AMD nals 2010

> QUALITY INDICATORS IN DIABETES CARE IN ITALY

The AMD Annals 2010 Working Group\* and Antonino Cimino, Danila Fava, Carlo B. Giorda, Illidio Meloncelli, Antonio Nicolucci, Fabio Pellegrini, Maria Chiara Rossi, Salvatore Turco, Giacomo Vespasiani



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(data referred to May 2010)

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# Introduction

Now in its fifth edition, the 2010 AMD Annals may be rightly viewed as a mature work thanks to the growing involvement in this annual quality care survey of Italian diabetes centers. The number of participating centers has risen from 124 in 2008 to 251 this year, and the number of cases from about 200,000 to about 500,000, which accounts for about one fifth of the population with diabetes in Italy. National coverage now includes all regions, with data for six consecutive years (2004-2009). This goal marks a milestone for the AMD and diabetologists seeking to improve the delivery of services to their patients.

It would be difficult to identify all the reasons for the extraordinary response, but three clearly merit consideration.

The first is the opinion of a legal consultancy the AMD contacted to solve privacy and legal issues connected with data collection by the Annals system. In the lawyers' opinion, the entire procedure, the regulation and the result of the Annals pose no violation of privacy and confidentiality; instead, they may provide a valid model for similar initiatives designed to analyze clinical data for public use.

The second is the appointment of 40 regional tutors around the country who worked alongside the editorial committee on the design and development of the Annals and disseminated knowledge of the project in their respective areas. This led to a greater involvement of centers in most regions, both large and small, as well as university centers, all sharing in the objective to improve their services. There was no formal classification scheme for performance; instead the information was aggregated at the national and regional levels and compared against the best-performing centers, which remain anonymous, with a view to create a virtuous circle of improvement which has consistently guided our activities.

The third is the quality of the data processed by the Consorzio Mario Negri Sud and the coherence the AMD has demonstrated between the declaration of intent and the objectives attained.

Data collection, which has just closed, will provide the basis for the 2010 and 2011 Annals. We have decided to utilize biennial data collection to allow sufficient time for in-depth analysis of the data now in the database. The 2010 edition presents the standard "transversal analyses" carried over from the 2009 edition on national and regional indicators. In addition, analysis was performed on the "new entries", as a contribution to the AMD's Subito! project, and an analysis of a new total quality care indicator, the Q score. Created by Antonio Nicolucci and his group at Mario Negri Sud within the framework of the QuED study and validated by evidence from the literature and the QUASAR AMD study, this super-indicator is calculated not only from the values of the parameters for cardiovascular risk but also the quality of services delivered. The Q score correlates closely with the occurrence of cardiovascular complications and shows that while many centers achieve better than average scores, there is a wide variation that does not follow the northsouth divide. In other words, while many centers perform well, many still have to improve and will catch up thanks also to the Annals and ongoing AMD initiatives.

Besides the publication of the Annals, the AMD has singled out topics that merit further study and could be the subject of other publications. The AMD database can be accessed for analysis projects approved by the AMD national executive board; however, this unique resource has not yet been utilized to date. Therefore, to maximize utility of the wealth of data contained in the Data File, we have drawn up a list of analyses that can directly tap into this data source and may be conducted on commission upon request.

#### Potential AMD Annals Monographs

- Longitudinal study of prescription patterns for antidiabetic drugs in relation to patient characteristics (age, sex, duration of diabetes)
- Longitudinal study of prescription patterns for antihypertensives in relation to patient characteristics (age, sex, duration of diabetes)

- Longitudinal study of prescription patterns for lipidlowering agents in relation to patient characteristics (age, sex, duration of diabetes)
- Longitudinal study of prescription patterns for antiplatelet drugs in relation to patient characteristics (age, sex, duration of diabetes)
- Study on the achievement of metabolic targets in relation to patient characteristics (age, sex, duration of diabetes)
- Study on the achievement of target blood pressure in relation to patient characteristics (age, sex, duration of diabetes)
- Study on the achievement of target lipid profile in relation to patient characteristics (age, sex, duration of diabetes)
- Geographic variation in prescription patterns and reaching treatment targets
- Study on rates of reaching multiple targets in relation to prescription patterns and patient characteristics
- Study on the therapeutic approach to patients with newly diagnosed diabetes
- Study on the therapeutic approach to the older old
- Study on the therapeutic approach and intermediate outcomes in severe obesity
- Study on prescription patterns for antihypertensives in patients with incipient nephropathy and geographic variation
- Longitudinal study on prescription patterns for diabetes and cardiovascular risk factors in patients with type 1 DM
- General medicine: comparative study on prescription patterns and targets reached in relation to patient sex
- Study on unmet treatment needs in relation to cardiovascular risk profile
- Definition of care profiles of patients with retinopathy

- Definition of care profiles of patients with nephropathy
- Definition of care profile of patients with cardiocerebrovascular complications

The Annals have garnered national and international recognition. This should encourage us to improve further and to promote positive actions. To this end, the AMD will launch a series of initiatives which, by utilizing the AMD indicators, can open new improvement pathways. One such example is the BENCH-D study conducted in collaboration with Novo Nordisk within the framework of the Changing Diabetes Barometer project. The aim of the study is to facilitate benchmarking of results in diabetes care within a region and to encourage the implementation of improvement strategies. The project has been started up in four regions (Piemonte, Marche, Lazio, and Sicilia), and its extension to the remaining regions is planned. This approach is part of clinical research and, in our opinion, represents the future of diabetes care in Italy from both a medical and a political perspective.

Although our efforts in data collection have attracted increasing interest from public agencies, our work will need to demonstrate practical implications for improving our actions.

The editorial committee wishes to thank all of you who have supported this initiative by providing data, the tutors who will be entrusted with further developing the Annals, the Consorzio Mario Negri Sud for completing the data analysis in record time, Lifescan Italia for funding the data analysis, and the AMD executive board for their continued support.

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# **Methods**

Now in its fifth edition, the AMD Annals are a consolidated reference source for the description of diabetes care in Italy. Participation in the initiative continues to grow: from 86 providers in 2006 to 122 in 2008-2009 to 251 in the current survey.

Steady growth in the number of centers is important for statistical purposes as it increases sample stability, robustness of internal data, and representativeness of care profiles, which has been consistency high since publication of the first Annals. The primary aim of the AMD Annals is to furnish a tool for improving the quality of diabetes care services delivered by participating centers. To this end, increasing participation in the survey is a fundamental goal of the AMD as it allows for including centers in a pathway of assessment and continuing improvement of their performance.

With the two-fold increase in the number of newly participating centers, the study population has been completely redefined, rendering the comparison between this year's survey and past surveys difficult. However, because all participating centers reported data for the 2004-2009 period, an indepth analysis of time trends will be presented in the 2011 AMD Annals.

#### **ELECTRONIC HEALTH RECORD**

To participate in the survey, centers must have computer systems (electronic health record) for normal data management of their patients and for standardized functionalities for accessing the AMD Data File. This file contains all the information necessary for the description of process and outcome indicators.

There is an inevitable nexus between the quality of care and the quality of data collection. In other words, reliable evaluation of the quality of care depends directly on proper use of the electronic health record. Partially entered or missing data make it impossible to distinguish between whether a procedure (e.g., eye exam) was actually performed or simply not noted on the record. As will be discussed below, this problem precluded the use of certain indicators and influenced the selection of centers in the analysis.

#### **SELECTION OF CENTERS**

In order to ensure sufficient representativeness of their clinical practice, centers reporting <10 patients with type 1 DM or <100 patients with type 2 DM were excluded from the care profile analysis. On the basis of these criteria, 236 centers were included in the description of care profiles. Similarly, centers were excluded from the intermediate outcome analysis if they reported <10 patients with type 1 DM or <100 patients with type 2 DM. These criteria were operated because in some centers computerized systems for managing electronic health records were only recently implemented and included only a portion of the patients in their care.

#### **SELECTION OF THE POPULATION**

All analyses included active patients, i.e., all patients with either type 1 or type 2 DM who had presented at least once during 2009 to have their glycosylated hemoglobin (HbA1c) measured or a drug prescription ordered for diabetes.

## **DEFINITION OF THE GOLD STANDARD**

In the analysis of the process and intermediate outcome indicators, the total performance and the individual performance of each center was evaluated in reference to a gold standard. These reference values were calculated from the data from centers which had provided adequately complete data. Specifically, centers were selected if their reported data met the following criteria:

Variable	Threshold value (≥)
Sex	90%
Age	90%
Type of diabetes	90%
Glycosylated hemoglobin (HbA1c)	70%
Blood pressure	70%
Body-mass index	
(weight in kg/height in m <sup>2</sup> [BMI])	70%
Lipid profile or LDL-cholesterol	50%
Antidiabetic therapy prescribed	85%

In all, 131 centers (55.5% of evaluable centers) were selected. To define the gold standard, the 75<sup>th</sup> percentile of the distribution of values in these centers was taken. This value represents the best performance, i.e., the performance attained by 25% of centers with the highest values. For example, the gold standard was set at 98% for the process "HbA1c value in type 2 DM patients". This means that 25% of the selected centers had measured HbA1c at least once in at least 98% of their patients during 2009; in the remaining 75% of centers, the percentage of patients was obviously lower.

The same method was applied to measure the positive intermediate outcome indicators (e.g., patients with HbA1c  $\leq$ 7%). To measure the negative intermediate outcome indicators (e.g., patients with HbA1c  $\geq$ 8%), the gold standard was based on the 25<sup>th</sup> percentile (e.g., the value obtained in 25% of centers with a lower percentage of patients with HbA1c  $\geq$ 8%).

## **GENERAL DESCRIPTIVE DATA**

Except for certain descriptors of the total sample, the characteristics of the study population are shown separately for type 1 and type 2 DM. The data include sociodemographic (age, sex) and clinical parameters (body-mass index [BMI], HbA1c, blood pressure, triglycerides, total cholesterol, HDL-C, and LDL-C levels). When missing on the electronic health record, the LDL-C values were calculated using the Friedwald equation and only if the values for total cholesterol, HDL-C, and triglycerides had been noted the same day.

Since the normal HbA1c values vary among centers, the values were mathematically transformed to allow for comparative analysis: the value for each patient was divided by the upper limit of the norm for the center, thus obtaining the percentage deviation of the value from the upper limit of the norm. This value was then multiplied by a factor of 6.0 in order to interpret the HbA1c value against the normal reference value of 6.0.

#### **SELECTION OF INDICATORS**

As mentioned, this report is based in part on the indicators operated in the AMD Data File.

#### Process indicators

The process indicators selected for analysis were five monitoring parameters for which values were measured at least once during 2009:

- HbA1c
- Lipid profile
- Blood pressure
- Renal function monitoring
- Diabetic foot examination

For all parameters, the denominator is the number of active patients examined during 2009, except for the centers that reported <10 active patients with type 1 DM and <100 with type 2 DM.

A further process indicator is the mean number of visits by type of treatment. This was evaluated only for those centers that had recorded at least one visit in at least 80% of active patients. Application of this section criterion was necessary because in some centers the electronic health record was not used for quantifying the procedures performed, so that not all the procedures actually performed were recorded in the field necessary for creating the AMD Data File.

In this connection, among the process indicators in the AMD Data File, eye exam and diabetic neuropathy examinations were not included in this survey, because many electronic health records provide a text box for documentation of the findings from these examinations; this type of information cannot be utilized in a statistical analysis.

## Intermediate outcome indicators

The following indicators were used:

- Percentage of patients with HbA1c ≤7% and ≥8%
- Percentage of patients with LDL-C <100 mg/dl and ≥130 mg/dl
- Percentage of patients with blood pressure ≤130-80 mm Hg and ≥140/90 mm Hg
- BMI class
- Percentage of smokers
- Percentage of patients with LDL-C ≥130 mg/dl not receiving statin therapy
- Percentage of patients with blood pressure ≥140/90 mm Hg not receiving antihypertensives

In accordance with recent guidelines, the target blood pressure has been revised from  $\leq 130/85$  mm Hg to  $\leq 130/80$  mm Hg. Therefore, the 2010 AMD survey findings for this indicator differ from those reported in previous editions.

The denominator for these indicators was the number of patients who had been monitored at least once during 2009 for these parameters. As mentioned above, centers were excluded from the analysis if they reported <10 patients with type 1 DM and <100 with type 2 DM.

The final two indicators on the list were calculated only for centers which had provided sufficient treatment data (at least 5% patients receiving statin therapy and at least 10% receiving antihypertensive treatment).

The percentage of smokers was calculated only for centers which had reported at least 10% smokers among their patients.

#### Final outcome indicators

Despite their importance and functionality in the AMD Data File, these indicators were not included in the survey. As with other process indicators, information on long-term complications is often given as text rather than according to a standard coding scheme (although such schemes are included in the electronic health records).

#### Quality score (Q score)

For the first time, the AMD Annals present a section on the evaluation of the quality of care expressed as the Q score. The Q score was developed within the framework of the QuED study (Nutr Metab Cardiovasc Dis 2008;18:57-65) and then applied in the QUASAR study (poster presentation at the 70<sup>th</sup> Scientific Session of the American Diabetes Association, held in Orlando, FL, 25-29 June 2010). The Q score is calculated from the process and intermediate outcome measures, which are easily retrieved from the AMD Data File, in relation to HbA1c, blood pressure, LDL-C and microalbuminuria (measured within the last 12 months, achievement of specific target values, and prescription of adequate treatment) (Table 1). For each patient a score from 0 to 40 is calculated as an ascending index of goodness of quality of care received. The Q score has been shown to be able to predict the occur-

#### Table 1. Q score components

Quality of care indicators	Score	
HbA1c measured less than once a year	5	
HbA1c ≥8.0%	0	
HbA1c <8.0%	10	
Blood pressure measured less than once a year	5	
Blood pressure ≥140/90 mm Hg irrespective of treatment	0	
Blood pressure <140/90 mm Hg	10	
Lipid profile measured less than once a year	5	
LDL-C ≥130 mg/dl irrespective of treatment	0	
LDL-C <130 mg/dl	10	
MA measured less than once a year	5	
No ACE-I and/or ARBs therapy in patient with MA	0	
ACE-I and/or ARBs therapy in patient with/without MA	10	
Score range	0-40	
ACE-I denotes ACE inhibitor; ARBs angiotensin II receptor antagonists; MA microalbuminuria		

rence of such cardiovascular events as angina, acute myocardial infarction, stroke, transient ischemic attack, revascularization, lower-limb complications, and mortality. Specifically, the QUASAR study, in line with the results of the QuED study, reported that the risk of experiencing a cardiovascular events within a median 2.3 years was over 84% in patients with a Q score <15 and 17% in those with a Q score from 20 to 25 versus those with a score >25. Furthermore, the QuED study showed that patients attending a center with a mean difference of 5 points in the Q score had a 20% difference in the risk of cardiovascular events. These data indicate that the Q score may provide a useful instrument for describing a center's performance and for comparing performance between centers and different geographic areas.

In the AMD Annals, the Q score was used as a continuous measure (mean score  $\pm$  standard deviation [SD]) and a categorical measure (<15, 20-25, >25). The information is given by type of diabetes, sex, age group and region of the country. Like the gold standards, the Q scores were calculated for the best-performing centers: centers positioning in the upper 25% of the ordinate distribution of a center's mean Q score. In addition to the total scores, specific details (expressed as star plots, see below) are given on the magnitude of the four variables (HbA1c, blood pressure, LDL-C, and microalbuminuria) in relation to the total score.

# **GRAPHICAL SUMMARY OF DATA**

The data are presented in tables and various other graphic formats. In addition to the familiar histograms and pie charts for reporting frequency distribution, the data are illustrated in a variety of graphic formats to enhance comprehension.

#### Map of geographic representativeness

This map gives a general idea of the percentage of patients with diabetes for each region and contained in the AMD Data File. To this end, a known estimate of the prevalence of diabetes (4.5%) was used. This value was applied to each region using the 2002 ISTAT data to quantify the resident population. The shading is proportional to the percentage of patients included in the AMD Data File versus the estimated percentage.

### Box plots

Box plots are a quick yet comprehensive way of examining the distribution of a given variable. As shown in the figure, a box plot consists of a rectangle with a central horizontal line for the median, while the upper and lower edges correspond to the  $75^{\text{th}}$ and the  $25^{\text{th}}$  percentile, respectively. The upper and lower bars correspond to the  $90^{\text{th}}$  and  $10^{\text{th}}$  percentile, respectively. The symbols outside the bars represent the outliers. The width of the box and the bars indicates the variation of the variable in question: the shorter the box, the more homogeneous the measure within the data set for a study population; conversely, the longer the box, the more heterogeneous the measure within the data set for a population.



#### Star plots

Star plots examine the relative behavior of all variables in a multivariate data set and provide a simple graphical summary of a set of data. Each variable (e.g., a process measure) is expressed as a percentage on a spoke of the star plot (scores from 0 to 10). The values on the spokes are then connected to create a polygon.

Each graphic contains two polygons: the one in dashed lines represents the gold standard values calculated as described previously; the one in solid lines represents the reported values for the entire sample or for each center or patient subgroup. The closer the ends of the polygon in solid lines approximate those of the polygon in dashed lines, the



closer the quality of care delivered by a center or for a patient subgroup to the desirable target value (i.e., the value achieved by the best-performing center). For the process measures, the wider the polygon, with its vertices approaching 100%, the higher the quality of care delivered.

A polygon much smaller than the one in dashed lines (on one or more of its spokes) indicates a greater distance between the actual quality of care and the target quality. For the intermediate outcome indicators, the polygon is divided into two halves: the upper half in green represents the percentage of patients with a favorable outcome (HbA1c  $\leq$ 7%, blood pressure  $\leq$ 130/80 mm Hg, LDL-C <100 mg/dl); the lower half in red indicates the percentage of patients with unsatisfactory values (HbA1c  $\geq$ 8%, blood pressure  $\geq$ 140/90 mm Hg, LDL-C  $\geq$ 130 mg/dl). Therefore, the larger the green area and the smaller the red area, the greater the percentage of positive results obtained.

The star plots also give details on the magnitude of each variable (HbA1c, blood pressure, LDL-C and microalbuminuria) relative to the total Q score. The distance between the best-performing group (dashed lines) and the entire sample (green area) indicates a gap between the total performance of the entire sample and that of the best-performing centers. The distance between the dashed or solid lines and the end of each spoke is proportional to a center's performance for a given variable.

#### Variation graphs

The variation graphs for differences in process or intermediate outcome across centers were created using multilevel analysis techniques, after adjustment



for patient sex and age, duration of diabetes, and the clustering effect (patients followed by a center cannot be considered as an independent variable since they all tend to receive the same type of treatment).

The mean value or percentage plus 95% confidence intervals estimated within the multilevel model are reported for each center. In this way, comparison can be made between the mean HbA1c reported for each center (or the percentage of patients with HbA1c  $\leq$ 7%) after adjustment for age and sex. The values are presented in ascending order in order to show variation across centers for a given variable. The horizontal line represents the mean for the entire sample, thus showing the distance between the individual values for each center and the mean for a given variable.



The bar graphs permit comparison between the



Q score as a continuous measure (vertical bars) and as a category (horizontal bars). The sample is compared versus the results obtained by the best-performing centers.



#### **REGIONAL ANALYSES**

Like the analyses in the 2008 AMD survey, the 2010 edition contains a section on indicators presented according to region and evaluation according to interregional variation.

To ensure sufficient representativeness of regional activity, only those regions were included in the analysis which had at least five centers participating in the survey.

The 2010 AMD survey is the first to include all regions, as all had met this criterion.

The two regions with fewer than five participating centers (Valle d'Aosta and Molise) were grouped together with Piemonte and Abruzzo, respectively.



# Proportion of AMD Data File patients out of the estimated total of patients with diabetes (prevalence 4.5%)

In all, the AMD Data File comprises the data on 451,859 patients seen during 2009 in 236 centers (median, 1575 patients per center; range, 100-7507). Of these, 439,748 presented a diagnosis of type 1 DM (n = 24,428) or type 2 DM (n = 415,320). Stratified by geographic region, 54.0% patients with type 1 DM were from the north, 22.6% from the center, and 23.4% from the south; 51.0% of patients with type 2 DM were from the north, 25.3% from the center, and 23.7% from the south.

The map illustrates the distribution of the sample by region. Compared to past years, no change can be observed in the estimated figures for the Marche and Sardegna (over 45%), whereas a marked increase is seen for the number of regions which reported an estimated 15-45% of patients with diabetes. In addition, this is the first AMD Annals to have received data from all regions in the country.



# Indicators for the general population



# Distribution according to type of diabetes

Although substantially unchanged in comparison to past years, the distribution according to type of DM confirms the greater burden of care associated with type 2 DM, which accounted for over 90% of all cases seen during 2009.



# First-time visits versus total number of visits

Of a total of 439,748 patients seen during 2009, 48,257 (12.0%) were first-time visits to a diabetes care center. This percentage is in line with the

estimates of past years and shows that many more patients are seeking care at specialist centers.

# Distribution according to sex



There is a slight male predominance among patients seeking specialist care.

# Distribution according to nine age groups



In comparison with past years, no change in distribution according to age groups was observed. Over half of patients are 65 years of age or older, indicating a higher burden of care in the older population segments.



# First-time visits versus total number of visits

During 2009, of a total of 22,737 cases evaluable, 1649 (7.3%) presented with type 1 DM; of a total of 380,158 cases evaluable, 46,608 (12.3%) presented

with type 2 DM. The percentage difference shows that many more patients with type 2 DM accounted for first-time visits.



# Distribution according to sex

A slightly higher male prevalence was noted for both types of DM.

# Distribution according to nine age groups



40 34.9 35 30 25.5 25.2 25 20 15 10.4 10 5 07 0.0 0.0 0.1 0 0-5 5-15 15-25 25-35 35-45 45-55 55-65 65-75 >75 Years

DM<sub>2</sub>

As expected, there was a net difference between types 1 and 2 DM when stratified by age group. Type 1 DM was more prevalent in the younger age groups: <15% of patients were 65 years of age or older; >50% were between 15 and 45 years of age.

Type 2 DM was more prevalent in the older age groups: one-fourth of patients were 75 years of age or older. Nonetheless, the prevalence of type 2 DM in the 45-55-year age group should not be disregarded. The prevalence of type 2 DM in the younger age groups was low.

# Mean number of visits per year according to treatment group

	Type 1 DM	Type 2 DM
Diet alone	-	1.8
Oral hypoglycemics	-	2.0
Insulin	2.8	2.5
Insulin + hypoglycemics	_	2.6

The mean number of visits according to treatment group reflects the increase in care related to transitioning treatment from diet alone to oral treatment to insulin therapy. The frequency of visits by patients under insulin therapy does not appear to differ substantially between type 1 and type 2 DM. Compared to past years, there was a general decline in the mean number of visits per patient across all therapeutic classes.



#### Distribution according to treatment in patients with type 2 DM

Among patients with type 2 DM, 7.4% received education about lifestyle changes, less than onethird received insulin therapy alone or in combination with oral hypoglycemic agents, and 61.3% received only oral hypoglycemic therapy.

# **Comments on general indicators**

The compilation of the 2010 AMD Annals was made possible through the participation of 251 diabetes care centers throughout the country. The data from a subgroup of 236 centers are discussed below.

The data from 451,859 patients with diabetes and seen during 2009 were analyzed. Thanks to the growing commitment to our initiative, the sample base is now twice that recorded for 2007, with an increase of 125%, testifying to the success the initiative continues to achieve. The purpose of the initiative is to give an accurate picture of diabetes care in Italy that can inform clinical governance for diabetologists and regulatory bodies.

In figures, the percentage of type 1 DM was 5.4% (n = 24,428) and that of type 2 DM was 91.9% (n = 415,320); 2.1% patients are affected by secondary DM.

Thanks to the increasing number of participating centers, some regions account for over 45% of the

estimated regional total of patients with DM, whereas many regions account for over one-third of the estimated number of patients. Despite these good reporting rates, some regions accounted for <5% of estimated cases. The map illustrates the distribution of the sample by region. The Marche and Sardegna continue to furnish excellent reporting rates.

There was a slight male predominance in the prevalence of DM (54% versus 46%).

Among patients with type 2 DM, 65,768 (14.6%) were first-time visits. Although this percentage may appear lower compared to past years, the difference should be interpreted against the change in the number of participating centers.

Again, the 2009 survey revealed the greater care burden among the older age groups: 80% of patients 55 years of age or older and 33% of the 65-75-year age group. This suggests that the number of diabetes care centers be increased and that the delivery of and access to services better suited to the needs of the elderly.

Among patients with DM type 1, the largest age group comprises those aged 35-45 years (24.7% of total); patients between 25 and 55 years of age account for 62% of those attending diabetes care centers. A health care priority for this large segment is to provide adequate patient education with a view to enhance compliance with care and minimize complications of the condition with aging.

That DM occurs in all adult age groups, although differently distributed, may be considered as an advantage insofar as it is increasingly seen as a common enemy which public health prevention campaigns have singled out. Economic and institutional policies permitting, this greater awareness may well push the agenda forward for improving approaches to diabetes care.

The mean number of visits per year for type 1 DM was 2.82; for type 2 DM the number varies depending on the type of treatment: from 1.76 for those following a restricted diet alone to 2.6 visits for those

receiving combined insulin and oral hypoglycemic therapy.

Treatment for type 2 DM is generally with oral hyperglycemic agents (61.3%); few patients (7.4%) are treated with restricted diet alone; more often, patients receive insulin therapy (17%) or combined insulin and oral hypoglycemics (14.3%). Although recent guidelines recommend the use of metformin following the diagnosis of type 2 DM, about 30,000 receive no treatment. In contrast, a moderate proportion of patients receive insulin therapy alone despite insufficient metabolic control in a large percentage of cases. This point will be discussed in the following chapters. In general, the data reveal the persistence of therapeutic inertia.

In conclusion, besides reflecting the current levels of diabetes care, the data collected for compiling the AMD Annals allow for comparison with a view to improve clinical performance and enhance diabetes services in Italy.

Salvatore Turco


# AMD process indicators according to type of diabetes



#### Patients who had their HbA1c measured at least once

Compared to previous years, there was an increase in HbA1c monitoring, already an integral part of care in the majority of patients with diabetes: over 90% had their HbA1c level monitored at least once during 2009.



#### Patients who had their lipid profile evaluated at least once

Despite the two-fold increase in the number of participating centers, lipid profile was monitored in over 70% of patients irrespective of type of DM.

The lack of a lipid profile for nearly one-third of patients signals the need to raise attention to this important cardiovascular risk factor.



#### Patients who had their blood pressure measured at least once

Percentages for blood pressure measurement paralleled those for lipid profile; again, signaling a margin for improvement, given that values for this parameter were missing in nearly one-fourth of patients.



Patients monitored for nephropathy

As in past years, with regarding of monitoring, renal function falls behind the management of cardiovascular risk factors in patients with type 1 DM, and in those with type 2 DM in particular. Documentation of monitoring for nephropathy in patients with type 1 or type 2 DM was missing in far more cases than in previous years. A possible explanation may be the effect many new participating centers had on this trend.



At-risk subjects monitored for diabetic foot

Among at-risk patients (neuropathy, history of ulcers or amputation, lower-limb arteriopathy) with either type 1 or type 2 DM, just over 20% underwent a diabetic foot examination during the survey year. This percentage, lower than estimates for previous years, signals the need to increase monitoring (or improve noting of examination results on the health record) of diabetic foot, one of the most incapacitating complications of diabetes.



Subjects monitored for diabetic foot

Across the entire sample, alarmingly scarce attention is given to monitoring for diabetic foot: documentation of clinical findings on the electronic

health record during the survey year was noted in less than 15% of patients with either type 1 or type 2 DM.

## Star plots according to type of diabetes, patient sex and age

#### **Process indicators**



The following star plots illustrate the process measures. Each spoke represents the percentage of patients whose electronic health record reported at least one of the following parameters: HbA1C; blood pressure; lipid profile; renal function; diabetic foot examination. The polygon (dashed lines) around each star plot refers to the gold standard (see Methods); the polygon in solid lines refers to a specific patient subgroup.

#### Sample according to type of DM



The polygon (dashed lines) for type 1 DM shows that highly satisfactory percentages were obtained by the centers that concur in defining the gold standard for: monitoring metabolic control (98%); blood pressure (96%); lipid profile (90%); and renal function (77%); data on diabetic foot examination are suboptimal (27%). Analysis of the entire sample shows divergence from the gold standard. For example, the gap for HbA1c monitoring is minimal (95%) but widens for the other parameters: blood pressure (74%); lipid profile (73%); renal function (51%); diabetic foot examination (15%).

The polygon (dashed lines) around the star plot for type 2 DM shows that highly satisfactory percentages were obtained by the centers concurring to define the gold standard for monitoring metabolic control (97%), blood pressure (96%), and lipid profile (91%), and a good percentage for renal function monitoring (73%), whereas reporting of diabetic foot examination was suboptimal (22%). There was a wide gap between the gold standard and the entire sample for type 2 DM: HbA1c monitoring (92%); blood pressure (79%); lipid profile (73%); renal function (41%); and diabetic foot examination (15%).

Comparison between types 1 and 2 DM shows no stark differences in parameter monitoring versus the gold standard or the entire sample, except for renal function which was more often monitored in patients with type 1 DM than in those with type 2 DM.

#### Sample according to type of diabetes and patient sex



No gender-related differences emerged between type 1 and type 2 DM for these process indicators. The gap between the gold standard and the total sample, irrespective of patient sex, shows a margin for improvement in diabetes care.



#### Sample according to type of diabetes and age group



#### Sample according to type of diabetes and age group



#### Variation in process measures among centers



The box plots show the variation in process measures among the centers. For example, the percentage of patients with type 1 DM for which at least one HbA1c value was reported for 2009 was generally high (around 95%) in most centers, this value was reported in a lower percentage of cases by some centers (minimum of just over 60%).

Variation was far more marked for other process measures, as shown by box plot height, particularly for renal function monitoring.

Variation among the centers for monitoring HbA1c and blood pressure in patients with DM type 2 was low but higher for the other process measures.

### **Comments on process indicators**

Measurement of process indicators is one method that can be used for controlling the performance of diabetes care centers and for evaluating an organization's capabilities. While participation by many new centers in the survey gave a broader picture of diabetes care, it also presented one slightly different from past years.

And although comparison with previous situations cannot (and does not intend to) indicate any trend, it may be useful for gaining a better appreciation for the extent to which the increase in the number participating centers affected the overall picture.

Trends in process indicators will be examined in the 2011 AMD Annals.

The 2010 AMD Annals considered five major activities of the care process: glycometabolic control; lipid profile; blood pressure; renal function monitoring; and diabetic foot examination. Analysis of process measures for eye exam could not be included because of issues with the quality of data collection.

#### **Glycometabolic control**

During 2009, 94.7% of patients with type 1 DM and 92.4% of those with type 2 DM had their HbA1c measured at least once. These percentages are similar to those reported for 2007, with a slight increase for patients with type 2 DM.

#### Lipid profile

During 2009, 72.7% of patients with type 1 DM and 73.3% of those with type 2 DM had their lipid profile measured at least once. These figures are slightly higher than those reported for 2007.

#### **Blood pressure**

During 2009, 74% of patients with type 1 DM and 78.8% of those with type 2 DM had their blood pressure measured at least once. These figures are slightly higher than those reported for 2007, especially for patients with type 2 DM.

#### **Diabetic nephropathy**

During 2009, 51% of patients with type 1 DM and 41.3% of those with type 2 DM were assessed for

nephropathy. These figures are markedly lower than those reported for 2007, with a decrease of 10% for patients with type 1 DM and 7% for those with type 2 DM.

#### **Diabetic foot**

The percentage of patients with either type 1 or type 2 DM, whether or not at risk and monitored for diabetic foot, was much lower (about 25% less) than that reported for 2007.

## **Comparison with best-performing centers** (star plot)

Comparison of process measures for the gold standard centers against the entire sample (types 1 and 2 DM) shows a moderate shift (less than in 2007) in HbA1c, lipid profile, and blood pressure monitoring. A marked gap was observed (less than in past years) for diabetic nephropathy monitoring. A cause for concern is the sharp decline in the percentages of diabetic foot monitoring in the gold standard centers and across the entire sample.

#### Variation among centers (box plot)

The variation among centers for all process measures, except for nephropathy monitoring, was less than that reported for 2007. Although monitoring rates in some centers are low, the overall variation in HbA1c monitoring was minimal.

In conclusion, the increased number of participating centers highlighted a major criticality: lack of attention to monitoring of nephropathy and diabetic foot. Process indicator analysis proved, once again, to be a useful method (even more revealing, given the increase in the number of newly participating centers) for describing the quality of care delivered in Italy by diabetes services.

Comparison of each center's indicators against those of the AMD Annals (the entire sample and the gold standard) should form the basis for systematic review in the interest of improving quality of care.

Illidio Meloncelli



### **AMD** intermediate outcome indicators according to type of diabetes

#### Trend for five classes of HbA1c (normalized to 6.0)



The data shown in the figure indicate that achieving adequate metabolic control in patients with type 1 DM remains particularly difficult: 45% have HbA1c >8.0 (>9.0 in 20.8%); only 5% have HbA1c <6.0.

% The situation among patients with type 2 DM appears better: <30% with HbA1c >8.0 and 12.4%





with HbA1c  $\leq 6.0$ .



Patients with HbA1c ≤7.0%

Achieving adequate metabolic control appears to be more difficult in patients with type 1 DM than in those with type 2 DM. The graphs show that less than one-fourth of patients with type 1 DM have HbA1c  $\leq$ 7.0% and that just over 40% of those with type 2 DM do. Considering new, recent guidelines targets, 12.3% of type 1 DM patients and 26.6% of type 2 DM patients have HbA1c <6.5%.

#### Trend by LDL-C class



#### 45 41.8 40 35 32.2 30 % 25 20 18.0 15 10 8.0 5 0 <100 100-129 130-159 ≥160 mg/dl

DM2

The graphs show that 26% of type 2 DM patients and 25% of type 1 DM patients have particularly high LDL-C levels ( $\geq$ 130 mg/dl), indicating a

dyslipidemia-related cardiovascular risk in both patient subgroups.



#### Patients with LDL-C <100 mg/dl

Elevated cardiovascular risk in these patients is further highlighted in these graphs showing that about 40% of patients (DM types 1 and 2) have LDL-C levels <100 mg/dl.



#### Patients with LDL-C ≥130 mg/dl receiving lipid-lowering therapy

In all, 22.6% of patients with type 1 DM and 41.2% of those with type 2 DM were receiving lipid-lowering agents. Of these patients, two-thirds with type 1 DM and three-fourths with type 2 DM had LDL-C <130 mg/dl, demonstrating the efficacy of

treatment in attaining adequate therapeutic targets, while also underscoring the need to initiate more aggressive treatments in patients with elevated LDL-C levels.

#### Patients with LDL-C ≥130 mg/dl not receiving lipid-lowering therapy



About one-fourth of patients with type 1 DM and 30% of those with type 2 DM not receiving lipid-lowering therapy had LDL-C levels ≥130 mg/dl

and therefore could benefit from treatment. The data indicate that a wide margin remains for improving lipid profiles.



#### Trend by class of systolic blood pressure (SBP)



The trend by class of SBP shows extremely high values (>160 mm Hg) in 10% of patients with type 2 DM and in a minority of those with type 1 DM. The difficulty in achieving the recommended values

(<130 mm Hg) is more pronounced in those with type 2 DM, where only one-fourth of patients have achieved the target value.



#### Trend by class of diastolic blood pressure (DBP)



One-half of patients with type DM 1 and one-third of those with type 2 DM have target DBP (<80 mm Hg); 10% of those with type 1 DM and 20% of those with type 2 DM have DBP >85 mm Hg.

These data show that the unsatisfactory DBP values in a high percentage of cases are mainly attributable to elevated SBP. Patients with blood pressure ≤130/80 mm Hg



The graphs show that less than one-third of patients with type 1 DM and less than one-fifth of those with type 2 DM have achieved target values.



#### Patients with high blood pressure (≤130/80 mm Hg)

Among patients with high blood pressure and receiving antihypertensive therapy, 27.6% have type 1 DM and 58.6% type 2 DM; furthermore, 80% of those with type 1 DM and 87% of those with type 2 DM do not reach their target blood pressure. These data suggest the need to initiate drug therapy with more "aggressive" agents in order to reach the recommended target values.



#### Patients with high blood pressure (≥140/90 mm Hg) receiving antihypertensive therapy

Further confirming the above finding, over half of type 1 DM and 60% of type 2 DM patients have

elevated blood pressure values (≥140/90 mm Hg) despite their receiving antihypertensive therapy.



#### Patients with high blood pressure (≥140/90 mm Hg) not receiving antihypertensive therapy

The attitude to an insufficiently aggressive approach to this important cardiovascular risk factor is again shown by the high percentage of patients not receiving antihypertensive therapy despite elevated blood pressure: one-half of type 2 DM patients and one-fourth of type 1 DM patients have a blood pressure value  $\geq$ 140/90 mm Hg but do not receive specific therapy.

#### Trend by class of body-mass index (BMI)



60 50 40 37.3 % 30 25.3 20 17.9 15.4 10 4.1 0 ≤25 25.1-27 27.1-30 30.1-40 ≥40 Kg/m<sup>2</sup>

DM2

Some 18% of patients with type 1 DM are overweight and one-fourth are frankly obese; in contrast, 40% of those with type 2 DM are frankly obese (BMI >30 kg/m<sup>2</sup>) and less than one-fifth are normoweight.



#### Smokers

Less than one-third of patients with DM type 1 and 17% of those with DM type 2 currently smoke. The proportion among type 1 DM patients gives cause for alarm in view of the high risk of microvascular risks associated with cigarette smoking.



#### Heavy smokers (>20 cigarettes/day) versus total number of smokers

Although more patients with type 1 DM are smokers, the proportion of heavy smokers (>20 ciga-

rettes/day) among patients with type 2 DM is twice that among those with type 1 DM.

# Box plots of mean values according to type of diabetes, patient sex and age



HbA1c (mean ±SD) (last value normalized to 6.0) by type of diabetes

The mean HbA1c was  $8.1\pm1.6$  for type 1 DM and  $7.5\pm1.5$  for type 2 DM. The data show a marked

variation within each type of diabetes and between type 1 and type 2.

HbA1c (mean ±SD) (last value normalized to 6.0) by type of treatment for type 2 DM



As expected, the mean HbA1c values were associated with the type of treatment. The lowest values were recorded for patients following only a restricted diet, whereas the highest values were recorded for those receiving insulin therapy, especially when combined with oral hypoglycemic agents. Here, too, marked variation was observed.



#### Mean values of main clinical parameters according to type of diabetes

These data indicate that compared to patients with type 2 DM, those with type 1 DM tended to have a lower risk profile for blood pressure but a risk profile that otherwise fairly approximated that of patients with type 2 DM as regards lipid profile, and values for total cholesterol and LDL-C in particular. Consistent with the typical presentation of the metabolic syndrome, patients with type 2 DM tended to have higher triglyceride levels and lower HDL-C levels.



#### Mean values of main clinical parameters according to type of diabetes and patient sex



#### Mean values of main clinical parameters according to type of diabetes and patient sex

Among patients with type 2 DM, the females tended to have higher HbA1c, total cholesterol and HDL-C, SBP, LDL-C and BMI, whereas minimal differences were noted for mean triglyceride and DBP values.

Taken together, these data indicate a poorer control of major cardiovascular risk factors among women with type 2 DM.



#### Mean values of main clinical parameters according to type of diabetes and patient age

DM1







Among patients with type 1 DM, there were minimal variations in mean HbA1c, with a slight increase and greater variation among those <25 years of age. There was a gradual increase in SBP, but not in DBP, and triglyceride levels and BMI. There was an upward trend in total cholesterol and HDL-C values until age 45 years, after which it flattened, whereas the highest LDL-C values were noted in the 35-55-year age group.



#### Mean values of main clinical parameters according to type of diabetes and patient age



Among patients with type 2 DM, there were only minimal variations in mean HbA1c. There was an upward trend in SBP until age 55 years, after which it flattened, whereas DBP tended to decline with age. Lipid profiles were stable across all age groups. The highest mean BMI was observed in the 35-55-year age group.





The following star plots illustrate the intermediate outcome measures. Ideally, each polygon is divided into two halves: the upper three spokes represent the percentages of patients with a favorable outcome for HbA1c, blood pressure and LDL-C. The lower three spokes represent the percentages of patients with unsatisfactory values (see Methods). For each star plot, the polygon (dashed lines) refers to the gold standard; the polygon in solid lines refers to each patient group in question. Green polygons denote favorable outcomes, red polygons unfavorable outcomes.

#### Total sample divided according to type of diabetes





In type 1 DM, the polygon in dashed lines indicates that even among the centers that concur in defining the gold standard only a moderate proportion of patients had acceptable HbA1c (28%), blood pressure (45%), and LDL-C (42%) values. In contrast, there was a sizable proportion of patients with very high values for these parameters: HbA1c (40%); blood pressure (24%); and LDL-C (21%).

In type 2 DM, there was a higher proportion of patients with acceptable HbA1c (52%), a far lower proportion with acceptable blood pressure values (18%), and a fairly similar proportion with accepta-

ble LDL-C (48%). The proportion of patients with very high values for these parameters was: HbA1c (23%); blood pressure (51%); and LDL-C (21%).

In contrast with the process measures, there was no large gap between the total sample and the gold standard for either type of DM.

Compared to entire sample, the percentage of type 1 DM patients with acceptable values was: HbA1c (24%); blood pressure (36%); and LDL-C (37%). The percentage of patients with unfavorable values was: HbA1c (46%); blood pressure (31%); and LDL-C (25%).

Compared to the entire sample, the percentage of type 2 DM patients with acceptable values was: HbA1c (44%); blood pressure (15%); and LDL-C (42%). The percentage of patients with unfavorable values was: HbA1c (29%); blood pressure (57%); and LDL-C (26%).





In type 1 DM, the LDL-C values in the males and females were fairly similar; among the females there was a lower percentage of those with acceptable HbA1c values and a higher percentage of those with elevated values. Among the males, far fewer reached the target blood pressure value. In type 2 DM, no substantial differences between the sexes were noted.

#### Sample divided according to type of diabetes and age group



In type 1 DM, there was a gradual decrease in the green-colored area (favorable outcome) with increasing age and a corresponding increase in the red area (unfavorable outcome), indicating greater difficulty in achieving acceptable values. In type 2 DM, despite the similar trend, the extent of change was much less pronounced.

















## Box plots of mean values for centers according to type of diabetes

#### Distribution of mean main clinical parameter values for each type of DM by center



This series of figures shows the distribution of the mean values of the main parameters for each center. In type 1 DM, there was pronounced variation across all parameters. As concerns metabolic control, for example, the mean HbA1c (normalized to 6.0) was 7.7-8.2% in 50% of the centers. However, there were also centers with much lower (6.7%) or much higher (9.4%) mean values. This should be taken into account when interpreting the data for all parameters in question.

Also for type 2 DM there was sizeable variation among centers for the parameter values. A further important consideration is the number of outlier clinics with much higher or lower values than the mean calculated for the other centers. These data reflect the heterogeneity of the outcomes of diabetes care and underline the need to align therapeutic approaches with current scientific evidence.



#### Intermediate outcome indicators for each center according to type of diabetes

In type DM 1, the majority of centers reported low percentages of patients with Hb1Ac levels  $\leq$ 7.0%, and in very few centers the percentage was 40% or higher. Similarly, the majority of centers reported that <50% of patients had blood pressure values

≤130 mg/dl and LDL-C <100 mg/dl.

The difficulty in attaining adequate metabolic control in patients with type 1 DM is further underscored by the percentage of patients with HbA1c  $\geq$ 8.0%. This proportion of patients tends to vary widely among centers, ranging from 18 to 84%. This is likewise true for the percentage of patients with elevated blood pressure, whereas

LDL-C levels appear to be more similar across centers.

In type 2 DM, the proportion of patients with acceptable HbA1c levels tends to be higher, though variation across centers is high. The proportion of patients with acceptable blood pressure is low (45% or lower in most centers). Nearly all centers reported that about 40% of their patients have acceptable LDL-C. The mean percentage of patients with target blood pressure values is particularly low. These findings, and the high rates of elevated blood pressure in particular, indicate room for improvement in diabetes care.

### **Comments on intermediate outcome indicators**

In comparison with the results of the 2008 AMD survey, the newest findings point to a lapse in diabetes care, as evinced by the high rates of suboptimal HbA1c and blood pressure values. As regards blood pressure this observation is based on two indicators (cut-off values of 140 mm Hg and 90 mm Hg) which reflect efforts to reach target values and attitudes toward initiating treatment. But because the new target for DBP has been lowered from 85 to 80 mm Hg, comparison with other indicators in previous editions of the AMD Annals is difficult.

The differences are more pronounced for type 1 DM, where the worst performance for achieving target HbA1c and blood pressure control are clearest. In type 1 DM, a suboptimal performance can also be noted for lipid profiles, with an increase in mean LDL-C and a decrease in the number of patients with optimal LDL-C (<100 mg/dl).

The explanation for this phenomenon resides in the inclusion of over 100 new centers, with a corresponding increase in patients numbering 440,000 in the 2010 survey. As mentioned by Illidio Meloncelli with regard to process measures, the dramatic rise in the number of new centers in the AMD Annals database provides for a broader picture of diabetes care in Italy, but also limits the validity of comparison with past years.

The scenario in the 2010 survey approximates more closely diabetes care in the real world, and perhaps also the total population with diabetes, yet it invites serious considerations. Although the Annals control data entry quality, there is the possibility that some findings, such as the higher rates of missing documentation of drug therapy (e.g., statins and ACEinhibitors) which was absent in some cases, were due to errors in recording a prescription rather than non-prescribing of therapy. The suboptimal data on type 1 DM care could also have resulted from the inclusion of less specialized centers lacking experience in diabetes management.

A comparison with previously published data cannot (and is not intended to) indicate any trends, yet it can give insights into the extent to which the greater number of participating centers might have affected the overall picture.

## Glycosylated hemoglobin and glycometabolic control

Mean HbA1c (±SD) rose from 7.8±1.5 to 8.1±1.6 in type 1 DM and from 7.3±1.4 to 7.5±1.5 in type 2 DM. From an analysis of the mean HbA1c values by type of treatment information can be gleaned about the promptness of therapeutic intervention; the HbA1c values are comparable with those reported in previous AMD surveys. The gradual increase in mean HbA1c between patients following a restricted diet alone and those receiving combined insulin and oral hypoglycemic agents is more suggestive of duration of the condition rather than its severity. Insulin therapy combined with oral hypoglycemics continues to produce the worst results. These graphs illustrate, except for the difficulty due to patient category, the well-known phenomenon of therapeutic inertia in which the patient is left for too long without sufficient coverage until therapy is revised. It is widely recognized that reducing HbA1c from 8 to 6.5% will not have the same favorable effect on micro- and macrovascular prevention as will preventing HbA1c against rising from 6.5 to 8%. Here, the role of prompt intervention is key. This, however, is easier said than done. For many years, because of the lack of equally effective therapies, maintaining hyperglycemic control was more difficult than managing other cardiovascular risk factors. Newly emerging "innovative" therapies, although accompanied by high costs, hold promise.

The 2010 survey data confirm that in type 1 DM HbA1c control is generally worse owing to the greater overall complexity of the patient and to the lack of the proportion of patients following restricted diet alone, but generally well controlled, which tends to reduce the mean HbA1c in type 2 DM.

#### **Cardiovascular risk factors**

As in past years, the difference in the mean blood pressure between type 1 and type 2 DM is relevant especially for SBP. Patients with type 2 DM have elevated SBP, which needs to be considered with regard to prevention because of the higher risk of cardiovascular events. Although this finding is influenced by the mean age of patients, it has little effect on prevention. Efforts to reach the objectives are insufficient, as revealed by the indicator "Patients with blood pressure  $\geq$ 140/90 mm Hg". It is likely that drugs are prescribed but therapy is not intensified to attain the goal.

As regards gender-related issues, the analysis disclosed a slight improvement among women with type 2 DM who presented with marginally better mean SBP and DBP. Nonetheless, it is unclear whether the lapse in LDL-C control is due to a genetic predisposition or to differences in approach to therapy. Overall, efforts need to be stepped up to improve cardiovascular treatment especially among women. The continuing positive trend for lipid profiles in patients with type 2 DM is probably due to the simplicity and efficacy of treatment, whereas the poorer profiles in patients with type 1 DM probably results from an overly "glucocentric" approach by many diabetes care centers to these patients.

## Variation among centers after adjustment for case mix and clustering

The wide range in variation, first reported in the DAI and QuED studies, continues to characterize diabetes care. New analyses on attitudes toward treatment merit special attention. Compared to previous surveys, there was a higher rate of missing data: the forest plots for HbA1c, blood pressure and lipid profile tend to widen to zero for statin and ACE-inhibitor prescriptions. This is because of the entry of data from newly participating centers in the analysis and probably because of less accuracy in data recording (or a major component thereof). The training courses carried out by the AMD and the sense of responsibility the clinicians working at the centers furnishing the data for the Annals need to be increased in order to improve data collection quality. In outcome research analyses, the best results in efficacy of care are achieved by centers which place more attention on accurate documentation of clinical findings.

As regards attitudes towards treatment, the survey highlights that not all diabetes care services respond in the same way to a certain blood pressure value or LDL-C level. There was a high rate of missing data on all drug classes with proven efficacy for type 2 DM. This phenomenon is neither particular to diabetes care nor to the Italian health care system in general. Similar observations in cardiology and general medicine, in Europe and the United States, can be found in the literature. Factors that impact on correct therapeutic outcome, such as patient age, total number of tablets to be taken, cost of drug therapy, control of expenditure appropriateness by health care providers, the Italian Medicines Agency (AIFA) reports, physician beliefs and background, and patient compliance, all continue to play a decisive role in treatment. The AMD, building on the experience with the Annals surveys, published a study in Diabetic Medicine that shows that four years of data collection have led to higher performance levels than in other areas of diabetes care in Italy.

#### **Overweight**, obesity and smoking

Compared with the 2008 Annals, the newest survey revealed a slight worsening in BMI among patients with type 2 DM linked perhaps to the inclusion of centers less attentive to educating patients about weight control and to the continuing negative trend revealed by past surveys.

Ending on a positive note, greater attention appears to be placed on reducing tobacco use.

Carlo B. Giorda

## VARIATION AMONG CENTERS AFTER ADJUSTMENT FOR CASE MIX AND CLUSTERING EFFECT

### Variation among centers: means adjusted for patient age and sex, duration of diabetes, and clustering effect














DM2







DBP





As discussed in the Methods section, the variation in process measures and intermediate outcome among centers could be partially due to the different characteristics of the population attending a center and to clustering. Therefore, the variation among centers shown in these figures has been adjusted for the clustering effect, patient age and sex, and duration of diabetes. Nonetheless, even after correction of potential confounding factors, substantial variation among centers in mean parameter values remains, particularly for type 2 DM, with some centers far below or above the estimated mean for the entire population.

In type 1 DM, because of the lower number of cases per center, the estimated values have wider confidence intervals.

## Variation in the propensity to prescribe lipid-lowering and antihypertensive agents



## DM2



An identical statistical approach was used to evaluate the propensity of centers to treat patients with LDL-C  $\geq$ 130 mg/dl or blood pressure  $\geq$ 140/90 mm Hg. The graphs show a greater variation among pa-

Patients with LDL-C ≥130 mg/dl not

receiving lipid-lowering therapy

tients with type 2 DM in the percentage of potential candidates for statin therapy and the percentage of candidates for antihypertensive treatment.

Patients with high blood pressure (≥140/90 mm Hg)

not receiving antihypertensive therapy

75

# Variation in drug prescription



The graphs show that for patients with type 1 DM, matched for age group and sex, the percentage of those treated with statins varies between <5% and >40% among centers.

A similar range was noted for the percentage of patients receiving ACE-inhibitors or sartans.





The range in variation was even wider for patients with type 2 DM. The percentage of patients receiving statin therapy (mean, 40%) ranged from <10% to >70%. Similarly, the proportion of patients receiving ACE-inhibitors or sartans (mean, approximately 50%) ranged from <10% to >70%.

A wide range in variation was also seen for the prescription of other drugs.









## **Comments on variation among centers**

Again, in this edition of the AMD Annals, the variation in the main indicators of quality of care in the 236 participating centers confirms the heterogeneity of the results obtained throughout the entire country. Similarly, all over the world health systems demonstrate a wide variation in the delivery of their medical services and reducing the variation, in conjunction with closer adherence to standards of adequate treatment, is one of the main goals of clinical governance strategies implemented by many countries.

In Italy, we have demonstrated that regular participation in the Annals initiative can contribute to enhancing the quality of diabetes care through the systematic review of care performance and comparison with results obtained by other centers. For this reason, participation in the initiative may be considered as a useful and adjunctive tool for diabetes centers to promote and develop local clinical governance initiatives. Interestingly, even before being demonstrated by statistical analysis, the effect the initiative has on improving clinical practice was noted by diabetologists involved in the AMD survey for many years and who therefore have become active supporters in collecting data. Thanks to their efforts, survey coverage is wider than ever before, and the data fairly approximate those of previous surveys, albeit with certain important differences.

As concerns type 1 DM, the mean values and the variation in intermediate outcome indicators (HbA1c, blood pressure, lipid profile, BMI) are substantially unchanged versus the 2008 AMD survey, except for a slight increase in mean HbA1c, total cholesterol, LDL-C, and triglycerides.

Also for type 2 DM, the mean values and variation in the intermediate outcome indicators are comparable to those of the 2008 survey, except for a slight reduction in mean SBP and DBP and a slight increase in mean triglyceride levels and BMI.

For both types of DM, no major change versus the

2008 survey data was observed for the indicators of propensity to prescribe lipid-lowering and antihyper-tensive agents.

A major innovation to the AMD Annals is the analysis of the prescription of specific drug classes in the treatment of DM types 1 and 2. As concerns type 1 DM, with the 2010 survey, data could be collected on the use of ACE-inhibitors or sartans, beta blockers and at least two antihypertensives, thus providing a starting point for following trends in the therapeutic approach of diabetologists to the management of blood pressure in both types of DM. The graphs also show, in terms of the impact of variation in the number of participating centers, a marked rise in the mean percentage of type 1 DM patients treated with statins (from 16% in 2008 to 20% in 2010), taking into account the wide range in variation (1-40%).

In type 2 DM the data indicate a sharp rise in the use of drug therapy: the mean percentage of patients receiving statins increased from 33 to 40% (2008 versus 2010, respectively); ACE-inhibitors from 19 to 27% (2008 versus 2010, respectively); sartans from 9.5 to 22% (2008 versus 2010, respectively); beta blockers from 9 to 18% (2008 versus 2010, respectively).

The variation for each of these drug classes was very wide. The overall increase may have been due in part to greater attention to entering these data on the electronic health record rather than because of a real increase in drug prescription. Nonetheless, this trend may be judged favorably in the light of national and international evidence that greater accuracy in compiling the electronic health record goes hand in hand with improved delivery of care.

Therefore, having considered that one of the ways to reduce variation in care delivery is to ensure correct data entry on the electronic health records, the AMD has already launched numerous initiatives to assist its society members in this effort.

Danila Fava





Microalbuminuria

The following star plots show the magnitude of each variable used for calculating the Q score for types 1 and 2 DM. Like the process indicators for intermediate outcomes, the polygon in dashed lines represents the mean score of the best-performing centers for each variable, while the colored area refers to the sample in question. The mean score for each spoke is from 0 to 10.



#### Total sample according to type of diabetes

The graphs offer ample room for reflection. For both types of diabetes, the distance between the best-performing group (dashed lines) and the total sample (green area) is short for Hb1Ac, blood pressure and lipid profiles, whereas the distance is longer for microalbuminuria. Furthermore, the distance between the dashed or solid line and the end of each spoke is longer for HbA1c in type 1 DM and for blood pressure in type 2 DM. In other



words, insufficient glycemic control in type 1 DM and insufficient blood pressure control in type 2 DM will produce a suboptimal quality score. In general, the distance between the lines and the end of each spoke indicates a gap between current and theoretically achievable performance: if all patients are monitored for the variable in question (e.g., HbA1c) and adequately treated, an acceptable value could be achieved (e.g., HbA1c <8%).



## Sample according to type of diabetes and sex

These star plots show no substantial difference between type 1 and type 2 DM, indicating that the

magnitude of each of the four variables to the score does not differ according to sex.

## Sample according to type of diabetes and age group





## Sample according to type of diabetes and age group



In type 1 DM, the scores of the best-performing centers differ from that of the total sample for younger patients and for those age 55 years or older. In type 2 DM, the differences are less pronounced and fairly similar across all age groups.

## Mean Q score

DM2

### Total sample according to type of diabetes



The graphs show the mean Q scores for the bestperforming centers and for the total sample. The mean difference is about 4 points in type 1 DM and about 3 points in type 2 DM. The data should be interpreted taking into consideration the QUED study results which showed that patients attending

## Sample according to type of diabetes and sex





centers with a mean score of 5 have a 20% difference in their risk of experiencing a major cardiovascular event within 5 years.

Furthermore, the quality score is higher for type 1 DM, especially among the best-performing centers.





Sample according to type of diabetes and age group

Different trends emerge for the two types of DM. In type 1 DM, the quality score is lower for younger patients, gradually improves for older age groups, peaks for the 25-35-years age group, before declining for the older age groups. In type 2 DM, the score is highest for the younger age groups, remains unchanged across the older age groups, before declining for the over-75-years age group.



### Sample according to type of diabetes and region (see key for ISTAT regional codes on page 89)

The regional comparison of the mean quality score shows a high degree of heterogeneity. There is a 6-point range in scores (22.6–28.8) for type 1 DM

and a slightly narrower range (22.8–26.5) for type 2 DM.



Total sample according to type of diabetes



The graphs illustrate (best-performing centers and total sample) the proportion of patients with scores <15, 15-25, and >25. Both the QuED and the QUASAR studies reported that a score <15 is associated with a significantly higher risk (80% in the QUASAR study) of experiencing a major cardiovascular event, and an elevated risk (about 20%) in those with a score from 15 to 25.

Although the proportion of patients with a score <15 is very low, this patient subgroup is twice the size in the total sample compared to the best-performing centers. The intermediate score range (15-25) is more frequent in the total sample than in the best-performing centers. The score distribution is similar in both types of DM.



Sample according to type of diabetes and sex



No differences emerge between the sexes for type 1 DM. The proportion of patients with scores <15

and 15-25 is slightly greater among females with type 2 DM.



### Sample according to type of diabetes and age group

Some 10% of type 1 DM patients with scores <15 are 55 years of age or older; the percentage of patients with scores >25 is lower among those under 15

years of age, and lower still in those over 75 years of age. The age factor appears to have little impact on scores, at least until age 85 years, in type 2 DM.

## Sample according to type of diabetes and region

### DM1

0	10	20	30	58.4% 40	50	60	70	33.1 80	90	10
	%	51.1%					42.1%	0/		
80		63.1%				32.2%				
70		4	18.9%			47.5%				
60		4	9.4%			48.3%				
50 5 69	6		56%	16		38.4%				
30 9.	8%			63.9%	5	26.3%				
20 6.49	16	50.3%				12		43.3%		
10		50.8%					4	6.3%		
00		50.2%			-		-	15.2%		
90 7.8	%	49.9%						42.3%		
80 7.1	%	57.8%				35.1%				
70 6.7	%	48.1%			_	45.2%				
60 87	7%		45.8%		-	45.5%				
	9%			55.1%		35%				
	5%	00.170	50	4%		40.1%				
30		33.7%	40.0	570		62%				
_	0%	01.070	48.6	6%		41.4%			_	
est 4%		31.5%					64.5%			



The regional comparison shows a high degree of heterogeneity in score classes. In the best-performing centers, 4% of type 1 DM patients have scores <15; the percentage of this score class ranges from 2.3 to 1.2% across regions. Similarly, in the bestperforming centers, 4.9% of type 2 DM patients have scores <15; the percentage of this score ranges between 3.1 and 10.7% across regions.

A similar interregional variation can be seen for the proportion of type 1 DM patients with scores >25 (range, 26.3-62.0%) and type 2 DM patients (range, 28.3-50.3%).

#### ISTAT regional code numbers

Region	Code
Piemonte and Valle d'Aosta	010
Lombardia	030
Trentino Alto Adige	040
Veneto	050
Friuli Venezia Giulia	060
Liguria	070
Emilia Romagna	080
Toscana	090
Umbria	100
Marche	110
Lazio	120
Abruzzo and Molise	130
Campania	150
Puglia	160
Basilicata	170
Calabria	180
Sicilia	190
Sardegna	200

## Variation in the Q score

Variation among centers after adjustment for age, sex, duration of diabetes, and clustering effect





The graphs above show the variation in the mean quality score among centers, after adjustment for age, sex and duration of diabetes, and the clustering effect. In type 1 DM, and more markedly in type 2 DM, there is a sizeable proportion of centers with mean scores far below or far above the mean for the total sample (dashed line).

The graphs below show the variation in the percentage of patients with scores <15 for each center. Here, too, there is a proportion of centers with a high percentage (far above 20% in some cases) of patients (both type 1 and type 2 DM) with particularly low quality scores.



**Interregional variation after adjustment for age, sex, duration of diabetes, and clustering effect** (see key for ISTAT regional codes on page 89)

The graphs show the interregional variation of quality scores after adjustment for age, sex, duration of diabetes, and clustering effect. The upper graph reports the mean for each region; the lower graph reports the percentage of patients with scores <15 for each region.

The upper graph shows the highest scores for Lombardia and the lowest for Abruzzo and Molise, Veneto and Sardegna. Within the low percentage bracket of type 1 DM patients with scores <15, there is wide variation (3.3% for Marche versus 9.9% for Veneto).

Although less wide, there is some variation in the quality scores of patients with type 2 DM: the highest scores for Lombardia and Marche, the lowest for Abruzzo and Molise and Toscana; variation was greater for patients with scores <15 (3.5% for Puglia versus 10% for Trentino Alto Adige, Friuli-Venezia Giulia, and Toscana).

## **Comments on total quality score**

With this edition of the AMD Annals, the introduction of a systematic analysis of quality of care represents an important innovation. Separate analysis of individual process and intermediate outcome indicators, although an aid to identifying criticalities requiring action for improvement, does not allow for making an overall performance assessment of a diabetes care center. The qualifying element of the Q score, besides its ease of calculation, resides in its ability to mirror the major aspects of care, as shown by its predictive power for major cardiovascular events. In this connection it should be underlined that, unlike the UKPDS or Framingham risk equations, the Q score is not a score for predicting cardiovascular risk in individual patients; instead, it quantifies the cardiovascular risk attributable to suboptimal quality of care. As such, the Q score should be viewed as a summary measure of the quality of care delivered by a diabetes center to an individual patient and which informs the center as to whether or not such care should be improved. The Q score offers another advantage: until standardized and complete information about cardiovascular events can be gleaned from an electronic health record, the Q score, precisely because it correlates with cardiovascular events, may serve in the meantime as a proxy for comparative assessment between centers.

To correctly interpret the data, however, several limitations need to be taken into account. The Q score validly mirrors the quality of diabetes care to the extent that it includes the aspects most often associated with the risk of macrovascular complications. Although these factors (metabolic control, hypertension, dyslipidemia, microalbuminuria) may very well be equally important for predicting microvascular events, there are no data that would validate them as such. Furthermore, when making regional comparisons, it is essential to remember that the data representativeness derives from the number of centers participating in the survey and the number of patients examined in each region. While all or nearly all centers from some regions participated, participation rates for other regions still remain low.

Analysis of the data shows marked differences in the quality of care, as measured by the Q score, between the best-performing centers and the total sample. The mean difference in scores is >4 points for type 1 DM and >3 points for type 2 DM. Although the proportion of patients with extremely low scores (<15) is generally small (<5% in the best-performing centers and <8% in the total sample), the proportion of patients with scores between 15 and 25 accounts for over 50% of the total sample and just under one-third of those attending the best-performing centers. Because scores <25 are associated with a 20% higher risk of major cardiovascular events, patients with these scores need to receive better care that can be translated into a reduction of such events.

Another aspect to emerge from the data is the wide variation in scores; this was not associated with patient-related factors because no substantial differences were noted when the data were adjusted for patient age and sex. Instead, variation was most evident in the comparison between centers and regions. Variation across centers, after adjustment for age, sex and duration of diabetes, as measured by mean Q scores, ranged by 10 points in patients with type 2 DM, and the percentage of those with scores <15 was over 20% in a sizeable proportion of centers. These data signal a marked difference in the risk of major cardiovascular events in the next 2-3 years. In an era of decentralization and regionalization of health care mandates, the analysis of regional differences is revealing. The analysis shows no clear north-south trend in the quality of care, but rather a marked heterogeneity between regions. A difference of up to 5 points for the mean score, as well as a 3-fold difference in the percentage of patients with scores <15, signals the lack of uniform care in this country and that this variation will lead to disparities in the use of resources and the health of the nation.

Like other quality measures analyzed by the AMD, the Q score may furnish an additional means to better mirror performance in the real world and to promote improvement actions for reducing disparities in health care.

Antonio Nicolucci



## **Premise**

With the 2010 AMD Annals, profiles of diabetes care for all regions in Italy are presented for the first time. National coverage was achieved by collecting data from the many newly participating centers. The table below reports the sample size for each region versus that of the previous survey (2008). The 2008 survey comprised data from 11 regions, i.e., only those with more than five large diabetes centers.

		2008 Ar	nnals		2010 Annals				
Region	Centers	Active patients	DM1	DM2	Centers	Active patients	DM1	DM2	
Piemonte and Valle d'Aosta	7	11,850	423	11,169	20	46,987	2312	43,150	
Lombardia	18	32,234	1835	29,910	17	40,291	2174	37,433	
Trentino Alto Adige	3	3923	485	3338	9	14,223	1121	12,631	
Veneto	19	35,410	1999	32,424	31	73,170	4046	65,793	
Friuli Venezia Giulia	8	11,127	956	9990	11	15,694	1180	14,100	
Liguria	2	1500	49	1442	10	6846	223	6525	
Emilia Romagna	7	14,847	963	13,462	22	35,641	2143	32,353	
Toscana	5	11,491	652	10,515	13	32,225	2059	29,104	
Umbria	3	3643	71	3528	7	11,703	309	11,266	
Marche	8	31,661	1551	29,395	10	32,514	1834	29,980	
Lazio	7	9337	696	8454	21	36,400	1310	34,612	
Abruzzo and Molise	4	5649	189	5365	12	25,254	1026	23,654	
Campania	6	5062	236	4805	9	13,489	320	13,125	
Puglia	3	1152	41	1037	7	3612	87	3413	
Basilicata	2	3810	164	3559	3	6032	285	5613	
Calabria	2	2425	64	2355	11	13,985	480	13,214	
Sicilia	6	6279	292	5940	11	10,249	421	9659	
Sardegna	6	17,091	2176	14,371	12	33,544	3098	29,695	
ITALY	116	208,491	12,842	191,059	236	451,859	24,428	415,320	

### Regional sample size (2008 versus 2010).











There was wide interregional variation in all indicators for both type 1 and type 2 DM, as seen by the differently shaped green areas.

The only parameter for which satisfactory values were achieved by all regions is HbA1c monitoring, whereas only some regions approach the gold standard for blood pressure, lipid profile, and renal function monitoring. The parameter with the highest variation, probably because of criticalities in the documentation of clinical findings on the electronic health record, is diabetic foot monitoring, which approximates the gold standard in some regions but is completely missing for others.

In general, the Lombardia comes the closest to achieving the gold standard for all parameters.

## Box plots of mean HbA1c, SPB, DBP, and LDL-C according to type of diabetes

### HbA1c (normalized to 6.0)



_	Т	Т	т	T	т	т	т	-			Т				т	_	Т
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														-			

010	Piemonte and Val d'Aosta	8.0±1.4
030	Lombardia	8.0±1.5
040	Trentino Alto Adige	8.3±1.6
050	Veneto	8.3±1.5
060	Friuli	7.6±1.5
070	Liguria	8.0±1.5
080	Emilia Romagna	8.2±1.5
090	Toscana	8.0±1.4
100	Umbria	8.0±1.7
110	Marche	7.9±1.6
120	Lazio	7.9±1.6
130	Abruzzo and Molise	8.1±1.5
150	Campania	8.1±1.9
160	Puglia	7.3±1.6
170	Basilicata	7.5±1.8
180	Calabria	8.1±1.9
190	Sicilia	8.1±1.6
200	Sardegna	8.1±1.7

010	Piemonte and Val d'Aosta	7.4±1.5
030	Lombardia	7.6±1.5
040	Trentino Alto Adige	7.8±1.4
050	Veneto	7.6±1.5
060	Friuli	7.4±1.5
070	Liguria	7.4±1.4
080	Emilia Romagna	7.6±1.5
090	Toscana	7.5±1.5
100	Umbria	7.5±1.5
110	Marche	7.4±1.5
120	Lazio	7.2±1.5
130	Abruzzo and Molise	7.7±1.5
150	Campania	7.1±1.5
160	Puglia	7.0±1.4
170	Basilicata	7.0±1.5
180	Calabria	7.4±1.5
190	Sicilia	7.4±1.4
200	Sardegna	7.4±1.6

010 030 040 050 060 070 080 090 100 110 120 130 150 160 170 180 190 200

There are marked interregional differences in mean HbA1c among patients with type 1 DM, ranging from 7.3% (Puglia) to 8.3% (Trentino Alto Adige). The mean values hover around 8% in the majority of regions, whereas within region variation is fairly similar, except for Campania.

As compared with type 1 DM, values of HbA1c are generally lower in type 2 DM; they range from 7,0%) Basilicata) and 7,8% (Trentino Alto Adige). Results achieved in the different regions and the within region variation tend to be more homogeneous in type 2 than in type 1 diabetes.

### Systolic blood pressure (SBP)



DM2



010	Piemonte and Val d'Aosta	128.7±18.9
030	Lombardia	125.6±16.7
040	Trentino Alto Adige	129.8±20.2
050	Veneto	131.1±18.9
060	Friuli	127.8±17.5
070	Liguria	126.9±18.9
080	Emilia Romagna	129.6±18.4
090	Toscana	129.4±18.5
100	Umbria	127.8±16.2
110	Marche	123.0±17.7
120	Lazio	127.3±18.3
130	Abruzzo e Molise	129.3±18.6
150	Campania	117.8±15.7
160	Puglia	120.0±12.0
170	Basilicata	126.8±17.9
180	Calabria	124.3±19.5
190	Sicilia	122.2±16.9
200	Sardegna	125.4±18.3

:00	
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010	Piemonte and Val d'Aosta	138.8±18.2
030	Lombardia	137.2±18.6
040	Trentino Alto Adige	142.8±21.1
050	Veneto	144.2±19.9
060	Friuli	139.7±18.3
070	Liguria	140.8±21.5
080	Emilia Romagna	140.2±18.6
090	Toscana	141.7±18.4
100	Umbria	138.8±15.9
110	Marche	135.7±17.4
120	Lazio	137.9±18.6
130	Abruzzo and Molise	138.0±17.8
150	Campania	132.1±18.0
160	Puglia	133.5±18.6
170	Basilicata	138.1±18.7
180	Calabria	136.4±19.2
190	Sicilia	135.0±17.3
200	Sardegna	137.2±19.1

010 030 040 050 060 070 080 090 100 110 120 130 150 160 170 180 190 200

Systolic blood pressure values, in both type 1 and type 2 DM, are generally lower in the southern regions. Also for this parameter there is a certain interregional variation, with mean values between 118 mm Hg (Campania) and 129 mm Hg (Trentino Alto Adige and Emilia Romagna) for type 1 DM and between 132 mm Hg (Campania) and 143 mm Hg (Trentino Alto Adige) for type 2 DM. Within region variation is clearly evident, as can be seen from the different box plot heights.

### **Diastolic blood pressure (DBP)**





010	Piemonte and Val d'Aosta	74.9±9.3
030	Lombardia	74.2±9.1
040	Trentino Alto Adige	74.8±10.0
050	Veneto	78.2±9.7
060	Friuli	75.1±9.3
070	Liguria	75.2±8.7
080	Emilia Romagna	76.5±8.8
090	Toscana	75.5±8.8
100	Umbria	76.3±8.2
110	Marche	73.6±9.9
120	Lazio	75.3±9.8
130	Abruzzo and Molise	76.0±9.3
150	Campania	73.7±8.8
160	Puglia	74.3±8.6
170	Basilicata	76.6±7.8
180	Calabria	73.1±9.2
190	Sicilia	73.9±8.6
200	Sardegna	75.1±10.1

DM2



010	Piemonte and Val d'Aosta	78.9±9.2
030	Lombardia	77.9±9.5
040	Trentino Alto Adige	78.7±10.5
050	Veneto	81.7±10.0
060	Friuli	78.8±9.5
070	Liguria	79.4±10.5
080	Emilia Romagna	79.8±9.7
090	Toscana	79.8±9.4
100	Umbria	78.9±8.8
110	Marche	77.5±9.6
120	Lazio	79.3±10.0
130	Abruzzo and Molise	79.1±9.4
150	Campania	77.4±9.1
160	Puglia	77.2±9.2
170	Basilicata	79.9±8.5
180	Calabria	76.3±9.4
190	Sicilia	78.4±10.0
200	Sardegna	77.5±10.2

Diastolic blood pressure values are consistently homogeneous: in type 1 DM, 50% of the values fall within a range from 70 to 80 mm Hg for all regions; in type 2 DM, the mean values range from 76.3 mm Hg (Calabria) to 79.8 mm Hg (Umbria).

### LDL-C

DM1



010	Piemonte and Val d'Aosta	111.9±31.4
030	Lombardia	109.2±29.0
040	Trentino Alto Adige	110.8±28.7
050	Veneto	109.5±30.1
060	Friuli	111.9±31.5
070	Liguria	114.1±30.7
080	Emilia Romagna	108.8±30.3
090	Toscana	117.0±31.3
100	Umbria	113.1±30.7
110	Marche	112.2±32.6
120	Lazio	112.4±29.9
130	Abruzzo and Molise	112.2±33.0
150	Campania	109.8±33.5
160	Puglia	110.4±20.7
170	Basilicata	103.9±30.7
180	Calabria	107.0±35.7
190	Sicilia	102.7±32.3
200	Sardegna	112.4±30.7

DM2



010	Piemonte and Val d'Aosta	110.4±34.6
030	Lombardia	106.8±33.9
040	Trentino Alto Adige	110.6±34.6
050	Veneto	108.9±33.9
060	Friuli	108.1±34.7
070	Liguria	111.8±35.5
080	Emilia Romagna	108.6±34.5
090	Toscana	113.3±35.5
100	Umbria	112.0±35.3
110	Marche	111.9±34.4
120	Lazio	108.7±33.7
130	Abruzzo and Molise	113.9±34.2
150	Campania	108.4±35.3
160	Puglia	99.1±35.0
170	Basilicata	106.7±35.2
180	Calabria	105.5±34.4
190	Sicilia	104.3±34.8
200	Sardegna	106.7±33.3

The mean LDL-C values range between 103 mg/dl (Sicilia) and 117 mg/dl (Toscana) in type 1 DM, and between 99 mg/dl (Puglia) and 114 mg/dl (Abruzzo

and Molise) in type 2 DM. Within region variation is, again, clearly present in every region.

# Star plots of intermediate outcome indicators











As seen in the star plots of process indicators, so too for this parameter there is wide interregional variation for all indicators, as seen from the differences in the shapes of the green and the red areas. A greater variation in type 1 DM can be observed. The regions coming closest to the gold standard for type 1 DM are Sicilia, Campania, and Calabria, followed by Emilia Romagna and Piemonte. More regions approximated the gold standard for type 2 DM.

## Interregional variation in drug classes prescription after adjustment for age, sex, duration of diabetes, and the clustering effect

DM1



(see key for ISTAT regional codes on page 89)

These graphs illustrate the interregional variation in the prescription rates of several drug classes.

In type 1 DM, the prescription rate for statins varies from <10% (Abruzzo and Molise) to >25% (Friuli Venezia Giulia) (mean, 19%). The prescription rate for beta blockers varies between 3 and 6%;

the rate for ACE-inhibitors varies between 13% (Abruzzo and Molise) and 26% (Friuli Venezia Giulia) (mean, 19%). The percentage of patients treated with two or more antihypertensives is much lower, varying from 5% (Abruzzo and Molise) to over 10% (Campania).





20

180 160 130 150 200 100 070 090 110 120 170 080 190 050 010 030 040 060 Region

## **Comments on the regional analysis**

The regional data analysis provides an insight into diabetes care in Italy but also warrants caution in interpretation.

As emerged from the 2008 AMD survey, the regional analysis of process indicators, which measure an organization's efficiency, and the analysis of intermediate outcome indicators, which measure the efficacy of an organization's interventions, highlight convergences and divergences in diabetes care.

#### **Positive convergences**

Lombardia and Piemonte show the shortest distance between the mean (green areas) and the gold standard on the star plots of intermediate outcome and of processes. In other words, there is a well-balanced relationship between efficiency and efficacy.

#### **Negative convergences**

Abruzzo, Emilia Romagna, Lazio, Toscana and Umbria all show an evident distance between the mean and the gold standard on the star plots of intermediate outcome and of processes.

#### **Positive divergences**

Basilicata, Calabria, Campania, Marche, Puglia, Sicilia and Sardegna all show an evident distance between the mean and the gold standard for process indicators, which points to suboptimal organization. In contrast, they show good performance as evinced by the short distance from the gold standard in the green area in the intermediate outcome indicators.

#### **Negative divergences**

Friuli, Trentino Alto Adige and Veneto show a short distance between the mean and the gold standard for process indicators (denoting good organization), but an evident distance from the gold standard in the green area and entry into the red area in the intermediate outcome indicators (denoting suboptimal performance).

It is not among the objectives of the Annals to hand out report cards or to create classification schemes; instead, the goal is to provide a valid tool for improving and optimizing diabetes care.

Do the differences in performance as measured by the process indicators mirror clinical practice or attention to the proper recording of data? Furthermore, are the outcome indicators accurate, as calculated from the recorded data, the quality of which varies across regions, or do they, again, reflect attention to the proper recording of data?

A further limitation is that the data, especially those from Lombardia and Puglia, are collected from a selected number of centers; therefore, they may not adequately mirror the situation in a given region.

A negative convergence may be explained by an overdemand for services and an undersupply due to constrained capacities. This could lead to situations in which the organization of services cannot be optimized to ensure the delivery of all necessary services to all patients attending a center, resulting in lapses in meeting care objectives.

In Italy, diabetes care centers differ in organization and in delivery of care. For example, within the framework of the IGEA project, diagnostic-therapeutic care pathways are in place in centers in nearly all regions. The pathways focus on integrated healthcare management, mainly in patients with type 2 DM, jointly with general practitioners. The pathways have been variously implemented in the regions and in hospitals.

Complete and objective utilization of the data should permit a comparison of the process indicators (system efficiency) and of the intermediate outcome indicators (efficacy) of the diabetes centers with the indicator values collected from the general practitioners and those from the integrated management pathways. In this way, the quality of care delivered through these various channels, including the integrated management, could be objectively evaluated.

However, this is not yet possible because we have only the data from diabetes care centers; the lack of documentation and outcomes could be because the general practitioners did not record their examination findings or because of the different categories of patients treated in different diabetes care centers. Therefore, the data for each region should be interpreted within that specific context, where a greater homogeneity in modes of practice can be expected.

Greater harmonization could also be attained on the basis of the excellent performances revealed by

the Annals, also in relation to the local situation in reference to the regional gold standard, given the increase in the number of centers participating in the survey.

Antonino Cimino

# CHARACTERISTICS OF PATIENTS WITH TYPE 2 DM AT FIRST VISIT TO A DIABETES CENTER

## **Premise**

The aim of this analysis is to evaluate the characteristics of patients with type 2 DM at their first visit to a diabetes center in 2009. Recent evidence underlines the need for prompt and intensive intervention on metabolic control and cardiovascular risk factors. In view of the ample evidence for therapeutic inertia, the AMD has decided to counteract it with the Subito! project. In this connection, we felt it important to present the data on the clinical profile of first-visit patients to a diabetes center in relation to duration of diabetes.

In all, 46,513 first-visits accounted for 11.2% of all cases of type 2 DM seen in 2009. Of the total of first-visit patients, 57% presented with a duration of diabetes <2 years (median, <1 year), and over one-fourth presented with a history of the condition >5 years (median, 12 years).

Focusing on patients referred soon after diag-

nosis, it can be seen that they arrive at a center with elevated HbA1c; in over one-third of cases, the HBA1c level is >8.0%, requiring institution of insulin therapy in 12% of cases. Compared to patients with a longer duration of diabetes at first visit, early referrals present with a higher cardiovascular risk, especially among smokers and those with elevated total cholesterol, LDL and triglyceride levels. Early referrals present with slightly elevated DBP and lower SBP values. Of note is that early referrals are generally younger (mean, about 6 years) than those with a duration of diabetes >5years, which might explain the difference in SBP. Early referrals are less frequently treated with lipidlowering, antiplatelet or antihypertensive agents. No differences can be noted in the quality of care score in relation to duration of diabetes at first visit in either the mean or the distribution of classes according to duration of disease.



Variable		Total	Duration of diabetes (yrs)		
Variable	<2		2-5	>5	
No. of patients		46,513	26,508	7418	12,587
Males (%)		57.5	58.6	57.4	55.3
Age (yrs)		63.6±12.1	61.8±12.4	63.3±11.6	67.4±10.9
Age groups (%)	<50	13.7	17.3	13.3	6.3
	50-70	54.3	55.5	56.5	50.5
	>70	32.0	27.2	30.2	43.2
Body-mass index (kg/m <sup>2</sup> )		30.1±5.5	30.3±5.6	30.5±5.5	29.4±5.3
Body-mass index classes (%)	≤30	54.5	52.8	51.6	60.1
	>30	45.5	47.2	48.4	39.9
Smokers (%)		19.1	20.4	19.8	16.0
Duration of diabetes (yrs)		1.0 (0.0-6.0)	0.0 (0.0-0.0)	3.0 (2.0-4.0)	12.0 (9.0-19.0)
HbA1c (%)		8.0±2.1	8.0±2.2	7.7±1.9	8.2±1.9
HbA1c classes (%)	≤7	39.0	42.2	43.2	29.9
	7-8	22.9	21.3	24.4	25.4
	>8	38.1	36.5	32.4	44.7
Diabetes treatment (%)	Diet alone	11.9	18.1	7.5	2.2
	Oral hypoglycemics	69.2	69.6	79.9	62.4
	Insulin	11.8	8.5	8.0	20.7
	Insulin+oral hypoglycemics	7.1	3.9	4.7	14.7
Diastolic blood pressure (mm Hg)		80.9±10.5	81.4±10.5	81.1±10.4	79.6±10.3
Systolic blood pressure (mm Hg)		138.8±19.7	137.8±19.5	139.1±19.4	140.7±20.2
Blood pressure ≤130/80 mm Hg (%)		37.2	38.1	36.8	35.4
Blood pressure ≥140/90 mm Hg (%)		57.4	56.1	58.0	59.8
Patients treated with antihypertensive (%)		54.7	50.1	57.9	62.5
Total cholesterol (mg/dl)		202.2±47.1	208.2±47.8	199.8±45.3	190.7±44.2
HDL-C (mg/dl)		47.5±13.2	47.2±13.0	47.6±13.2	48.2±13.6
LDL-C (mg/dl)		120.3±38.4	125.0±38.7	118.1±37.2	111.4±36,8
Triglycerides (mg/dl)		178.3±162.0	187.2±178.8	176.6±139.1	160.3±132.8
LDL-C <100 mg/dl (%)		31.2	26.8	32.7	39.6
LDL-C ≥130 mg/dl (%)		39.1	43.8	37.3	30.0
Patients treated with lipid-lowering agents (%)		30.3	27.1	32.7	35.7
Patients treated with aspirin (%)		22.8	18.2	24.4	31.5
Q score		22.1±8.4	22.0±8.4	22.6±8.4	22.0±8.4
Q score classes (%)	<15	12.6	13.0	11.1	12.5
	15-25	60.8	60.9	60.3	61.0
	>25	26.6	26.1	28.6	26.5

## Table. Characteristics of first-visit patients with type 2 DM to a diabetes center in 2009

Values are expressed as means ± standard deviation, median and interquartile range or percentage

## **Comments on first-visit patient profiles**

The real candidates for the Subito! project are those listed in the first column: they present with <2 years of duration of diabetes and account for about 6% of routine visits to a diabetes center.

The last column in the table (duration of diabetes >5 years) may describe a new category of patients arriving at a center but not a new type of admission: these patients are less obese, older, with a far longer duration of diabetes, and a higher proportion are treated with insulin, antihypertensive and lipid-lowering agents.

To the unfamiliar eye, 6% may seem a marginal segment of total routine visits. However, the burden of care is proportionally much higher: a new diagnosis requires about 2 hours on average to establish, or 6 to 7 times longer than a follow-up visit.

#### **SPECIFIC POINTS**

#### **Elderly patients**

These patients are of advanced age and fall into the geriatric age range. Here it is important to follow the Geriatric Society recommendation to evaluate biological and chronological age on the basis of quality of life and life expectancy. In these cases, treatment objectives should be adjusted to the patient's circumstances within the perspective of personalized therapy, which has been re-evaluated following the controversies raised by the ACCORD and VADT studies. Until recently, in a patient diagnosed with diabetes at age 65 years, preventing associated potential chronic complications was far less a concern than preventing acute metabolic insufficiencies. Today, however, there is greater appreciation that an older person may still look forward to decades of active life, during which micro- and macroangiopathic complications may arise unless the patient is adequately monitored. In general, persons 70-75 years of age, unless presenting with comorbidities, are able to comply with even complex therapies and should therefore be treated the same way as a person perhaps 20 years younger. According to recent guidelines, the objectives of therapy are HbA1c 6.5-7% and all means for achieving that target are warranted.

#### **Glycosylated hemoglobin and starting therapy**

About 58% of newly admitted patients present with HbA1c >8%. Future AMD Annals will include an analysis of glycemic exposure during the first months, as measured using an ad hoc indicator. The future stakes are high. The goal is to reach target values rapidly. The 2010 AMD survey revealed that only 12.4% of patients receive insulin therapy, which is highly suggestive of therapeutic inertia. The last column in the table (patients with duration of diabetes >5 years) shows that these patients have a similarly elevated HbA1c level and that over 35% receive insulin treatment; this means that insulin treatment is more an expression of duration of diabetes than metabolic insufficiency. In other words, a diabetologist is more likely to initiative insulin therapy only at some point well into the disease and after proven secondary failure. Instead, insulin therapy should be viewed as a temporary means to achieve the target objective. When we compare this finding with the analysis of the online questionnaire of the Subito! project (II Giornale di AMD), we see that it is at odds with the widely held policy voiced during the data collection: in response to the clinical case of a patient with HbA1c >8%, a 6-month duration of diabetes, and receiving oral hypoglycemic agents, about 23% of the 600 diabetologists stated they would have prescribed insulin. The Annals data confirm an important audit that verifies the service delivered.

# Hypertension and lipid profile at onset of diabetes

Over 56% of patients have blood pressure >140/90 mm Hg. This signals an urgent need to effectively treat high blood pressure; this challenging task requires both method and attention. The response of the diabetes centers appears encouraging: >50% of patients are currently under treatment. But other factors also need to be kept under control: foremost, intensification of therapy to reach therapeutic targets. Evaluation of this aspect revealed that this is often a sore point, and the 2010 Annals are no exception (see intermediate outcome indicators).

Mean LDL-C 125 mg/dl and 26% of patients not reaching the target value of 100 mg/dl should make adequate lipid profile management a top priority at admission to care. Since only 27% of patients are treated and the majority have followed a restricted diet for >3 months, it appears that in many centers institution of therapy is delayed. The reasons are difficult to understand. Lipid-lowering treatment is among the simplest to begin, as long as it is continued together with intensification of therapy to reach the therapeutic objective.

### **Smoking**

Cessation of smoking is a cardinal rule of health prevention, especially in patients with diabetes. That the percentage of smokers declines with duration of diabetes is an encouraging finding. We may optimistically interpret this as a result of effective patient education by diabetologists and general practitioners.

Carlo B. Giorda

## **Conclusions**

AMD Annals: indicators of quality of diabetes care in *Italy* – now in its fifth edition.

This edition is extraordinary for the number of participating centers and data on treated cases (one-fifth of patients with diabetes in Italy) and for the growing involvement of professionals.

The Annals are not a mere exercise in statistical analysis: the more robust, the greater the amount of data collected. The Annals are a choral experience of Italian diabetologists committed to sharing their professionalism. The title expresses the meaning of what we summarily call the AMD Annals.

The word "annals" describes the uniqueness of AMD, the essence of a way of thinking and acting that brings together medical knowledge, clinical activity, organization of services, self-analysis, benchmarking and continuing improvement. These concepts are difficult to appreciate by those unfamiliar with the AMD mission, vision and policies.

The driving force behind this ongoing experience reveals its strength in the increasing number of participating centers: double that of previous surveys. Through publication of the Annals, the AMD expresses its intension to take stock, to improve – and the longitudinal Annals data tangibly demonstrate this.

A dedicated database is an enormously attractive resource for marketing purposes, for example; but the AMD vision precludes commoditization of this product. It is equally true that that data mining can furnish valuable directions for orientating organizational strategies and can inform providers' decision-support protocols of health care pathways based on the data about first visits or patient-physician encounters. These are only some examples of the huge potential information resource that AMD makes available through the online publication of data and the subanalysis for the AMD work groups, as in gender medicine, in the use of insulin microinfusors, in gestational diabetes and many other areas.

Open to all, the Annals Group has become, by AMD national executive board decision, a study and project group composed of a panel of experts and data collection workers collaborating with the Consorzio Mario Negri Sud.

The Annals do not appear overnight as if by magic. A considerable amount of work goes into making the final product. Antonino Cimino, Danila Fava, Carlo Giorda, Illidio Meloncelli, Antonio Nicolucci, Fabio Pellegrini, Maria Chiara Rossi, Salvatore Turco, supervised by Giacomo Vespasiani, contributed to creating the 2010 AMD Annals. They constitute the biennial editorial board. Behind them are the continuity and history of the Annals since the work's inception, the board's predecessors, the team of 40 regional tutors and the many diabetologists who volunteered in data collection, the staff of the national AMD secretariat, the AMD Study and Research Center, and the national executive board which underscores the institutional valence of the Annals Group.

I am certain that the 2010 Annals will mark the beginning of this unique experience.

> Sandro Gentile AMD President