ORIGINAL research

Adoption of a New Technology in a Veterans Affairs National Formulary System With Local Implementation: The Insulin Glargine Example

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A study group gathered by the Pharmacy & Therapeutics Society reviewed data on the Department of Veterans Affairs (VA) health care system's implementation of a new technology (insulin glargine) for patients with diabetes. It examined local implementation of VA criteria for nonformulary use of insulin glargine in 21 VA treatment facilities that were surveyed about the issue. The examination found differences in the use of insulin glargine across the 21 treatment facilities and in the approach to implementing the criteria for nonformulary use of insulin glargine used at the individual VA treatment facility level. Differences were identified regarding the respective roles of endocrinologists and PCPs in prescribing insulins, including insulin glargine. The study group urges further short- and long-term research to better understand the utilization, cost, and health outcome implications of the implementation process for the nonformulary criteria. Lessons learned from such research could benefit other health care systems and formulary committees.

In March 2006, the Pharmacy & Therapeutics (P&T) Society, based in Glastonbury, Connecticut, assembled a study group of health services researchers and diabetes-treating physicians from the Department of Veterans Affairs Health Care System (VA). All had additional clinical and/or academic responsibilities outside of the VA. The four study group objectives were to (1) examine the process by which a new technology/drug is implemented in a well-managed, evidence-based national formulary system, such as the VA; (2) explore an example of the use of a new drug in the VA, which might be useful to formulary development committees in different settings, as they seek to implement and incorporate changes in technology into formularies; (3) identify a process that

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combines the rigor of an evidence-based formulary review with the ability to flexibly respond to local needs; and (4) offer insight to public and private health care systems that, increasingly, make national formulary decisions but still wish to maintain implementation flexibility for local health plans, clients, or affiliates.

The initial technology selected for consideration was the agent insulin glargine, and the example was its use in the VA. This example was selected for a number of reasons. Many patients are reluctant or unable to accept or adhere to a regimen of "traditional" insulins, partly owing to fear of hypoglycemia.[1,2] Furthermore, the prevalence of diabetes in the general population and particularly in the VA population is well documented.[3,4] Finally, insulin glargine and traditional insulin therapies are not equivalent in cost.

In the United States, insulin glargine was approved by the Food and Drug Administration in April 2001 for the treatment of type 1 and type 2 diabetes, and is the first long-acting insulin analog providing consistent insulin levels over a 24-hour period without a significant peak effect.

VETERANS AFFAIRS HEALTH SYSTEM: MANAGEMENT AND PRACTICE

The VA is a national integrated health care system that provides comprehensive health care to eligible U.S. veterans of the armed forces.[5] The VA operates in every state, the District of Columbia, and Puerto Rico, with more than 1,300 care sites. This includes 154 medical centers, 875 ambulatory care and community-based outpatient clinics, 136 nursing homes, 43 residential rehabilitation treatment programs, and 88 comprehensive home-care programs. Veterans Affairs health care facilities provide a broad spectrum of medical, surgical and rehabilitative care. Over the past six years, the VA has organized care into 21 regional Veterans Integrated Service Networks (VISNs).

In 2005, the VA health care system had 7.7 million veterans enrolled and eligible for care, and its facilities provided care to more than 5.3 million veterans. Veterans Affairs' outpatient clinics had 57.5 million visits and 587,000 patients were treated in VA hospitals. More than 65% of all disabled and low-income veterans received their health care from the VA.

Health care management is distributed across the system; some control emanates from the national level, but most functions are decentralized to the VISN level. The VA has a national formulary in which preferred prescription drugs are chosen based on evidence of safety and effectiveness. The VA negotiates favorable prices for formulary drugs. Criteria for use for both formulary and nonformulary therapies may be determined at the national level. However, system changes throughout the past decade have led to increased decentralization of management, with more control exercised at the VISN level. This allows for variation in local implementation of nonformulary criteria for the use of drugs and in prescribing practices across the system.

The VA Health Care System maintains an evidence-based national formulary process established by its P&T Committee with input from its Pharmacy Benefits Management Strategic Healthcare Group. Each of the 21 VISNs has its own drug formulary and can rely on the national formulary (also benefiting from national contracts) or utilize additional products based on VA procedures. Budget management for drugs is shared between the VISNs and their facilities.

The "Nonformulary Criteria for Use of Insulin Glargine" that are part of the subject of this paper were issued in January 2002 by the Veterans Health Administration Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel (Figure 1).[6]

METHODS

This project consisted of both qualitative research and data analysis components, designed to provide insight into how the national VA formulary provides for flexibility in local implementation.

The study group met on March 17, 2006 to review the VA criteria for use of the nonformulary drug insulin glargine, review information gained from interviews with

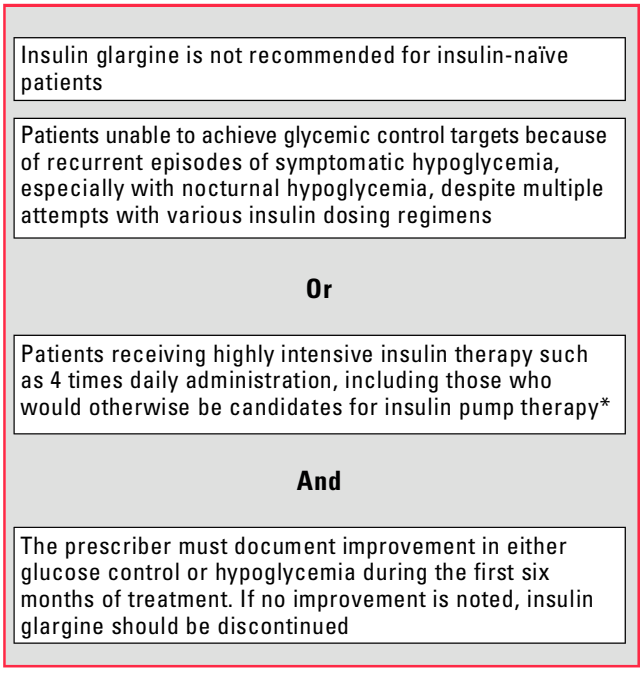

Figure 1. The specific Veterans Affairs Criteria for Nonformulary Use of Insulin Glargine. *This recommendation is based on the pharmacokinetic/pharmacodynamic profile of insulin glargine which suggest a more steady insulin level and which may assist patients who are trying to maintain very strict and tight control of their blood sugar while minimizing symptomatic hypoglycemia. Reprinted from Veterans Health Administration Pharmacy Benefits Strategic Healthcare Group and the Medical Advisory Panel: Criteria for Non-formulary Use of Insulin Glargine (Lantus) (www.pbm.va.gov/criteria/insulinglarginecriteria.pdf). With permission.

21 VA clinicians treating diabetes, review an analysis of national VA data describing the use of insulin (including insulin glargine) at the VISN level, and examine the experience of the individual treatment facilities with respect to use of insulin glargine. The study group reviewed the qualitative and data analysis components together to better understand the use of insulin glargine in the VA to date. It also discussed the usefulness of this approach for further research to understand the implementation of a new technology, using insulin glargine within the VA as an example. Finally, the group considered the implications of this examination for formulary committees in other practice settings.

Diabetes-Treating Physician Interviews Regarding Implementation of the Criteria for Nonformulary Use of Insulin Glargine at the Individual VA Treatment Facility Level. The P&T Society interviewed a convenience sample of 21 diabetes-treating physicians in March and April 2005 to better understand how their facilities managed the adoption of insulin glargine at the local level. A convenience sample is a sample based on accessibility and availability and not collected systematically to represent the base population. The sample comprised 20 endocrinologists and one PCP who was a chief of medical services. Physicians were selected to include one physician from each VISN willing to be interviewed. Beyond that, no other specific selection criteria existed. Lists of endocrinologists and other physicians treating patients with diabetes in each VISN were obtained and potential interviewees were randomly selected for recruitment. Working down the lists, physicians were contacted, and the first available volunteer was then interviewed.

A structured discussion guide was developed for the interviews to ensure consistent coverage of pertinent information across the interviews. All interviews were conducted one on one over the telephone and lasted 45 to 60 minutes. Interviews were recorded, and the information obtained was subsequently abstracted into summaries using standardized methods. The physicians interviewed offered a perspective on how they treat diabetes and how they may access insulins in general, insulin glargine in particular. However, given the limited size of the sample and the lack of rigor in selecting interviewees at each facility, this interview program must be considered exploratory; it cannot be taken to accurately represent the position of each VA facility or VISN. It offers the perspective of a practicing physician and often influential member of the medical community at each facility.

Specific Interview Findings. Most respondents suggested that insulin glargine is a potentially useful new component of patient care. However, they also expressed concerns about the agent, particularly regarding its higher net cost than that of other types of insulin and the fact that it cannot be mixed with other insulins.

The interviewees generally expressed the belief that the adoption of new technologies within the VA at the treatment-facility level may be influenced by available guidelines and prescribing criteria. For example, according to respondents, almost all endocrinologists and PCPs are familiar and compliant with the prescribing criteria for insulin glargine as a nonformulary agent and recognize that NPH and ultralente are cost effective for many patients with diabetes. Almost all interviewees described a situation in their facilities where pharmacists require PCPs to strictly comply with centrally developed insulin glargine prescribing criteria. A few of the responding physicians said that their facilities do not permit PCPs to prescribe insulin glargine; instead, PCPs must refer patients appropriate for insulin glargine to endocrinologists for evaluation.

Many of the specialists interviewed were open to evaluating new technologies and using them within the VA's nonformulary criteria. The endocrinologists interviewed estimated that, on average, 10% of their patients with diabetes received insulin glargine, ranging from 0% to 50% of each endocrinologist's population of patients with diabetes. They expect that use of insulin glargine within the VA may rise over time, owing to an increasing number of patients with diabetes, overall growth in the use of insulin, and increasing awareness of and familiarity with insulin glargine. However, for the VA endocrinologists who also maintain practices at local academic medical centers or in the community, almost all those interviewed reported a greater use of insulin glargine outside their VA practices.

To the contrary, interviewees indicated that many PCPs prescribe insulin, including insulin glargine, less frequently than endocrinologists. The responding chief of medicine (commenting on PCP prescribing in his VA facility) estimated that PCPs prescribe insulin glargine for 5% or fewer of their patients with diabetes compared with the 10% average for endocrinologists. The reasons for this difference, as suggested by all interviewees, include the harried nature of the primary care practice, which limits the time available to learn when and how to utilize new technology, based on prescribing criteria; the tendency to refer patients with diabetes to endocrinologists for the prescribing of insulin glargine; and a lack of time to educate and monitor patients about the new technology.

Study Group Observations Regarding Application of the Nonformulary Criteria for Insulin Glargine Use. Study group members confirmed the observations from the interview program and recognized that it might take a long time for the VA to completely evaluate the economic effect of a new technology, as adoption rates can vary across individual treatment centers. It also can be challenging to separate the implications of a new technology from other factors, such as therapy adherence, lifestyle modifications, or the effect of other treatment modalities.

The desire to achieve long-term benefits from any new

technology further highlights the need to understand the relationship between who invests in an intervention and who realizes its benefits. For example, one VA facility could invest in the use of a new technology whereas another provider setting or health plan, either within or outside of the VA, could realize the cost savings if the patient relocates or changes payers.

Interview respondents and study group members suggested that both short- and long-term cost savings, as well as related investments, should be considered in formulary and policy development. Currently, the ability of a facility to achieve short-term savings may affect its approach to the use a new technology where benefits might not be realized for some period of time. It also was observed that few studies may initially document the economic effect of a relatively new technology, leading to different adoption rates based on how an individual provider or treatment setting interprets and applies the available body of evidence.

This also provides a lesson for formulary decision makers in other practice settings. As pharmaceutical care becomes more expensive over time, and as the benefits of pharmaceutical interventions may take a long time to accrue, it is important to recognize drugs that have long-term clinical benefits for the patient. Unbiased pharmacoeconomic analyses that demonstrate cost savings, especially short-term cost savings, can effectively support the adoption of a new technology. To be credible, however, analyses must separate the effect of the new technology from other clinical and economic factors. Furthermore, underlying assumptions and variables must be customizable to specific health care settings. The analysis needs to also directly compare the economic effect of the new technology to that of the existing standard of care. Finally, the analysis must evaluate the economic effect of a new technology over several years, if it is a chronic treatment (as is insulin glargine). The study group indicated the need for further research to more precisely assess the influence of the nonformulary criteria at the individual VISN and facility level.

Changes in the VA adoption of a new technology is both a national and regional decision, combining national and VISN formulary decisions with local facility application. Support for a change in local policy that cuts across both medical and pharmacy services requires detailed discussion between pharmacy, medical, and senior management of all key clinical and pharmacoeconomic criteria.

The study group concluded that the evaluation and successful implementation of a new technology requires the development of an educational process that facilitates exchange of information among medical and pharmacy leadership, including primary care and specialist physicians, and accommodates any needed new practice patterns. Such a process should facilitate dissemination of formulary and guideline decisions and supporting rationale to diabetes clinics, endocrinologists, PCPs, as well as patients.

The Perceptions of Individual VA Diabetes Treaters' Regarding Implementation of Nonformulary Use of Insulin Glargine Criteria at Their Treatment Centers. After the interviews, the individual VA treatment centers represented by the physicians interviewed were divided into three groups based on the degree of flexibility in the centers' implementation of the nonformulary criteria for insulin glargine use. This was based on the interviewees' report of the degree of freedom of endocrinologists to prescribe insulin glargine outside of the VA's nonformulary criteria (Figure 1). It also included the prescribers' comments regarding the freedom of PCPs in their treatment centers to prescribe insulins in general and insulin glargine in particular. No effort was made to ascertain if the individual treatment facility approaches described reflected official policy or practice within its VISN. The study group, however, believes that a larger and more comprehensive examination of more of the treatment facilities in each VISN might enable this grouping to be made at the VISN level.

Of the 21 treatment facilities where a physician was interviewed, one-third were classified as having a flexible approach to implementation of the nonformulary criteria for prescribing insulin glargine (i.e., endocrinologists can prescribe insulin glargine outside the nonformulary criteria); one-sixth had a moderately flexible approach (i.e., endocrinologists can prescribe outside the nonformulary criteria, but only with justification); and the remaining half had a strict approach to implementation of the criteria (i.e., endocrinologists may not prescribe outside the nonformulary criteria) (Table).

Variation in the Use of Glargine Insulin in the VA Health System. Data from the VA health care system were used to characterize prescribing of insulin glargine and examine variation in its use across the system. The specific aims of the analysis were to measure the proportion of patients with diabetes, treated with insulin, who were prescribed insulin glargine; the proportion of patients with diabetes who were eligible for insulin glargine based on the VA's nonformulary criteria for use; the proportion of eligible patients who were actually treated with insulin glargine; the proportion of patients prescribed insulin glargine who were eligible to receive it; and the characteristics of patients who were eligible for treatment and/or were actually treated with insulin glargine. Variation in these measures was examined across the 21 VISNs of the VA health care system.

This study utilized extensive computerized medical and administrative data available for all VA patients nationally.[7–9] The VA has a mature electronic medical record system with national standardization and quality control that provides a rich series of national data available for research. This includes patient pharmacy records and laboratory data from the Health Care Analysis Information Group (Milwaukee) and the Decision Support System,

and VA service use records from the VA Austin (Texas) Data Center. Data were linked using scrambled Social Security numbers and processed into longitudinal patient records for all identifiable patients with diabetes in the VA. Patient-level data were available on sociodemographics, other patient characteristics, vital status, inpatient and outpatient medical encounters, prescriptions, procedures, diagnoses, and laboratory test results. After linkage, all analyses were conducted using de-identified data. This analysis received human studies review and approval from the institutional review board at the Bedford VA Medical Center. Data from outpatient prescription records and other medical records from October 1, 2001, through September 30, 2003, were used to report on insulin glargine use in fiscal year (FY) 2003 (October 1, 2002–September 30, 2003).

Miller and colleagues[3] developed and evaluated reliable methods to identify patients with diabetes in the VA and to describe their treatment regimen. Diabetes was identified based on the presence of two or more *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) codes for diabetes (250 [diabetes mellitus], 357.2 [polyneuropathy in diabetes], 362.0 [diabetic retinopathy], 366.41 [diabetic cataract]) in the medical records over a period of 24 months and/or a prescription for a diabetes medication (e.g., insulin, sulfonylureas, biguanides, thiazolidinediones, alpha-glucosidase-inhibitors, meglitinides).[10] These methods for diabetes identification were found to have high sensitivity (93%) and specificity (98%) against patient self-report. This identified approximately 1 million patients with diabetes in FY 2003, representing more than 23% of the VA population and a substantial increase in the diabetes prevalence since FY 1998 (16.9%).[3] The identified patients with diabetes had reasonable rates of treatment with diabetes medication (87%) and testing of glycated hemoglobin (HbA_1c) levels (75%). When diabetes prevalence was examined across the VISNs, researchers noted a modest variation in rates ranging from a low of 19.9% to a high of 25.8%.

Algorithms using available computerized data were developed as a working definition to assign patients as eligible for insulin glargine at a given point in time based on the VA Nonformulary Criteria for Insulin Glargine Use.[6] Based on these criteria, eligibility for insulin glargine was assigned if patients with diabetes had previous insulin use with inability to achieve glycemic control and symptomatic hypoglycemia despite use of various insulin regimes. Previous insulin use was determined by the presence of a VA prescription for insulin in the past six months. Inability to achieve glycemic control was based on the presence of an HbA_1c test of 7% or greater in the past six months. Symptomatic hypoglycemia was assigned if a hypoglycemia ICD-9-CM code was seen (250.8 [diabetic hypoglycemia, hypoglycemic shock], 251.2 [hypoglycemia, unspecified]) in the medical records in the past year, and use of one or more insulin regimens was assigned if changes existed in insulin formulations or dose within a year. These definitions were decided on after evaluating the effects of variations (such as requiring 2 hypoglycemia codes or limiting the window for changes in insulin regimen to 6 months).

The proportion of patients with diabetes eligible for insulin glargine may be underestimated. Although most VA patients receive the majority of their prescriptions from VA pharmacies, some prescriptions may be obtained from other sources and, therefore, would be missed in this analysis. It is also possible that some changes in insulin regimens may not be recorded in the physician's notes and pharmacy records. Furthermore, the researchers could not identify the small percent of patients who were taking intensive insulin therapy (4 administrations/day), which would have made them eligible for insulin glargine use according to VA guidelines. The most serious limitation stems from the underrecording of hypoglycemia episodes in the medical records. This would be most likely for less-severe hypoglycemia episodes or those that occur outside of VA health care. Many VA patients are eligible for non-VA health care, particularly care financed by Medicare. As a result, they may receive care for hypoglycemia in other settings and the episode may not be recorded in VA records. This underreporting may be substantial. Therefore, requiring coded hypoglycemia in the definition is very conservative and may severely underestimate the number of patients eligible for insulin glargine. On the other hand, the PTS study group considered a history of hypoglycemia to be a major reason

TABLE: SEGMENTATION OF INDIVIDUAL VA MEDICAL CENTERS BASED ON THE PERCEPTIONS OF 21 INTERVIEWEES ON THE DEGREE OF FLEXIBILITY IN IMPLEMENTING THE NONFORMULARY CRITERIA FOR INSULIN GLARGINE USE

	Criteria		
Variable	**Flexible**	**Moderately Flexible**	**Strict**
Number of VA Medical Centers	7	4	10
Interviewee Reported Conditions at VA Medical Center	Endocrinologists can prescribe insulin glargine outside the nonformulary criteria	Endocrinologists can prescribe outside the nonformulary criteria, but only with justification	Endocrinologists are are not permitted to prescribe outside the nonformulary criteria

VA = Veterans Affairs.

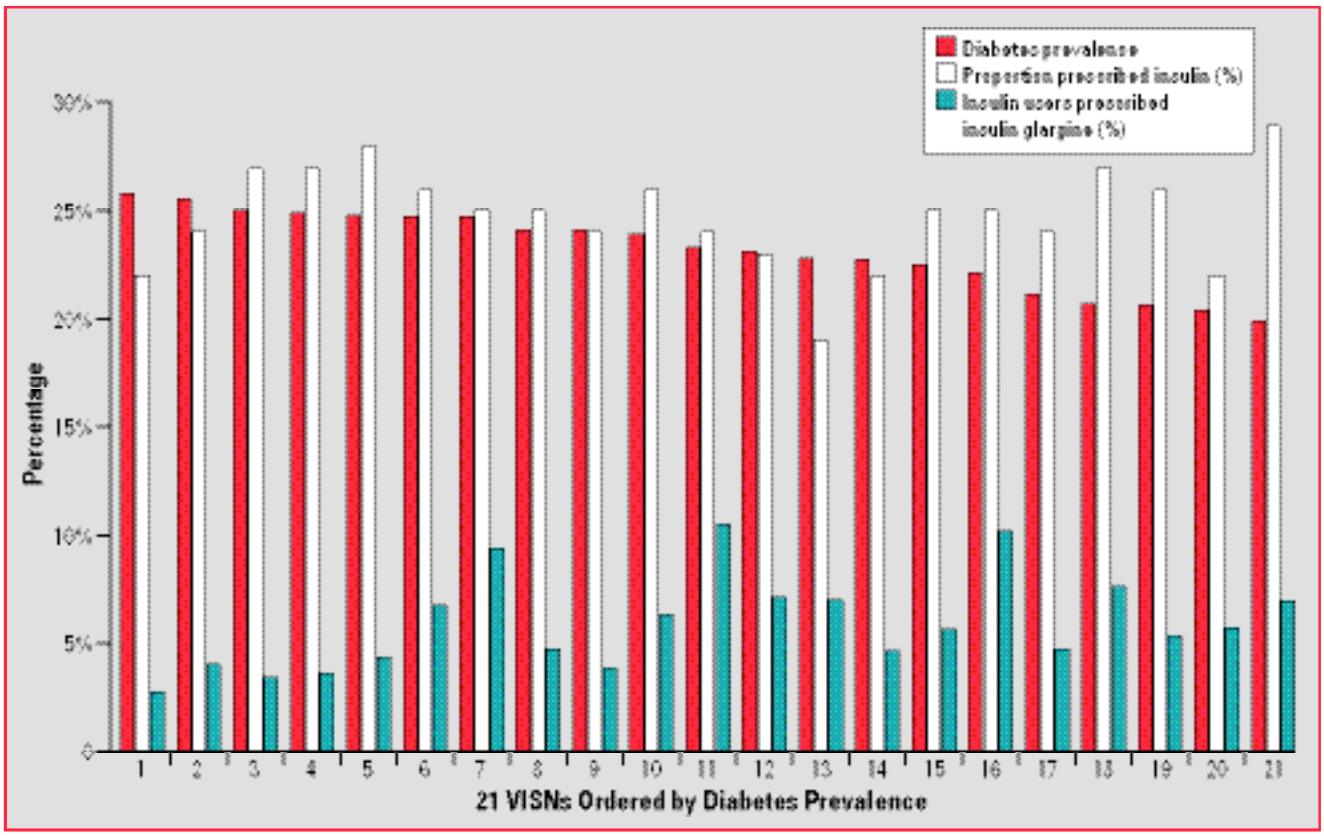

Figure 2. Diabetes prevalence and the proportion prescribed insulin and insulin glargine by Veterans Integrated Service Network (VISN). VISN numbers were assigned based on order, not actual VISN number.

for prescribing insulin glargine in the VA. Although many of those patients who were prescribed the drug were likely to have such a history, the requirement for documentation is quite liberal and probably would overestimate the number of patients eligible for insulin glargine. For this reason, and because the true estimate lies between the two, parallel analyses were conducted with and without the requirement of a code for hypoglycemia. The proportions of patients with diabetes eligible for insulin glargine were calculated as ratios of counts of those considered to be eligible (with or without the hypoglycemia requirement) over the total numbers of patients prescribed insulin. In this report, "insulin glargine eligible definition I" includes the hypoglycemia requirement, whereas "insulin glargine eligible definition II" does not include this requirement.

Variation in the Use of Glargine Insulin and Its Relation to Eligibility for Use Across the VA Health Care System. Variation in treatment practices were noted across the VA. Of the 924,062 VA patients with diabetes in FY 2003, 226,824 (24.5%) were prescribed insulin and the proportion of patients with diabetes who were prescribed insulin ranged from 19.1% to 28.6% across the 21 VISNs of the VA (Figure 2). The proportion of VA patients prescribed insulin who were prescribed insulin glargine in 2003 was 5.6% (12,614) and ranged from 2.7% to 10.7% across the VISNs. At the VISN level, little apparent relationship existed between the proportion of insulin users prescribed insulin glargine and the prevalence of diabetes. Those VISNs with a higher proportion of patients with diabetes who were prescribed insulin also tended to have a higher proportion of patients prescribed insulin glargine.

Since its introduction to the market in 2001, insulin glargine use has increased steadily in the VA, from 2.5% of insulin users in FY 2002 to 5.6% in FY 2003. With few exceptions, those VISNs that had the highest use of insulin glargine for their patients with diabetes in FY 2002 continued to have a high level of use in FY 2003. Although some variation existed in the racial profile of patients with diabetes using insulin across the VISNs, a relationship between race and insulin glargine use was not revealed. Likewise, no relationship of variations in insulin glargine use within VISNs and patient age appeared to exist. Furthermore, insulin glargine prescribing by VISN was not related to the size of the VISN patient population or any discernable geographic characteristic. A more extensive examination of VISN characteristics and insulin glargine prescribing might produce more definitive findings, but it is beyond the scope of this project.

The proportion of insulin users who were eligible for insulin glargine were estimated based on the working definitions described previously. For the VA nationally, 3.7% (8,392) met definition I (range across the VISNs,

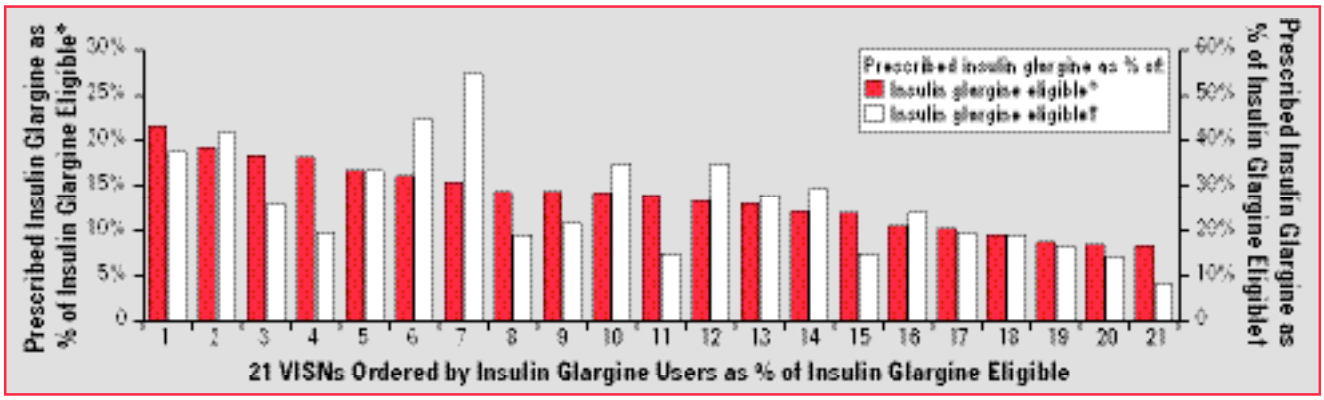

Figure 3. Insulin glargine use among the eligible (based on 2 definitions) by the Veterans Integrated Service Network (VISN). *Requiring hypoglycemia. †Eligible without requiring previous hypoglycemia. VISN numbers were assigned based on order, not actual VISN number.

1.9%–7.1%) and 7.0% (15,878) met definition II, not requiring previous hypoglycemia (range across the VISNs, 5.7%–9.1%). When insulin glargine use was examined among those who were considered to be eligible (Figure 3), it was revealed that 24.8% of those eligible by definition I (requiring hypoglycemia) were prescribed insulin glargine (range, 8.0%–52.6%); under the less stringent definition II (not requiring hypoglycemia), 12.6% of eligible patients received insulin glargine (range, 8.0%–20.7%). The ranking of proportions of eligible patients treated with insulin glargine are similar for the two definitions, although a few outliers were seen. Whereas differences in hypoglycemia coding or prescription notations may exist in these few outlying VISNs, these are regions where prescribing of insulin glargine follows the guidelines substantially more (or less) stringently.

In any case, this analysis indicates that between 6,311 (75.2% of those with definition I) and 13,877 (87.4% of those with definition II) of patients with diabetes who were eligible for insulin glargine, based on VA nonformulary criteria, were not prescribed the medication in 2003; this ranged from 47.4% to as high as 92.0% across the 21 VISNs.

Figure 4 presents a further examination of how well VA patients prescribed insulin glargine conform to VA nonformulary criteria as reflected in working definition I (requiring previous hypoglycemia). Insulin glargine use among the eligible as a percentage of all insulin glargine users averaged 44.6%, indicating that the majority of users did not meet the criteria for use. The majority of these patients did not have a code for hypoglycemia, so underreporting of this condition may account for much of this discrepancy. In addition, 12% of those prescribed insulin glargine had no record of prescribed insulin in the past six months, and another 31% had prescription records of only a single formulation and dose of insulin in the previous six months. This indicates that insulin glargine is substantially prescribed in patients who do not meet the VA nonformulary criteria for use. The proportion of insulin glargine users who were considered eligible for use ranged from 25.4% to 81.2% among the VISNs. Those VISNs with the lowest proportions tended to have the highest use of insulin glargine as a percent of all insulin users. This suggests part of the higher insulin glargine use in these VISN is accounted for by use among those who are not eligible for use according to VA nonformulary criteria.

This analysis has a number of limitations, including missing patient characteristics; missing prescribers' assessment of patient capabilities, family, and social

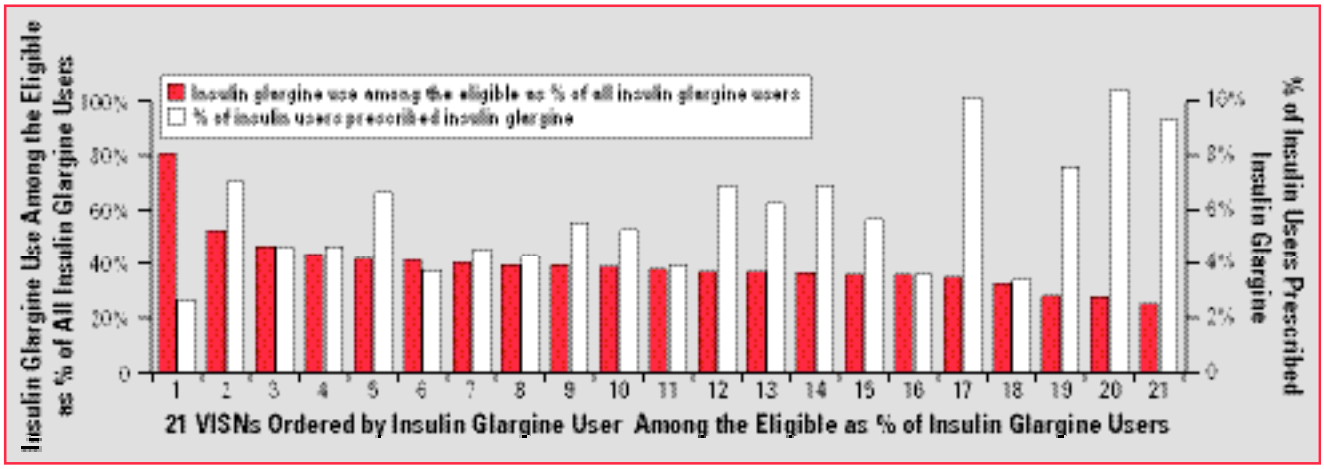

Figure 4. Insulin glargine use by eligibility and proportion prescribed insulin glargine by the Veterans Integrated Service Network (VISN). VISN numbers were assigned based on order, not actual VISN number.

environment; missing records for hypoglycemia, and missing information on non-VA supplied prescriptions and care; and potential errors in assessment of medication use, including difficulties in interpreting prescription records, limited regimen information, dose, and formulation changes between prescriptions and missing data. Furthermore, criteria eligibility does not always mean appropriateness of therapy.

RECOMMENDATIONS FOR FUTURE RESEARCH AND IMPLICATIONS FOR OTHER TECHNOLOGIES

The study group recognized the value of examining endocrinologist and PCP perceptions to assess the degree of flexibility associated with the implementation of the nonformulary criteria for insulin glargine use. They recommended that further research be undertaken with a larger number of respondents to gain a more representative picture of implementation of the criteria within VISNs. The group suggested that further studies interview physicians at more VA medical facilities per VISN, with more interviewees at each facility; include PCPs, pharmacists, nurses, and formulary managers; weigh longer-term as well as short-term clinical and cost benefits of new technologies, such as insulin glargine; and directly evaluate saving in costs and extent of patient care that may be appreciated with implementation of new technologies, such as insulin glargine.

The following suggestions may improve the process of adopting new medical technologies in general and insulin glargine in particular: First, one can promote education about insulin glargine, and how to administer it appropriately, within group or individual learning settings. For example, interviewees were asked to comment on a variation of the nonformulary criteria implemented at one Midwest VA medical center. Almost all respondents in this study wanted a better understanding of the rationale for this policy variation (i.e., educate other VA medical centers).

Second, one can provide partially completed nonformulary request forms or computer templates that prompt PCPs to provide the exact information that VA pharmacists require to approve insulin glargine use requests. Such forms are now in place at only some VA facilities.

Third, quicker referrals to an endocrinologist must be encouraged, as needed and as available.

The study group was sensitive to the cost of care in specialty versus primary care settings and believed the complexities of diabetes diagnosis and treatment might warrant more frequent referral to endocrinologists. However, study group members noted that in many treatment facilities, the number of endocrinologists is low relative to the diabetes patient population, potentially slowing the adoption of a new technology if it is primarily endocrinologists who drive adoption. In non-VA settings, these recommendations highlight the need to ensure complete and accurate information entry, use of the formulary committee as a coordinator and educator, and primary care friendly protocols for treatment and referral to subspecialty care.

Evaluation and adoption of new technologies should be based on credible clinical evidence, supported by short- and long-term safety and economic data that reflect and accommodate differences in primary care and subspecialty practice patterns, and identify where any anticipated cost savings will accrue (i.e., medical, surgical, or pharmacy services). The evaluation and adoption of a useful new technology requires the development of an educational process that facilitates the exchange of information and accommodates new practice patterns and relationships between primary care and subspecialty services.

CONCLUSION

The study group examined the approach by which a new medication, insulin glargine, has been implemented within the VA. Although the use of insulin glargine has grown over time in the VA, substantial variation exists among individual VISN and VA medical centers in the use of glargine insulin. The study group attempted to identify patients within the VA eligible to receive insulin glargine, the percentage of eligible patients receiving insulin glargine, the number of eligible patients within VISNs who might receive insulin glargine, and the percentage of those prescribed insulin glargine who are eligible by nonformulary criteria.

The study group believes this approach to understanding the implementation of new technology and pathways for application to an eligible population may hold lessons for formulary committees and other health care organizations. This is particularly true for organizations with national formularies or criteria-for-use that also seek to preserve flexibility and accommodate the needs of affiliated local health care systems.

The study group urges further research in this area to accumulate longer-term data and better understand the long- and short-term utilization, cost, and health outcome implications of insulin glargine use.

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