

BEST PRACTICES

The VA National Formulary

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Managed care systems use various means for allocating resources to covered enrollees. Such allocation decisions are sometimes explicit - e.g., certain individuals or services are excluded from coverage, or they may be implicit - e.g., resources are limited through inconvenience or unavailability. Distributing limited resources requires trade-offs; balancing criteria such as individual need and equal share may result in fewer individualized benefits in order to achieve more equitable access to care.

One strategy that managed care systems use to allocate resources is to control the range of drugs and other pharmacy products that are made available to their enrollees. This article highlights the Department of Veterans Affairs National Formulary (VANF) process as one example of how VA has attempted to ensure fair and rational allocation of health care resources through a systematic and explicit process on a national scale. The VANF may serve as a useful model for other organizations facing similar challenges.

Background

The Veterans Health Administration (VHA) is the largest system of managed care and the largest health care delivery system in the US.¹ VHA is a comprehensive, centrally managed health care system with a defined population of veteran enrollees. As with any managed care system, conflicting goals create tensions between standardization vs. flexibility, cost control vs. adequate access, and meeting needs equally for all vs. meeting individual needs.

In contrast to other managed care systems, VHA has several unique attributes. Public funding protects it from some of the market forces that influence allocation decisions in non-government managed care settings. It has a budget appropriated each year by Congress, and all cost savings are cycled directly back into the system for other uses, rather than leaving the system in the form of corporate bonuses or provider incentives. It serves only US military veterans, a population with unique demographic characteristics. Approximately 95 percent of VA patients are male, and as a group they are older, sicker, poorer, and more likely to have social problems and mental illnesses than persons using private health care systems.² Balancing the competing needs of equally deserving subgroups of veterans and convincing stakeholders that allocation choices are reasonable is challenging. Moreover, because VHA has more than 37 million patient visits annually, each allocation policy decision is magnified by the scale on which it is applied.

The VANF was established in 1997 as part of a larger mandate to reduce geographic variations in access to pharmacy products.³ It is a national list of generic, brand name, and over-the-counter drugs, devices, and supplies that may be provided to all enrolled veterans.⁴ The goals in establishing the VANF were: to standardize drug availability across VA facilities, to decrease variations in practice by using clinical guidelines, to centralize the process for evaluating evidence of safety and effectiveness in selecting drugs, to meet the standards of the Joint Commission for the Accreditation of Healthcare Organizations, and to help manage cost increases in VA pharmacy benefits.³ Drugs are an increasingly expensive budget item for VA. From October 1999 to October 2000, VA spent \$18 billion on health care for its 3.2 million veterans, of which \$2 billion was spent on drugs. Between 1990 and 2000 the portion of the VHA budget spent on pharmacy rose from 6 to 12 percent.^{3,5}

VHA managed care, although national in scope and design, is implemented in a decentralized system of 22 Veterans Integrated Service Networks (VISNs). At the national, centralized level, the VANF has several core requirements designed to promote equal access throughout the system. For example, every enrollee in the country is entitled to any drug on the VANF that is prescribed by a VA practitioner. But the VANF process also allows for several exceptions to this core requirement. First, VISNs are permitted to include additional drugs on their own formularies to supplement the VANF "to allow VISNs to be responsive to the unique needs of their patients..."⁵ A second exception is the non-formulary waiver process, which allows individual practitioners to request approval to prescribe a drug that is not on the list (e.g., if the formulary agent is not tolerated by a particular patient). A third exception permits VISNs to place restrictions on the general availability of medications that require close monitoring to ensure appropriate use (e.g., immunosuppressant agents such as cyclosporin).

Does the VANF Meet Ethical Standards?

The main ethical standard to consider in the allocation of scarce resources is that of justice. The concept of distributive justice emphasizes the fair and rational allocation of resources, but what is just can be determined in several ways. Allocations can be made by giving to each person an equal share (strict equality) or to each person according to individual need (equity), merit, contribution or effort.⁶ A theory of distributive justice that is consistent with the social and political traditions of the US in general, and within VHA in particular, has at its foundation the belief that all members of the affected group should be treated equally. VHA explicitly identifies both equal share (equality) and equivalent need (equity) as criteria guiding allocation decisions. However, strict equality alone is not instructive - men do not need gynecologic care, and those with healthy hearts do not need cardiothoracic surgery. Equality then means equal access to needed care, and equity⁷ allows for exceptions in order to care for the most needy or most vulnerable.

An allocation system, in order to be just, must have a way to balance competing criteria for distribution. Equal share can be addressed by standardizing the system and establishing rules that require equal access for veterans on a national level. However, responding adequately to local needs sometimes requires making exceptions to the rules. If a practitioner decides that the use of a non-formulary drug for a particular patient is justified, how can the practitioner meet this patient's need in a strictly egalitarian system? As with any practical model of resource allocation, more than one distributive principle guides the operation of the VANF. In theory at least, the VANF's system of rules and exceptions successfully balances the inherent conflict between providing equal shares and meeting individual needs.

In order for an allocation process to be truly just, however, it must be implemented consistently across the system. On the face of it, it appears that the VANF process is indeed consistently applied. For example, from October of 1999 to March 2000, 97 percent of all prescriptions written were for formulary drugs, indicating an extremely high degree of compliance with the formulary guidelines. At the same time, 84 percent of non-formulary requests were approved, reflecting responsiveness to individual patient needs. Yet closer examination reveals considerable variability from one VHA site to another. For example, a recent General Accounting Office (GAO) report found that some VISN formularies contain only a few drugs that are not on the national list, whereas others contain many.⁵ The time it takes for approval of non-formulary requests also varies widely; in some facilities requests are acted on within minutes or hours, while at others the process may take as long as 30 days. Similarly, restrictions on general access to certain formulary medications are not standardized across the 22 VISNs.

For the VANF process to work as intended, exceptions should occur if and only if they are justified by special clinical circumstances. For example, VISNs should add drugs to their formularies if and only if they can point to unique and recurring patient needs that differentiate their VISN from others. Second, requests for non-formulary drug use should be routinely approved if and only if the patient has a legitimate medical need, such as a history of allergy to the formulary agent. Finally, facilities should restrict general access to a drug (e.g., by requiring specialist approval) if and only if that drug requires close monitoring to ensure appropriate use. Consistent with the recommendations of the GAO, ongoing management on a national level is needed to assure that formulary exceptions are applied consistently throughout VHA.

Conclusions

The VANF is a model of ethical resource allocation because its processes are fair and rational. To the extent that the rules and exceptions are applied consistently from facility to facility, the VANF is an effective tool for just distribution, cost savings, and high quality care.

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