic hemodialysis. It was shown that the administration of erythropoietin was associated with other increased functional capabilities in these patients, and it was soon evident that erythropoietin was also of benefit to groups of patients with diseases in which anemia played an important part, e.g., patients with AIDS and

other malignant diseases receiving chemotherapy.

Since the drug costs $8,000 – $10,000/patient/year, treatment of every patient who might gain some benefit would constitute a very costly undertaking. Accordingly, each VA Medical Center developed policies for its use, through a process for dealing with expensive drugs that would take into account the need within that hospital for the drug, the local budgetary situation, and the impact that this expenditure would have on funding for other medical programs.

In addition to this local process, VA Headquarters played a role in guiding the utilization of this drug. Headquarters engaged the National Center for Cost Containment to analyze the use of erythropoietin by dialysis units throughout the system. The VHA Medical Service Ad Hoc Advisory Group on Renal Disease and Dialysis defined a group of guidelines for its use. On May 5, 1994, the Office of Clinical Programs distributed a Program Letter entitled "Guidelines for the Use of Recombinant Human Erythropoietin (r-HuEPO)," which dealt with the use of the drug both with dialysis patients and AIDS patients. This letter not only provided guidelines for its use but also provided information designed to maximize effectiveness and minimize cost in the patients designated to receive it.

In addition, in an effort to encourage an equitable distribution of the drug to veterans throughout the VA system, VA Headquarters distributed data indicating the use in each station. This permitted each VAMC to make a judgment about whether its usage and expenditure for the drug was in line with the general practice throughout the system.

The manner in which VHA dealt with this expensive drug illustrates several important ethical principles. The system found a reasonable middle ground between a tightly mandated, centralized policy for the distribution of the drug vs. policies dependent totally on local discretion that would make no attempt to provide equity across the system. In addition, local VAMCs were given the advantage of consultative expertise developed centrally, and the opportunity for reexamination of their own policies by comparison to the decisions made in other institutions throughout the system.

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