AMD

2008 Annals

Quality Indicators in Diabetes Care in Italy

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Production services: Kino – Torino, Italy

Printed by Stamperia Artistica Nazionale – Torino, Italy

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Quality Indicators in Diabetes Care in Italy

The data collection enabling us to publish the AMD Annals 2008 – already in their third edition – was very successful, as the number of participating Diabetes Centres has further increased to 122 Centres (approximately 205,000 patients) distributed across the entire country.
We should also highlight that the Centres provided data relating to 4 years, and not only 1 year as was the case in the previous data collections.
This resulted in a "humongous" database, thanks to which it has been possible to perform new data processing, design future ones, and which will enable the development of a large number of analysis and scientific works.
In the AMD Annals 2008, the Editorial Board has decided to also include – alongside the classic national analysis – an analysis of the indicators on a regional basis.
The regions selected and analysed had to have data from at least 5 diabetes Centres (in order to preserve the anonymity of the Centres themselves). All told, 11 regions achieved this minimum requirement.
However, we should remember that each diabetes Centre has specific software – freely supplied by the AMD – to measure the same indicators on their own database. In this way, each Centre can analyse its own data over the span of years, or compare them with the national reference data published by the AMD.
The previously announced longitudinal study covering 4 years (2004 to 2007) will be published in the AMD Annals 2009. This is necessary in order to investigate this delicate and complex analysis thoroughly, as well as to guarantee that each new entry (regional and longitudinal analysis) has a fair space for dissemination and discussion.
The Annals 2008 have been presented during the AMD Meeting in Cernobbio (October 2008), while the Annals 2009 will be presented on the occasion of the Congress to be held in Rimini, May 2009.
Today, based on previous experience, we can single out some of the crucial factors that contributed to the success of this initiative.

1. The universally equal extraction of the AMD Data File, even if starting from different patient records.
The AMD Data File is much more than a mere minimum dataset where the clinician identifies the medical information to be recorded. It is a list of clinical parameters explicitly aimed at calculating the AMD quality indicators. The list was written to be read and interpreted by both doctors and information technology specialists interested in extracting the information in a standard way from any patient's computer record. It should be noted that confusion sometimes arises with reference to indicators identified with identical or similar names, but processed in different ways; thus, producing number values which are not comparable. Every stage of the calculation based on the AMD Annals indicators is clearly explained on the official website. This will serve to preserve one of the main features of a quality measurement; i.e., homogeneity and the comparability of data.

2. The completely voluntary and free character of the information supply to the AMD.

3. The complete anonymity ensured to both patients with diabetes and the participating Centres, as it is impossible to couple graphical and numerical data with any given diabetes Centre.
This approach, distinctive of our country as it differs from the few other similar initiatives carried out abroad, aims at showing that the actual goal is cultural and aimed at continuously improving quality, rather than creating a rating system or comparisons leading to a distinction of A or B league Centres.
In other countries, such as Israel and the United States, the quality indicators are required by law on the part of the financing institutions, in order to monitor the quality of the healthcare provision; as such, the actual disbursement of funds is subject to them. This approach, which only regulations can make possible, is not feasible for a Scientific Society like the AMD. However, even though it might help identify an optimal organizational model to be used as a reference, on the other hand, it might also result in "sprucing up the figures" so as to attain a better placement in the national ranking.

4. The AMD quality indicators and their calculation method have stayed essentially unaltered over the years, and are available to anybody on the AMD website.
Other governmental initiatives, currently beginning, partly follow what we have done with our Annals, and this represents a further demonstration of the importance of this issue and of the AMD's far-sightedness.
Actual equal cooperation between different initiatives would be useful and desirable, so as to enable each party – within the realm of their specific experience – to contribute information and data without generating duplicates which might dissipate energy and, sometimes, give rise to confusion.

5. The AMD has the exclusive ownership of the database created in this way.
The national database represents a huge asset of data which, as per regulations, cannot be transferred to anybody, not even in part.

6. Third parties are given the possibility to query the database, after a careful evaluation on the part of the AMD and data processing internal to the AMD.
In fact, scientific information of varying nature can be extract from this database, under the condition that the data are processed directly by the AMD. In other words, those who are willing to query the database with reference to scientific issues are allowed to do so, but only after a specific request to the Society which, after examining and approving it, process it directly by returning only the answers to the questions asked. The actual source of the information is not disclosed.
Actually, as of today this option has not been made much use of; however, we believe its potential is huge, and that its importance will be understood over time.

7. A paper copy of the document is distributed to all members, as well as to the national and regional public health authorities.
We have been informed of the attention that the Annals have generated at various regional institutions due to the quality and quantity of the information that can be extrapolated from the document.

8. The PDF document can be accessed and downloaded freely from the AMD website.
In fact, the main goal of the AMD is to disseminate the information.

9. PPT slides are available from the AMD on request.

10. Anybody can use the published data, as long as the source is cited and the original material is completely unaltered.

The AMD Annals are reaching an editorial maturity which enable us to project this experience into the future.
The data collected have brought about, for our Society, visibility and scientific credit at a national and international level. This is demonstrated by the recent acceptance, on the part of *Diabetes Care*, of a report describing this experience and including its essential numeric information. Other publications are on their way, and each member can, starting from this common asset, produce specific publications and statistical processing by contacting the AMD.
Now our Society intends to move from data analysis to action, by encouraging, at a regional level, debates and management initiatives aimed at improving the quality of diabetes care.
The International Diabetes Federation has paid special attention to our initiative, due to the possibility of exporting it to an international level thanks to its voluntary nature and the connection with a Scientific Society which facilitates its implementation.
We all know, however, the commitment this work entails, not only to extract data but also to continuously improve. We also know that the clarity and transparency of each process and goal is indispensable, as any shadow might undermine this extraordinary experience, envied in Italy and abroad. For this reason, the AMD adopted specific rules (available on our official website, www.aemmedi.it) which regulate each stage of data collection and processing in strict compliance with the national laws and the professional code of ethics. Any alleged breach of rules should be reported to the AMD, so that it can be carefully evaluated and the rules themselves improved. Constructive criticism is always welcome, as well.
The AMD Annals are, by now, a symbol of our association. Each of us should look after them and make the most of them.
We would like to extend our gratitude to the Consorzio Mario Negri Sud, which have been working with our Society for years, for their exact and thorough statistical processing, supported financially and unconditionally by Lifescan Italia.
We thank Novo Nordisk Italia for its commitment towards realizing the English version of the Annals 2008.
We would like to conclude by also thanking, on behalf of the Annals Editorial Board, the AMD Executive Board and all the diabetes Centres which took part in the data collection. We are confident that we are providing a useful service to patients and the diabetes community, but also aware that without the contribution of each person involved this initiative would have never made it beyond the list of our intentions.

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Silvana Manfrini, Silvia Rilli	Ospedale di Senigallia	U.O. Diabetologia	Senigallia (AN)
Italo Tanganelli	Azienda Ospedaliera Universitaria Senese	Biotecnologie Applicate alle Malattie del Ricambio	Siena
Giuseppe Felace, Ida Fumagalli	Ospedale San Giovanni dei Battuti di Spilimbergo	Medicina - Ambulatorio di Diabetologia	Spilimbergo (PN)
Giovanni Divizia, Mafalda Agliani	Ospedale Generale San Matteo degli Infermi	U.O. Diabetologia	Spoleto (PG)
Augusto Travaglini, Patrizia Draghi	Azienda Ospedaliera "Santa Maria"	U.O. Clinica Medica - Amb. M. Dismetaboliche	Terni
Paolo Acler, Tiziana Romanelli, Sandro Inchiostro	Ospedale Santa Chiara di Trento	Serv. di Diabetologia	Trento
Riccardo Candido, Elisabetta Caroli, Elena Manca, Alessandra Petrucco, Roberto Da Ros, Paolo Da Col, Elisabetta Tommasi, Nevia daris, Maria Grazia Cogliatti, Angelina Pianca, Emanuela Fragiacomo	Azienda Per i Servizi Sanitari n. 1 Triestina	S.C. Centro Diabetologico	Trieste
Mario Vasta, Maurizio Sudano, Maria Grazia Pronti, Gigliola Martinelli, Mauro Andreani, Giordana Ciandrini, Stefania Lani	ASUR Zona 2 - Ospedale Civile di Urbino	S.I.T. Diabetologia e Malattie Metaboliche	Urbino
Anna Rosa Bogazzi, Giovanna Bendinelli	Ospedale di Venaria	Struttura semplice di diabetologia	Venaria Reale (TO)
Margherita Pais, Ermanno Moro	Ospedale civile di Venezia	Servizio di diabetologia	Venezia
Francesco Cervellino, Armando Zampino, Rosa Sinisi	Ospedale San Francesco ASL 1	Unità Speciale di Diabetologia	Venosa (PZ)
Antonella Schellino	Ospedale Castelli	Struttura Complessa di Diabetologia e Malattie Metaboliche	Verbania Pallanza (VB)
Roberto Mingardi, Luciano Lora, Cristina Stocchiero	Servizio di Diabetologia Casa di Cura Villa Berica	Dipartimento Medicina Unità Operativa del Piede diabetico e della Medicina Vascolare	Vicenza
Alfonso Basso, Elisabetta Brun, Marco Strazzabosco, Maria Simoncini, Consuelo Grigoletto, Francesco Zen, Chiara Alberta Mesturino	Ospedale San Bortolo	Endocrinologia e Malattie Metaboliche - Servizio di Diabetologia	Vicenza

Methods

This third edition of the AMD Annals represents a well-established reference source for the description of diabetes care profiles in Italy. Thanks to a trend of increasingly wide participation, the number of diabetes Centres taking part in the initiative has grown from 86 in 2006 to 122. All Centres are equipped with computerized systems (digital medical records) able to guarantee – besides the ordinary management of patients under treatment – the standardized extraction of the information required to build the AMD Data File. The latter is the basic cognitive tool, as it provides all the information necessary to describe the process and outcome indicators under examination.
A fundamental premise, necessary for the correct interpretation of the data displayed, concerns the unavoidable overlapping of care quality and the quality of the data collected. In other words, a reliable assessment of care quality cannot occur without the correct and comprehensive use of digital medical records. In fact, the incomplete recording of data relating to care makes it impossible to distinguish between the failure to perform a given procedure (e.g., the fundus oculi) and the failure to record the procedure. As discussed in detail below, this problem made using certain indicators impossible and influenced the selection of Centres included in the analysis.

Centre Selection

To ensure a representative level of clinical practice, Centres with fewer than 10 patients with type 1 diabetes (DM1) or fewer than 100 patients with type 2 diabetes (DM2) were excluded from the care profile analysis. Based on these criteria, a total of 116 Centres were therefore made eligible. Similarly, Centres with fewer than 10 DM1 patients or fewer than 100 DM2 patients were excluded from intermediate outcome analysis, when patient numbers were insufficient for a specific outcome. These selection criteria were necessary, since in some Centres the computerization of clinical data had only recently been activated and involved only a part of the patients receiving care.

Population Selection

All analyses regard active patients in the year 2007; i.e., all DM1 or DM2 patients who underwent at least one examination, one measurement of glycosylated haemoglobulin, or were prescribed diabetes drugs at least once during the index year.

Definition of a Gold Standard

For the selected process and intermediate outcome measures, the overall performance, as well as that of each individual Centre, were evaluated in relation to a gold standard. These reference values were calculated from those Centres able to guarantee an adequate degree of comprehensiveness in the information reported. In the specific, the Centres featuring the following information comprehensiveness were selected:

Variable	Threshold value (≥)
Gender	90%
Age	90%
Diabetes Type	90%
HbA1c	70%
Blood Pressure (BP)	70%
Body mass index (BMI)	70%
Lipid or LDL-cholesterol profile	50%
Indication of anti-diabetes therapy	85%

This process led to the selection of 64 Centres. To define the gold standard, the 75th percentile of the value distribution of these Centres was used. This value represents the best performance obtained by 25% of the Centres with the highest values. For instance, the gold standard of the process indicator "measurement of HbA1c in DM2" is 97%. In other words, 25% of the selected Centres measured HbA1c in at least 97% of the patients visited during the study period (in the remaining 75% of Centres, the proportion was obviously lower).
In the measurement of positive intermediate outcomes (e.g., the percentage of patients with HbA1c <7%), the interpretation was the same. When intermediate outcomes were negative (e.g., the percentage of patients with HbA1c ≥8%), the gold standard was based on the 25th percentile (e.g., the value obtained by 25% of Centres with the lowest percentage of patients with HbA1c ≥8%).

General Descriptive Data

Except for certain descriptive aspects provided for the entire sample, the characteristics of the population studied were reported separately for DM1 and DM2 patients. The data concern socio-demographic characteristics (age, gender) and clinical parameters (BMI, HbA1c, blood pressure, triglycerides, total cholesterol, HDL and LDL cholesterol). When not included in the medical record, the LDL levels were calculated based on the Friedwald formula. Of course, LDL cholesterol was only calculated when the medical record included total cholesterol, HDL, and triglycerides measured on the same day.
Since the normal range of HbA1c varied between Centres, in order to permit comparative analysis the values were mathematically transformed. That is, the value of each patient was divided by the upper limit of the normal range at a specific Centre, thus obtaining the percentage shift of the value from the upper limit of the normal range. The value was then multiplied by 6.0 to permit an interpretation of all data on HbA1c, using 6.0% as the normal reference value.

Selection of Indicators

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

Process Indicators
Among the process indicators, the selection included those regarding the monitoring, at least once annually, of the following parameters:

- HbA1c
- Lipid profile
- Blood pressure
- Kidney function
- Foot examination

For all indicators the denominator was constituted by the number of active patients during the index year, excluding Centres that reported data on fewer than 10 active DM1 patients, or fewer than 100 active DM2 patients.
A further process indicator – represented by the mean number of visits grouped according to the type of treatment – was evaluated only in those Centres that had recorded at least one examination in at least 80% of their active patients. This selection was necessary, because in some Centres the electronic medical record was not used to quantify the services delivered; consequently, not all examinations were recorded in the data field needed to create the AMD Data File.
It should be noted that the process indicators in the Data File do not include fundus inspection or neuropathic assessment. In fact, the results of the aforementioned evaluations are often found in the medical records in the form of free text. As such, they cannot be used for the purpose of statistical analysis.

Intermediate Outcome Indicators
The following indicators were used:

- Percentage of patients with HbA1c <7% and ≥8%
- Percentage of patients with LDL cholesterol level <100 mg/dl and ≥130 mg/dl
- Percentage of patients with blood pressure <130/85 mmHg and ≥140/90 mmHg
- BMI classes
- Percentage of smokers

- Percentage of patients with LDL ≥130 mg/dl not on statin therapy
- Percentage of patients with blood pressure ≥140/90 mmHg not on antihypertensive therapy

For all these indicators, the denominator was represented by those patients who underwent at least one measurement of these parameters during the index year. As mentioned above, Centres were not included where these parameters were measured in fewer than 10 DM1 patients, or fewer than 100 DM2 patients.
The last two indicators were only calculated in those Centres with sufficient information concerning therapies in progress (at least 5% of patients receiving statin therapy, and at least 10% of patients receiving antihypertensive treatment).
The percentage of smokers was only calculated in those Centres where at least 10% of patients were smokers.

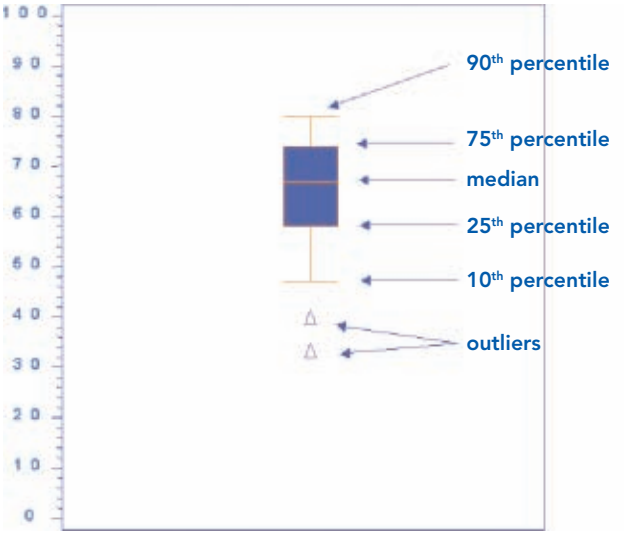
Final Outcome Indicators
Despite their tremendous significance, and the fact that they are adequately covered in the Data File, these indicators remain outside the scope of the present report. In fact, as with other process measures, information on long-term complications are often reported in free text in the medical records, rather than being coded (even though the corresponding standard code fields are available there).

Graphical Representation of Data

In addition to tabular form, the data on the chosen indicators are reported in various types of graphical representations. Besides the customary diagrams used for reporting frequency distribution (histograms, pie charts), more detailed diagrams have been included for better data comprehension.

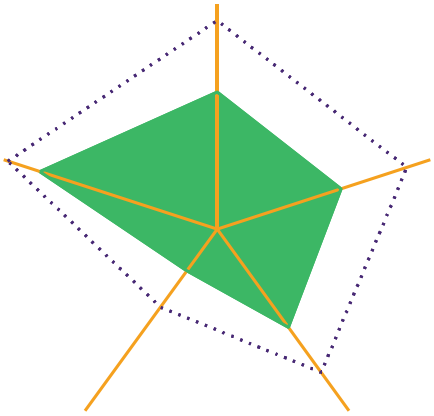
Prevalence of Diabetes by Region
This map provides an approximate picture of the percentage of patients with diabetes – within each region of the country – included in the Data File. To this end, the same estimation of the known diabetes prevalence (4.5%) was used for all regions. This figure was then applied to each region using the 2002 ISTAT data to quantify the resident population. The shading density of each region is proportionate to the percentage of patients included in the Data File, with respect to the estimated percentage.

Boxplots



Boxplots summarize in a simple yet comprehensive way the distribution of a variable's characteristics. As shown in the illustration, a boxplot consists of a rectangle crossed by a centre line indicating the median, while the upper and lower hinges correspond to the 75th and the 25th percentiles, respectively. The bars extending above and below correspond to the 90th and the 10th percentiles, respectively, while the notches outside the bars represent the outliers. The width of the box and the bars indicates graphically the variability of the index in question: a flattened box demonstrates that the measurement had a fairly uniform spread across the study population, while a stretched box shows that the measurement tended to have very different values within the study population.

Starplots
Starplots multiple variables summarize information in a single diagram, thus facilitating an overview of the variable in question. Each variable (e.g., a process measure) is represented as a percentage on a radius or spoke of the starplot, which has a value from zero to 100 moving outward from the starplot's centre to its border. The values on the radii are joined to form a polygon.
Each figure contains two polygons: the one with a dashed line border represents the gold standard values



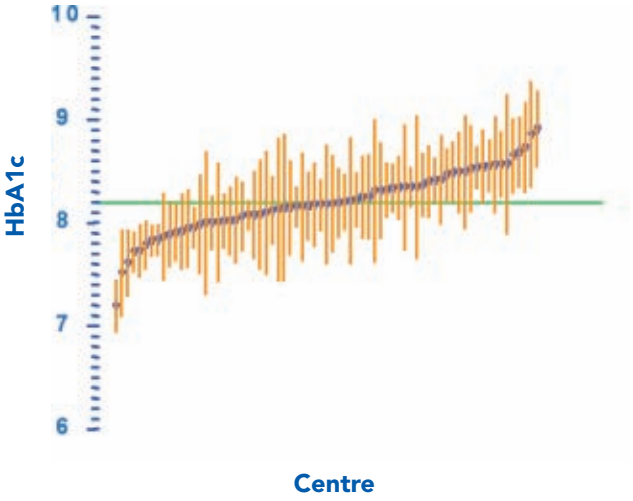
calculated as described above; while the one with solid lines represents the values obtained (on the entire sample or by single Centre/patient subgroup). The closer the points of the solid-bordered starplot are to those of the starplot with dashed lines, the closer the quality of care in that specific Centre/patient subgroup matches the desired value (i.e., that obtained by the "best" Centres). In process measures, the wider the polygon – with points close to 100% – the better the care delivered. If a polygon is much smaller than the one with dashed lines (on one or more radii), it denotes a gap between the quality of care delivered and the level of quality desired.

To represent intermediate outcome measures, the polygon is divided into two parts: the upper half (in green) indicates the percentage of patients with a favourable outcome (e.g., HbA1c <7%, blood pressure <130/85 mmHg, LDL <100 mg/dl); whereas, the lower half (in red) indicates the percentage of patients with unfavourable values (e.g., HbA1c ≥8%, blood pressure ≥140/90 mmHg, LDL ≥130 mg/dl). Subsequently, the larger the green area and the smaller the red area, the greater the number of positive outcomes.

Variability Diagrams

Variability in the process and intermediate outcome measures among Centres was obtained using multilevel analysis, adjusting the values for patient age and gender, as well as according to the clustering effect (patients followed up at the same Centre cannot be considered independent measures, since they tended to receive similar care).

For each Centre, the mean value (or percentage) is reported together with the 95% confidence interval estimated in the multilevel model. This approach makes it possible to compare the mean HbA1c values from different Centres (or, for instance, the percentage of patients with HbA1c <7%) for patients featuring the same gender and age. The values can be ranked in order of increase to gain an idea of the variability among Centres for a certain measure. The horizontal line indicates the mean value of the total study sample, thus allowing a quick evaluation of how far the values of each Centre lie outside the mean itself.



REGIONAL ANALYSES

For the first time, this edition of the AMD Annals includes the variability evaluation between specific regions, instead of variability diagrams divided by Centre. To guarantee a sufficient degree of representativeness in regard to the activities of a region, these analyses only covered regions where at least 5 diabetes Centres participated in the data collection.

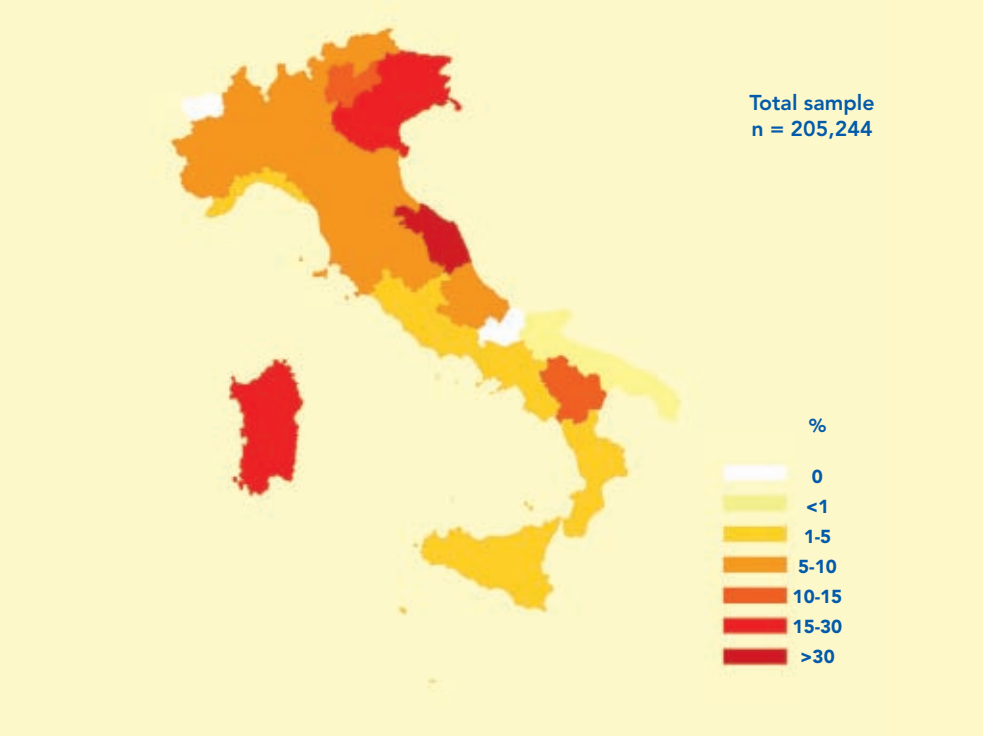
For this reason, the analyses refer to the following 11 regions: Piemonte, Lombardia, Veneto, Friuli-Venezia Giulia, Emilia Romagna, Toscana, Marche, Lazio, Campania, Sicilia and Sardegna.

With the exception of variability diagrams, which are arranged based on the frequency of the use of specific classes of drugs, all diagrams are arranged according to location from North to South.

Map and General Description Indicators

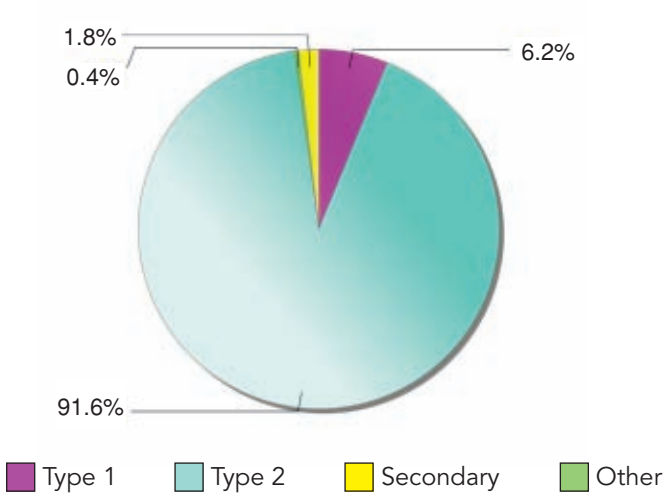
Proportion of Patients in the AMD Data File Compared to the Estimated Total Number of Diabetic Patients (Prevalence, 4.5%)

In all, data were provided on 205,244 patients examined at 122 Centres in 2007 (median, 1,450 patients per Centre; range, 118-7,141), 200,795 of whom were presented with a diagnosis of DM1 (N = 12,727) or DM2 (N = 188,068). Of the DM1 patients, 52.7% were recruited from the North, 22.4% from the Central Regions, and 24.9% from the South. Of the DM2 patients, the percentages from the North, Centre and South were 54.1%, 26.0% and 19.9%, respectively. The map shows the distribution of the study sample by region. With respect to previous years, the data from Marches – with over 30% of the estimated number of diabetic patients included in the analysis – has been confirmed, while there was a significant increase in the number of regions which included 10 to 30% of patients presumably living in the region.



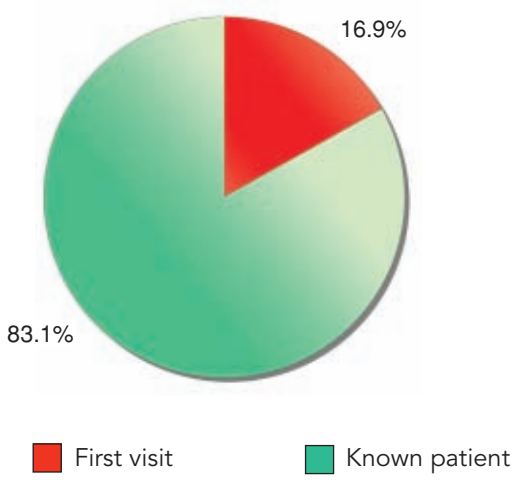
General Population Indicators

Distribution by Type of Diabetes



The distribution by type of diabetes – essentially unaltered with respect to previous years – confirms that the care load is predominantly linked to DM2, which represents over 90% of patients visited during the year.

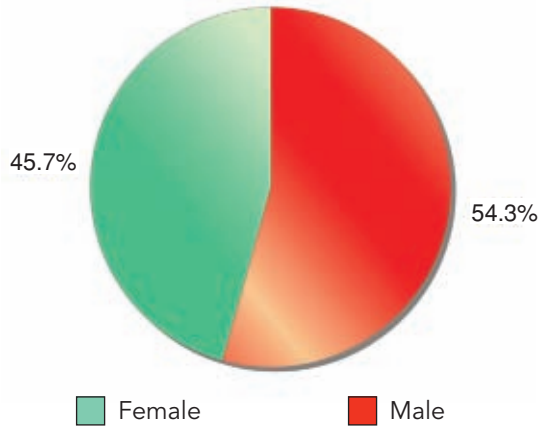
First Visits Versus Total Visits in the Reference Period



Of a total of 200,795 patients examined in 2007, 33,934 or 16.9% were visiting a diabetes care Centre for the first time.

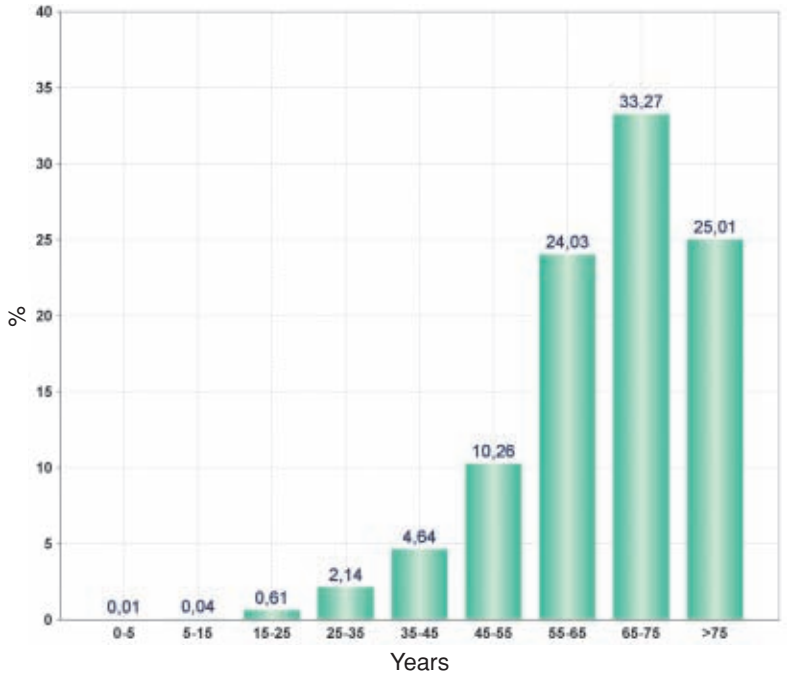
This data, higher than in previous measurements, show that the number of patients seeking specialist consultation increases every year.

Distribution of Patients by Gender



A slight predominance of men seeking specialist consultation is confirmed.

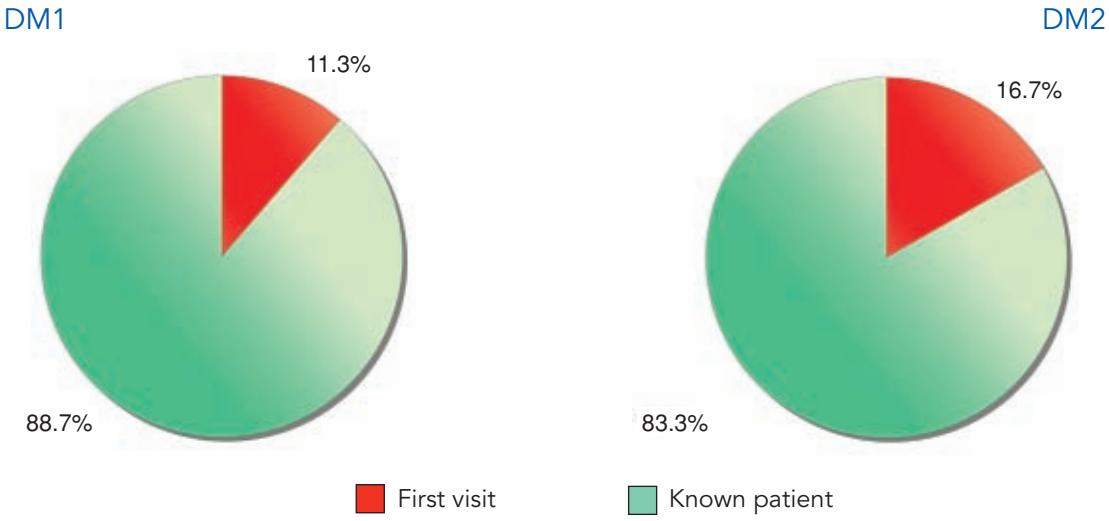
Distribution of Patients by 9 Age Groups



Distribution by age group, unaltered with respect to previous years, shows that more than half of the patients treated were over 65 years of age, highlighting once again that a significant amount of care is delivered to seniors.

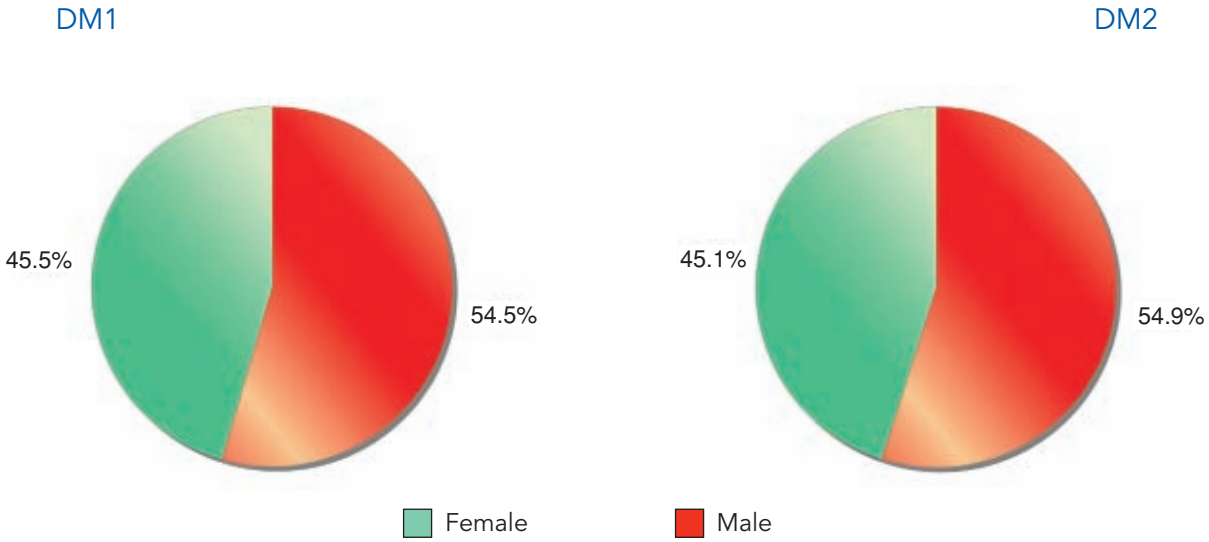
Type 1 and 2 Diabetes Indicators

First Visits Versus Total Visits in the Reference Period



As far as DM1 is concerned, the first visits in 2007 amounted to 1,438 out of 12,727, or 11.3%; whereas, the first visits for DM2 numbered 31,407 out of 188,068, or 16.7%. Thus, the comparative data shows that, in percentage, first visits represent a much more significant share for DM2 patients.

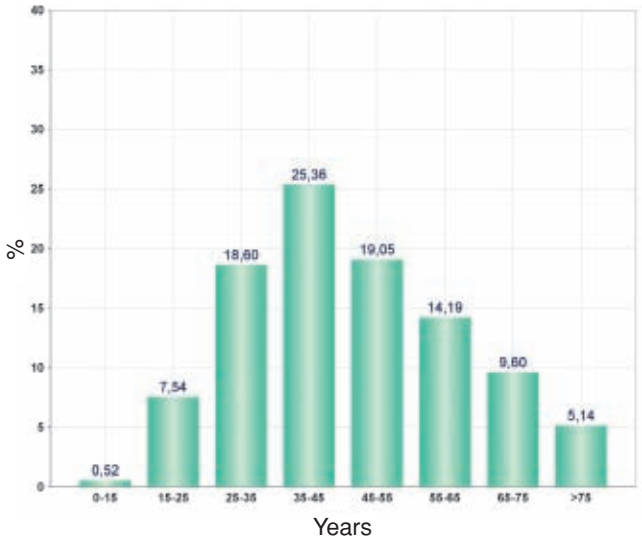
Distribution of Patients by Gender



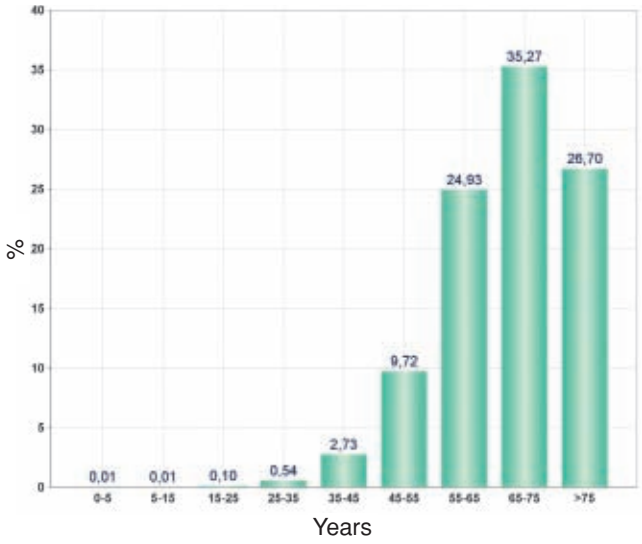
Among both DM1 and DM2 patients there was a slight predominance of men.

Distribution of Patients According to 9 Age Groups

DM1



DM2



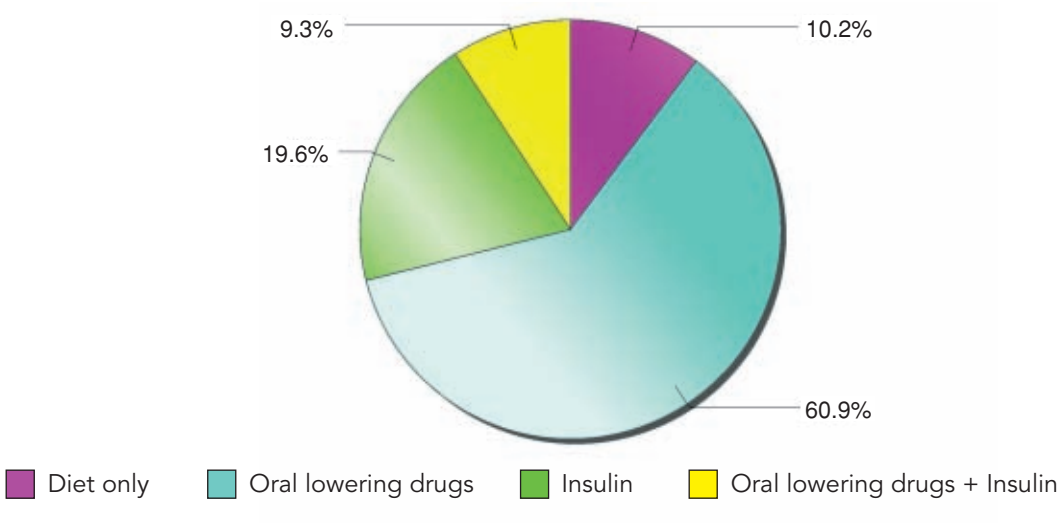
As expected, the distribution by age group differed between the two types of diabetes. DM1 features a greater concentration of patients belonging to the younger age groups. Less than 15% of DM1 patients are over 65 years of age, while over 50% are aged between 15 and 45. As far as DM2 is concerned, the distribution shifts completely towards older age groups. However, the percentage of patients aged 45-55 should not be underestimated, and neither should the presence of DM2 in younger age groups.

Mean Number of Visits/Year by Treatment Group

	DM1	DM2
Diet only	–	2.2
Oral lowering drugs	–	2.5
Insulin	3.5	3.3
Oral lowering drugs + Insulin	–	3.2

The mean number of visits by treatment group mirrors the increase in care intensity required by moving from diet alone to an oral treatment, to insulin therapy. The frequency in visits of patients on insulin therapy does not seem to differ substantially based on the type of diabetes.

Distribution of Treatment Types among DM2 Patients



As far as the distribution based on the treatment offered to patients with DM2 is concerned, 10% are treated exclusively with an action on their lifestyle, less than 1/3 are treated exclusively with insulin alone or in association with oral glucose lowering drugs, while 60% are treated with oral glucose lowering drugs alone.

A Comment on the General Indicators

In tune with the attention paid by the international scientific community to the quality of medical assistance, the AMD has designed a strategy aimed at developing programs which improve diabetes care. This strategy is based on a system enabling each diabetes Centre to verify its own clinical practice (AMD Data File), compare it to other Centres (AMD Annals) and assess it in relation to the best practice described by the AMD in the *Italian Standards for Diabetes Mellitus*.

Chronologically, the starting point of this journey was the creation of a dataset (AMD Data File) which enabled the diabetes Centres to carry out the statistical process required to improve activity and outcome, to illustrate the complexity of their work, and, at the same time, answer important questions raised by the stakeholders.

The second step was represented by the Annals project, which is not merely a collection of national data, but rather the sign of an inclination on the part of the diabetes Centres to perform a systematic revision of their clinical performance, as well as the expression of their will to make it available for consultation every year in the publishing of the AMD Annals.

The third step is represented by the creation of the *Italian Standards for Diabetes Mellitus*, which summarizes the scientific evidence currently available, and indicates the best practice attainable.

What results has this strategy for the improvement of diabetes care in Italy brought about so far? Which are the areas where we need to intervene in order to modify the quality of care? Many of the answers currently available come from the analysis of the indicators included in the AMD Annals, and, among them, the general indicators are able to shed light on some of the current critical issues in specialist care, as they describe the interface point of diabetes Centres within their context.

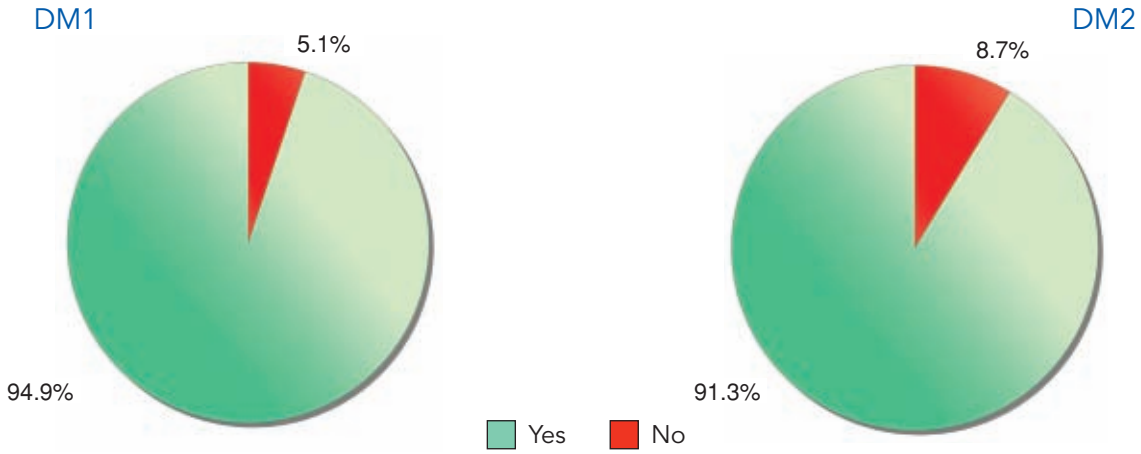
In fact, in the flow diagram describing the activities of a diabetes Centre, the general indicators measure the initial stages of the care process, making it possible to evaluate the initial actions and understand the needs and means of access characterizing a person with high blood sugar levels.
And specifically with reference to the needs of patients, the Annals 2008 show that, with respect to 2007, the percentage of first visits rose from 13.9 to 16.9% of active patients. This phenomenon might result in management issues for the Centres, which cannot possibly foresee the demand for first visits, and whose resources are often inadequate. In fact, in a condition of shortage of resources, recruiting new patients might correspond to a loss in yearly follow-up for an equal number of known patients. It is, therefore, important that each Centre closely monitors this phenomenon, so as to adequately govern its response to the demand for care coming from the people with diabetes.
The distribution by age group of patients suffering from the different types of diabetes, on the other hand, has not changed with respect to the previous years. In type 2 diabetes, most of the care load – corresponding to 62% of the total – is represented by people older than 65. In type 1 diabetes, over 51% of patients are aged 15-45. These figures highlight once again the heterogeneity of patients in terms of psycho-social, educational and clinical-therapeutic needs, and the fact that diabetes Centres must subsequently adjust the care they deliver.
The data related to therapies – with reference to both yearly visits and the type of treatment for type 2 diabetes – give rise to some interesting considerations. On the one hand, one might legitimately reflect on the appropriateness of visiting 2.4 times/year on average patients who are treated with diet alone. However, the increase in the proportion of people with type 2 diabetes on insulin therapy is beyond doubt a good sign, as it indicates a greater intensity in intervention concerning patients with poor metabolic control.
One last noteworthy consideration concerns the greater homogeneity in the rate of people with diabetes included in the Centre's database with respect to 2007. In fact, a reduction was registered in the number of Italian regions whose rate of inclusion ranged 1-5% of estimated diabetes patients (prevalence 4.5%). Conversely, the number of regions featuring a rate of inclusion ranging 5-30% increased, since the number of regions with a rate of inclusion >15% increased to 5 in the course of last year.
This phenomenon, together with the greater number of Centres participating in the Annals, shows that diabetes specialists more and more want to collect the data related to their activity correctly and in a systematic way, verify and assess their performance, make it available to the diabetes community and stakeholders, and improve it through adequate actions. This demonstrates that the strategy for improvement designed by the AMD is actually disseminating a culture of clinical governance, encouraging a comparison between peers, and strengthening the will to cover the distance between actual and desirable clinical practice.
The future participation of all diabetes Centres in the AMD Data File/Annals system will supply an important tool for clinical governance to both the diabetes community and the authorities, who will finally have an accurate description of the quality of diabetes care in Italy at their disposal.

Gualtiero de Bigontina and Danila Fava

Process Indicators

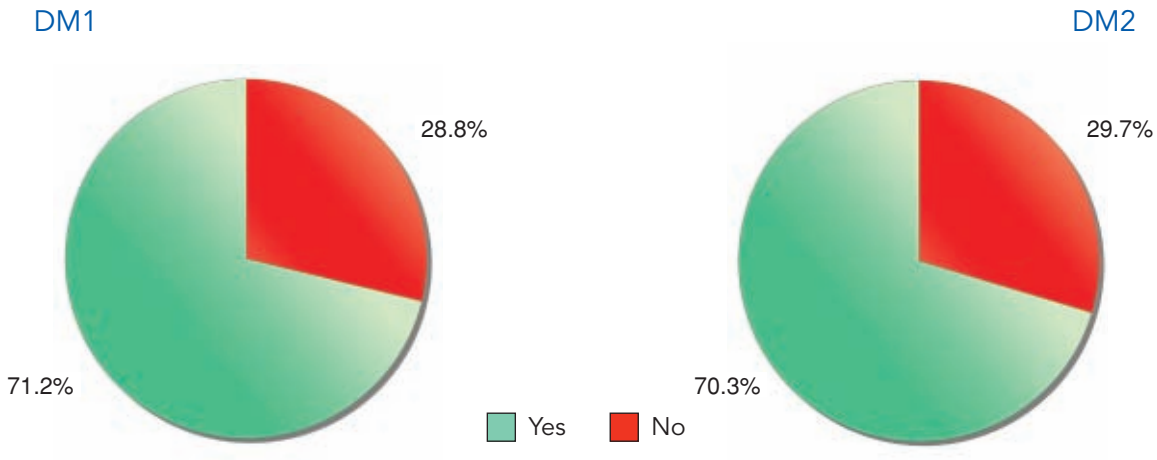
AMD Process Indicators Analysed by Type of Diabetes

Subjects Who Had Their HbA1c Measured at Least Once



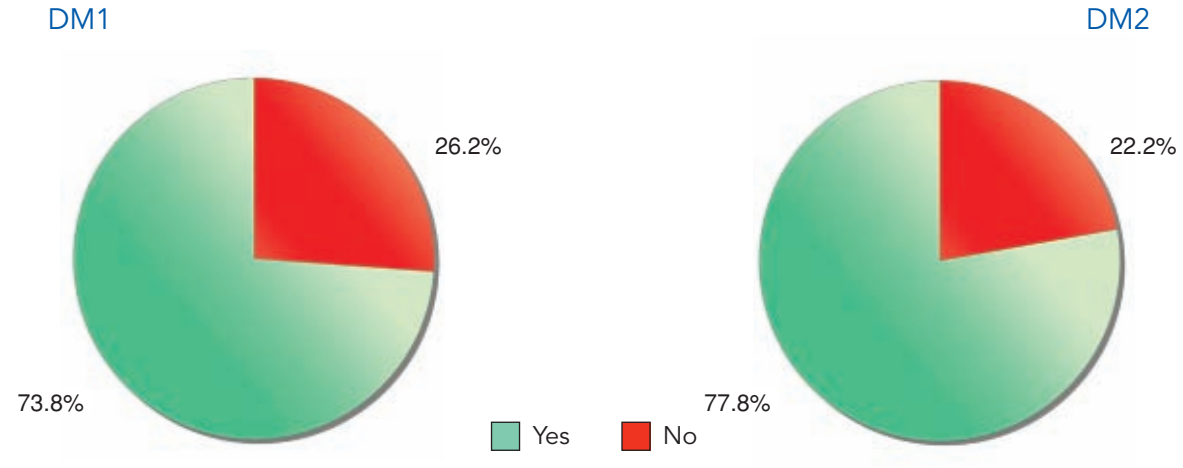
In both types of diabetes, HbA1c monitoring – which already represented an integral part of care in nearly all patients – recorded a further increase with respect to previous years. In fact, in the course of 2007, HbA1c was measured in over 90% of patients with both DM1 and DM2.

Subjects Who Had Their Lipid Profile Evaluated at Least Once



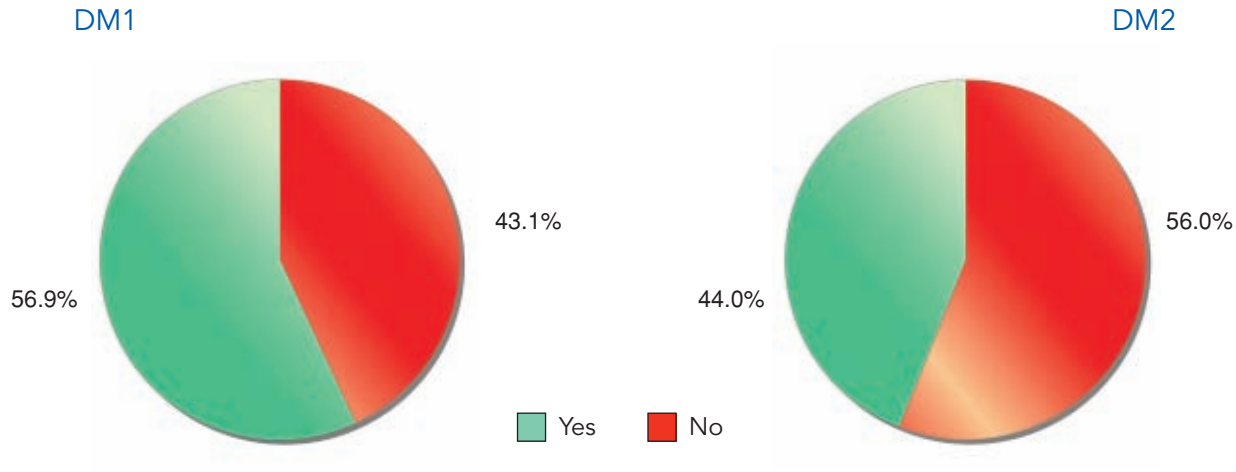
Lipid profile monitoring was also carried out more systematically than in previous years. In fact, this data was recorded in over 70% of patients, regardless of the type of diabetes; whereas, in previous years only 60% of patients were covered. The lack of information among nearly 1/3 of patients, however, suggests the need to further intensify the attention paid to this important factor of cardiovascular risk.

Subjects Who Had Their Blood Pressure Measured at Least Once



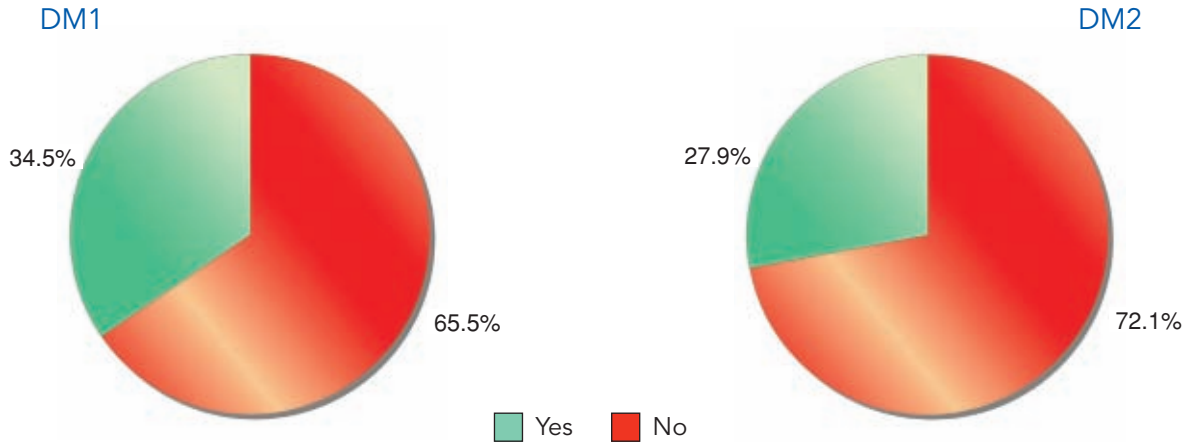
As with lipid profile monitoring, blood pressure monitoring improved, especially in regard to DM1. However, there is a concrete margin for improvement, considering that this data is missing for about 1/4 of patients.

Subjects Monitored for Nephropathy



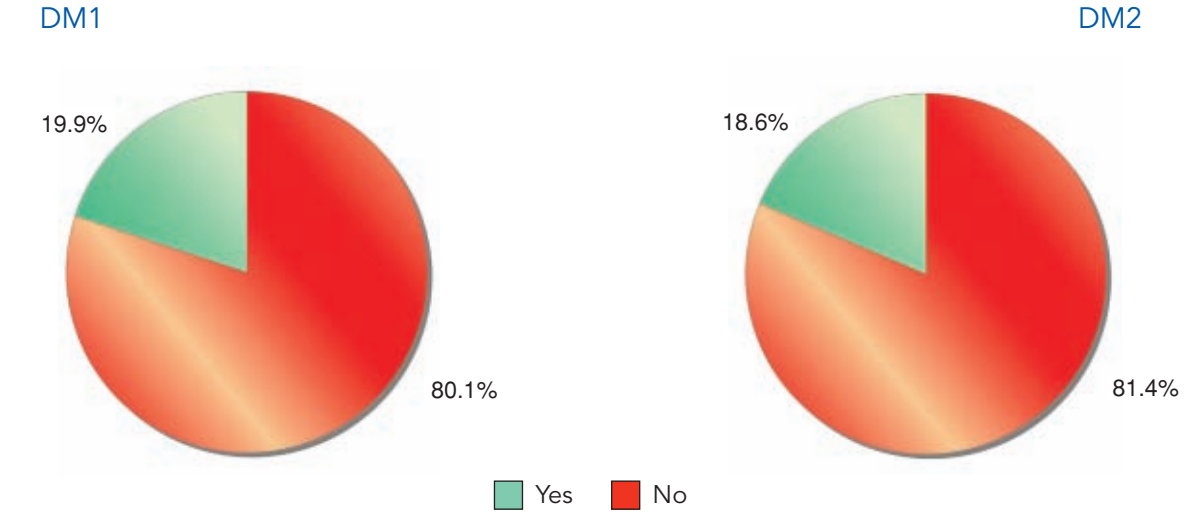
Unlike cardiovascular risk, monitoring for kidney function continues to be performed less frequently among both DM1 and, to a even larger extent, DM2 patients. In fact, the proportion of cases lacking the data is still quite high – and essentially unaltered with respect to previous years – for both types of diabetes.

Patients at Risk of Diabetes Foot Examined at Least Once



Among the patients considered at risk (neuropathy, previous trophic lesions or amputations, arteriopathy of the lower limbs), a little over 1/3 of DM1 patients and about 1/4 of DM2 patients had their feet examined during the index year. This underlines the need to intensify monitoring of one of the most incapacitating complications of diabetes.

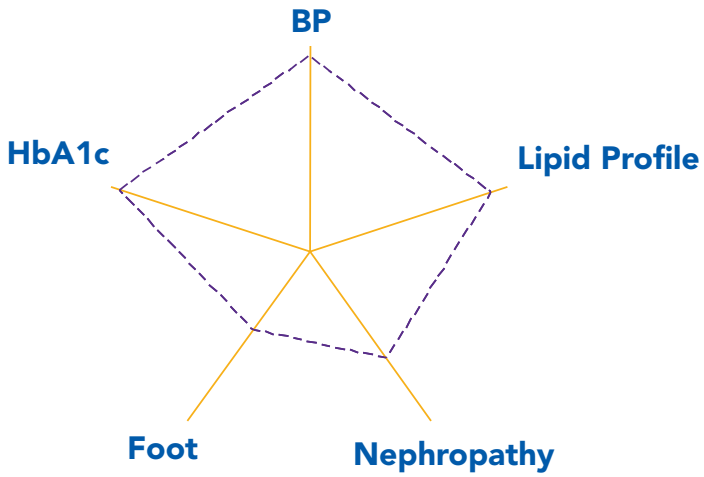
Patients Monitored for Diabetes Foot



Poor attention to foot examination is all the more evident from an analysis of the entire sample. Only 1/5 of patients, both DM1 and DM2, were recorded as having undergone foot examination during the year.

Starplot by Type of Diabetes, Gender, Age and Location

Process Indicators

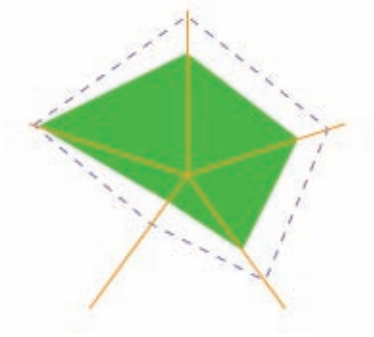


The following starplots concern the process measurements. In detail, each radius indicates the percentage of patients for which the digital medical record showed at least one examination during the year for the following parameters: HbA1c, blood pressure, lipid profile, kidney function, foot examination. For each starplot, the dashed line border represents the gold standard (see Methods section), while the solid polygon refers to the patient group in question.

Sample Analysed by Type of Diabetes

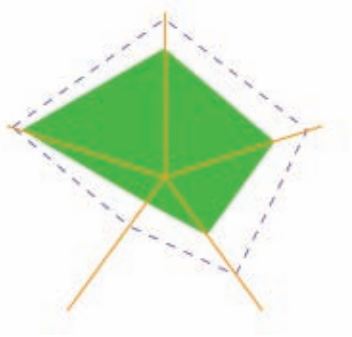
DM1

Entire sample



DM2

Entire sample

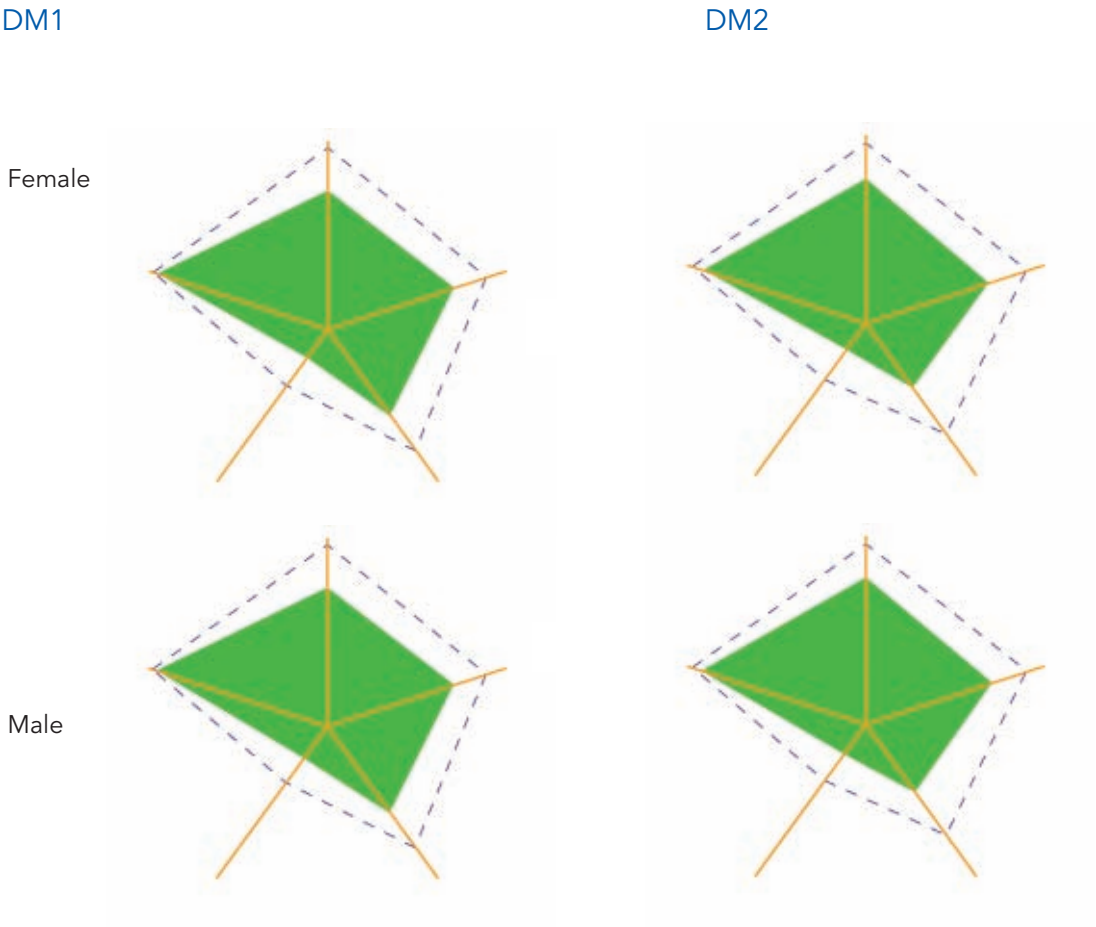


As far as DM1 is concerned, the dashed line starplot shows that extremely satisfying percentages were obtained by those Centres which contributed to define the gold standard related to monitoring glycaemic control (98%), blood pressure (97%), lipid profile (90%), and kidney function (80%); whereas, information on foot examination lies below optimal levels (37%). An analysis of the entire sample shows, however, a marked gap between the actual values and the gold standard. Only for HbA1c monitoring is the difference minimal (95%), while for all other measurements considered it is quite evident (blood pressure: 74%; lipid profile: 71%, kidney function: 57%, foot examination: 20%).

As far as DM2 is concerned, the dashed line starplot shows that extremely satisfying percentages were obtained by those Centres which contributed to define the gold standard related to monitoring glycaemic control

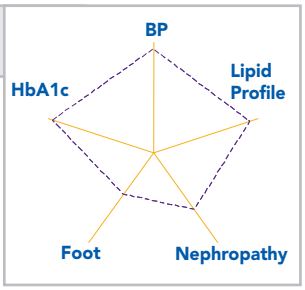
(97%), blood pressure (96%), lipid profile (91%). The percentage of patients monitored for kidney function (74%) was also satisfactory; whereas, in this case as well, information on foot examination lies below optimal levels (37%). The gap between the gold standard and entire sample was also significant in DM2; in fact, while the difference was small in terms of HbA1c monitoring (91%), it was very evident in all other measures under examination (blood pressure: 78%; lipid profile: 70%, kidney function: 44%, foot examination: 19%).
A comparison between the two patient groups did not show any relevant difference in the monitoring of the various parameters, neither in terms of gold standard nor entire sample. The only exception is represented by the monitoring of kidney function, which was monitored more frequently in DM1 than DM2.

Sample Analysed by Type of Diabetes and Gender



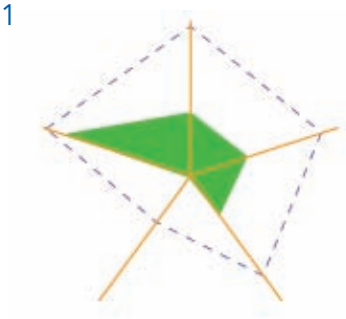
No differences emerged between male and female patients in either DM group for these parameters.
The gap between the gold standard and the total sample shows, regardless of the sex of the patient, the actual margin for improvement in patient care.

Starplot by Type of Diabetes, Gender, Age and Location

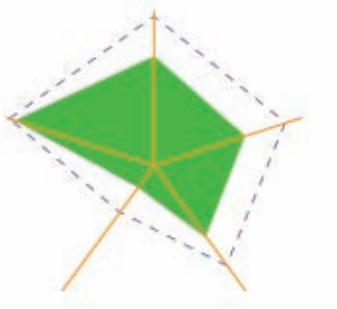


Sample Analysed by Type of Diabetes and Age Group

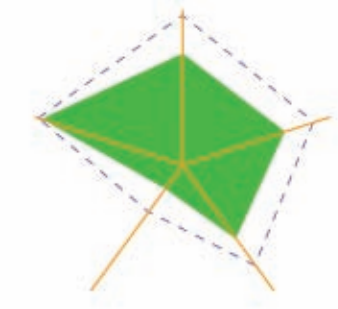
DM1



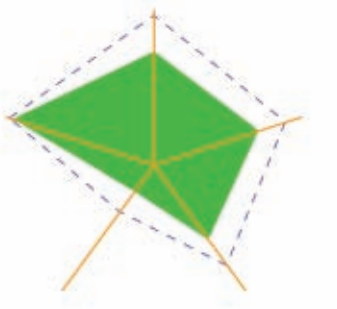
0 - 15



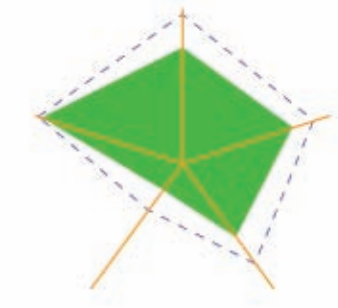
15 - 25



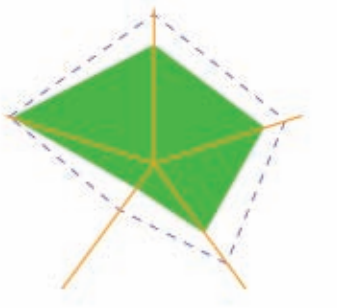
25 - 35



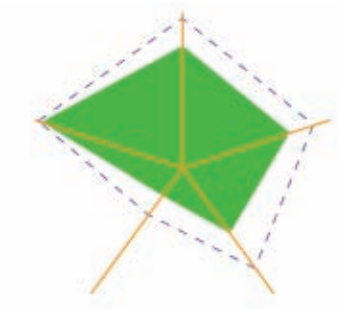
35 - 45



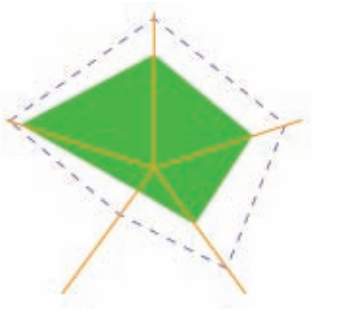
45 - 55



55 - 65



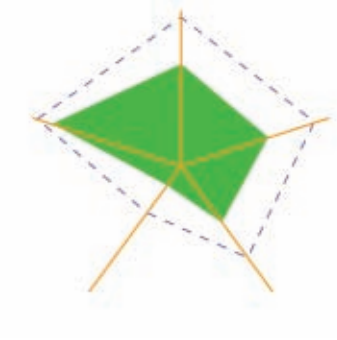
65 - 75



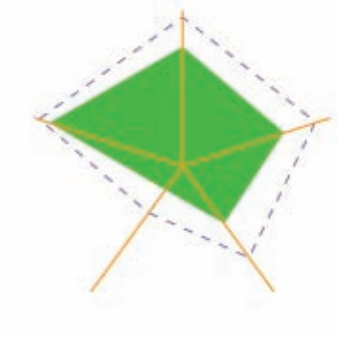
> 75

Sample Analysed by Type of Diabetes and Age Group

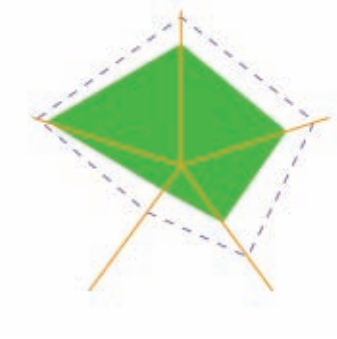
DM2



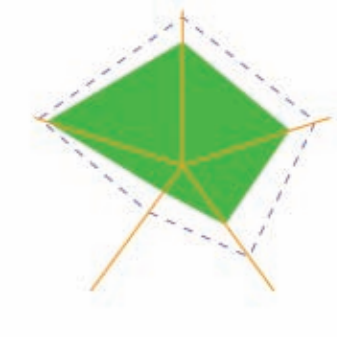
0 - 35



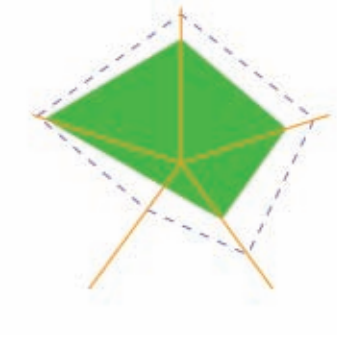
35 - 45



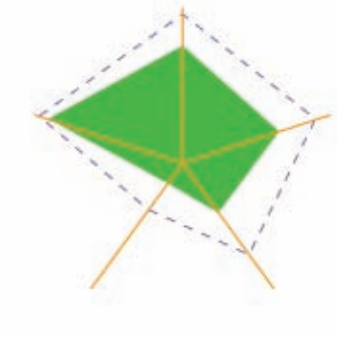
45 - 55



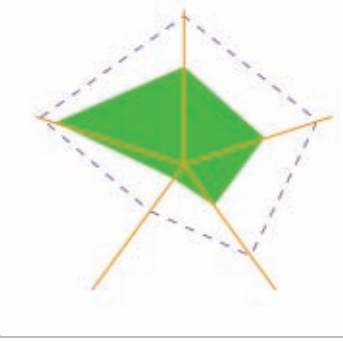
55 - 65



65 - 75



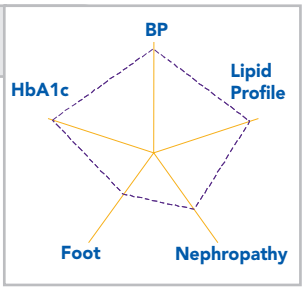
75 - 85



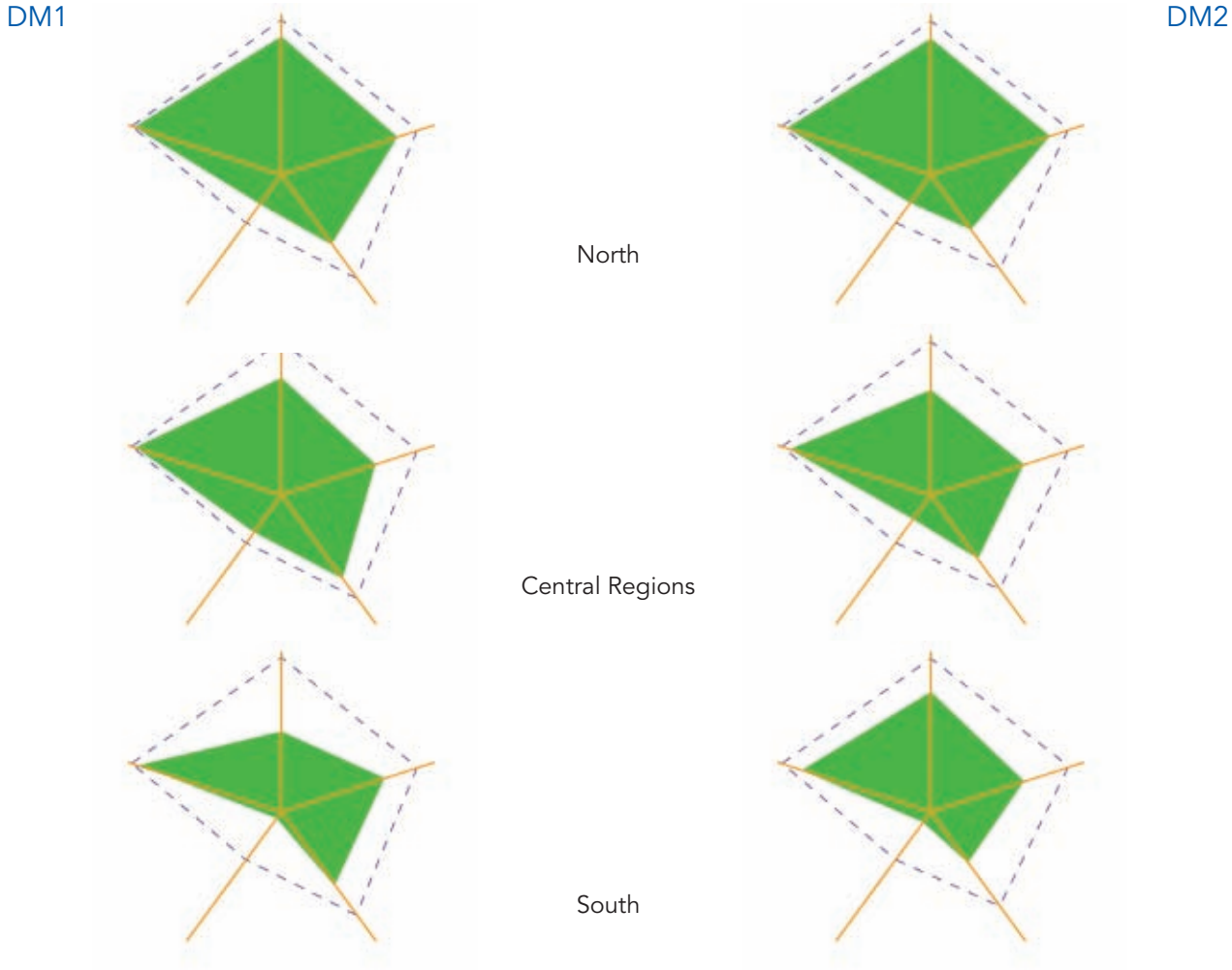
> 85

In DM1, except in the case of younger and older patients, for whom monitoring was less frequently performed, the care profile was relatively uniform.
In DM2, the picture was similar, with a marked reduction in the percentage of patients over 75 in age and even more so in those older than 85 years.

Starplot by Type of Diabetes, Gender, Age and Location



Sample Analysed by Type of Diabetes and Geographic Location



In DM1, the Northern regions feature an optimal level of comprehensiveness in the information related to monitoring HbA1c, blood pressure, and lipid profile. The figures tend to be lower in the monitoring of kidney function and foot examination.

The Central regions, compared to the North, have an comparable percentage of patients who had their HbA1c measured at least once; whereas, the percentages related to blood pressure and lipid profile are lower. The monitoring of kidney function and foot examination appear to be performed more regularly in the Centre, than in the North.

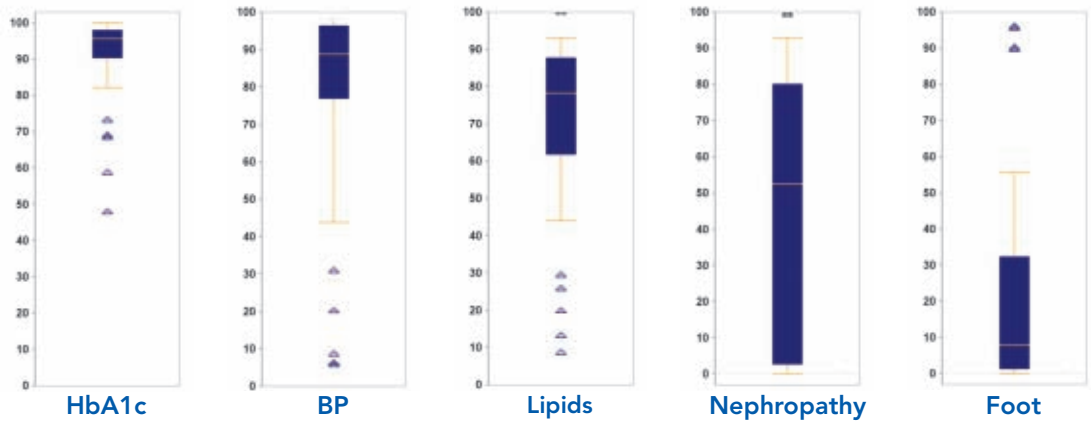
Southern regions are, in turn, comparable to the Central regions in terms of results obtained in monitoring HbA1c, lipid profile and kidney function, while those regarding blood pressure are deficient. Results for foot examination are absent.

In DM2, moving from North to South, the information appears less and less complete for all process indicators in question and in both types of diabetes. The one exception is kidney function, which is more frequently monitored in the Central regions.

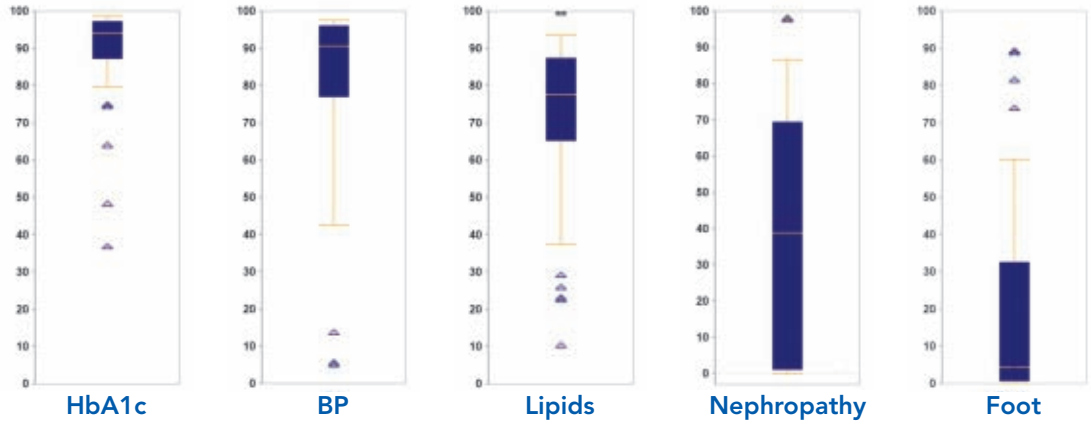
Boxplot of Centres by Type of Diabetes

Variability Level among Centres for Process Indicators

DM1



DM2



The diagrams show the variability level among Centres for the process indicators under examination. For instance, in regard to DM1, the percentage of patients for whom at least one HbA1c measurement was available during the year in question is generally very high: around 95% in most Centres. However, there are Centres where this data was available in a much lower percentage of cases (as low as a minimum of 45%). Variability was much more prominent with reference to the other process indicators, as shown by the boxes' height, and is especially marked in the monitoring of kidney function.

As far as DM2 is concerned, variability among Centres is narrow in the monitoring of HbA1c and blood pressure, but broader in the other parameters.

A Comment on the Process Indicators

Over the last decades, healthcare systems worldwide have had to take on the task, apparently paradoxical, of offering a quality service to an increasingly large number of people, while limiting costs and reducing the variability of services.

It has, therefore, been necessary to define both what care quality means, and how to start measuring the significant aspects of it, and great difficulties arise in starting this evaluation of service performance. In many countries, in fact, healthcare professionals have had to acquire a certain culture of improvement, the ability to use information technology, the habit of systematically recording data, confident that this commitment would facilitate decision-making processes and make their implementation more transparent.

The AMD has certainly made a significant contribution, showing that a Scientific Society can generate a cultural change, and, thanks to the involvement of its members, implement a national strategy of quality improvement.

All this has led to the definition of general indicators, process indicators and outcome indicators which describe, in diabetology, the different aspects of the quality of the care delivered. Process indicators are measures which permit an evaluation of how the care process is carried out, and also check the compliance of a diabetes Centre based on the criteria of good clinical practice.

The AMD Annals take into consideration 5 important activities in the care process: glycometabolic control, lipid profile, blood pressure, and the monitoring of the clinical condition of the kidney and foot.

The fundus oculi monitoring has not yet been analysed because of the quality of the data collected, determined by the manner in which related data was entered into the medical records. In 2008, the software was modified so as to improve the processability of the fields in medical records. The training program aimed at improving the quality of the data collection, started in October 2006, has so far involved 1/3 of the AMD Annals Author Centres.

The references of expected efficacy outlined in the *Italian Standards for Diabetes Mellitus* hope for: glycosylated haemoglobin measured at least twice a year (evidence level 6, recommendation strength B); lipid profile monitored at least once a year (evidence level 6, recommendation strength B); blood pressure measured at each visit (evidence level 5, recommendation strength B); retina check repeated at least every 2 years (evidence level 3, recommendation strength B); microalbuminuria and creatininemia checked at least once a year (evidence level 6, recommendation strength B); complete foot examination in diabetic people not at risk, at least once a year (evidence level 6, recommendation strength B). Moreover, geographic and social differences shall not be a factor.

As no threshold value was predetermined for any of the process indicators, the results have to be compared with the Italian standard and the best performers, which constitute the gold standard in the Annals.

The results show that patients with type 1 and type 2 diabetes, respectively, underwent glycometabolic monitoring in 94.9% and 91.3% of cases, lipid profile in 72.1% and 70.3%, blood pressure in 73.8% and 77.8%, nephropathy in 56.9% and 44%, foot examination in 19.9% and 18.6%, and patients at risk of foot damage in 34.5% and 27.9%.

Each diagram, whether it is a starplot or a boxplot, shows that:

- Extreme variability still exists among Centres in the process indicators examined;
- Centres exist which feature high performance levels for HbA1c, lipids, blood pressure, and kidney and foot for patients with both type 1 and type 2 diabetes; on the other hand, there are also Centres whose performance is still low;
- A group of best performing Centres can be singled out, which indicates the possibility of improvement and could be the reference for anyone who wants to benchmark indicators and processes;
- Centres seem to pay greater attention and feature greater sensitiveness towards collecting data related to glycometabolic condition, blood pressure and lipids, than that related to kidney and foot. This phenomenon can be observed among the best performers, as well;
- Moving from Northern to Southern Italy, the comprehensiveness of information becomes progressively lower.

This is the third edition of the AMD Annals. Their intrinsic ability to contribute to the improvement of the system of diabetes care is unquestionable. In fact, the participation of Centres, the number of patients, and the quality of the data collected have increased. A gradual improvement has also started, though not uniformly, in the process indicators, which indicate a Centre's compliance to good clinical practice criteria.

It must be clarified, however, that participating in the data collection does not automatically entail improvement in one's care processes: the AMD Data File/Annals system is only the first step, though an essential one, to start improving the quality of diabetes care.

In fact, the international literature to date has shown us that, in order to modify care outcome, obtaining optimal process indicators is not sufficient. This is why it will be necessary in the future to adopt a more complex approach which incorporates gradual and multidimensional improvement strategies involving management, healthcare professionals, and people with diabetes.

It is also evident that these strategies will have to identify and test new types of indicators which, by exploring other aspects of the care process (e.g., timeliness of therapy, compliance to therapy, composite measures of education efficacy, etc.), can correlate more to care outcome.

Before looking into the remote future, however, Italian diabetology must be able to guarantee its patients that we have built care processes which "do the right things well" across the country. The AMD Annals clearly tell us that there is still work to do in regard to this aim.

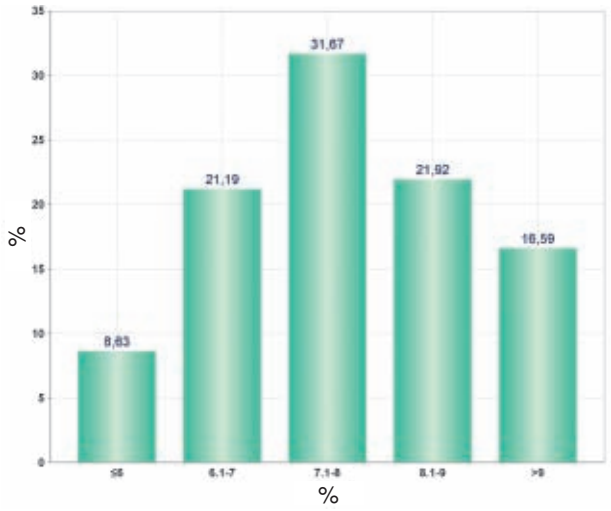
Danila Fava and Gualtiero de Bigontina

Intermediate Outcome Indicators

AMD Intermediate Outcome Indicators Analysed by Type of Diabetes

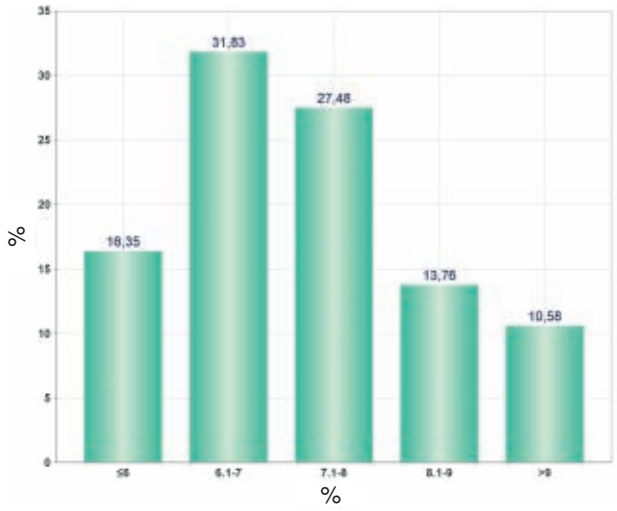
Trend by 5 Classes of HbA1c (Normalized to 6.0)

DM1



The data in the diagram show how obtaining adequate glycaemic control is still particularly difficult in DM1 patients. Almost 40% had HbA1c >8.0 (>9.0 in 16%), while only 8% had HbA1c ≤6.0.

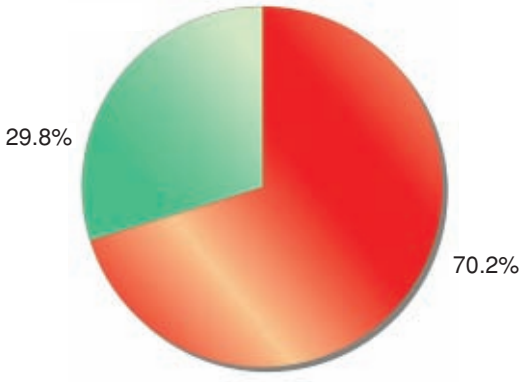
DM2



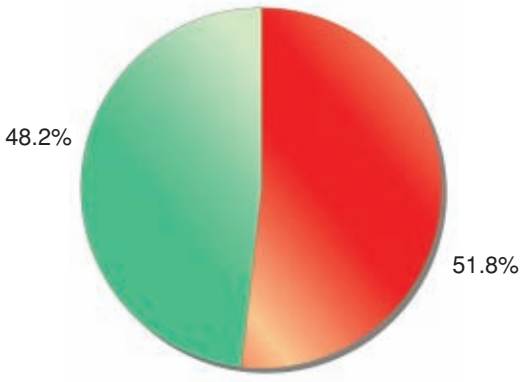
The situation appears somewhat better in DM2 patients. In fact, less than 25% had HbA1c >8.0, and 17% had HbA1c ≤6.0.

Subjects with HbA1c ≤7.0%

DM1



DM2



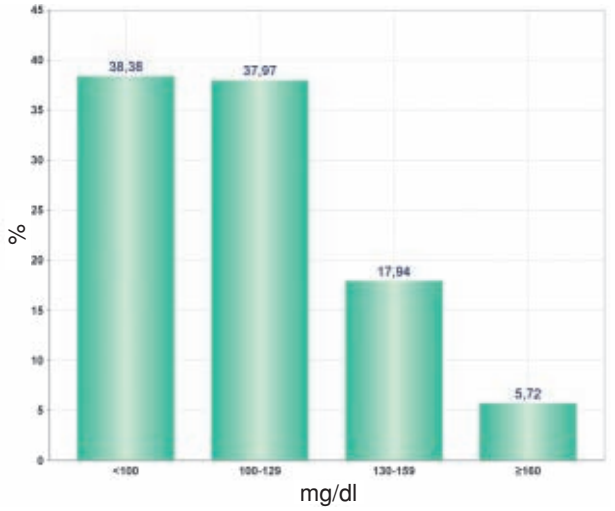
Yes No

The difficulty to attain adequate glycaemic control, especially in DM1, is further highlighted in these diagrams which show that less than 1/3 of DM1 patients and about 1/2 of DM2 patients had HbA1c ≤7.0.

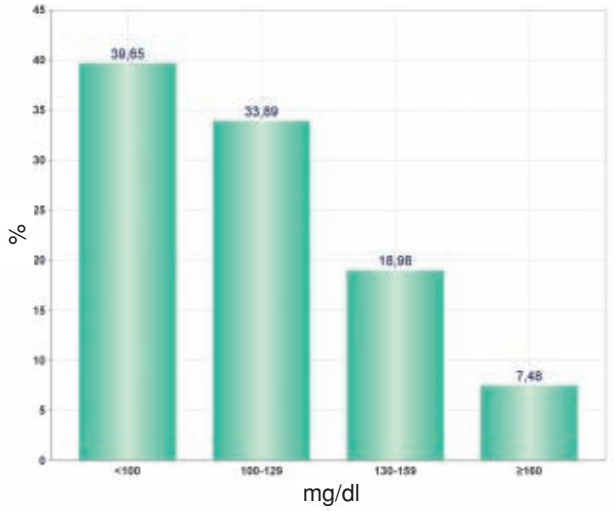
Based on the new targets set by the most recent guidelines, 17% of DM1 patients and 32% of DM2 patients had HbA1c <6.5%.

Trend by Class of LDL Cholesterol

DM1



DM2

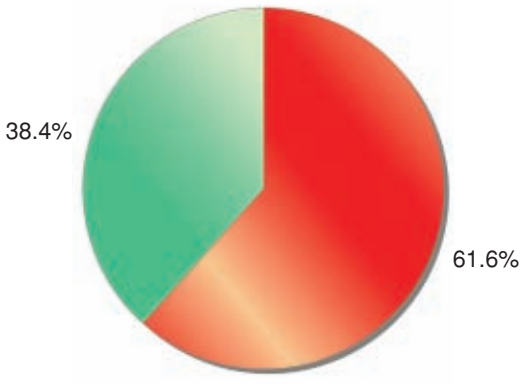


The diagrams show that 28% of DM2 patients and 23% of DM1 patients had particularly high LDL levels (≥130 mg/dl).

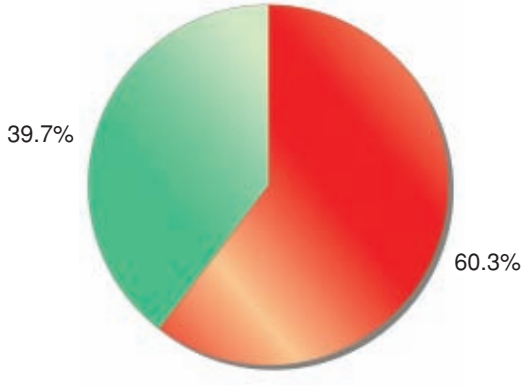
These data stress that cardiovascular risk connected to dislipidemia is similar in DM1 and DM2 patients.

Subjects with LDL Cholesterol <100 mg/dl

DM1



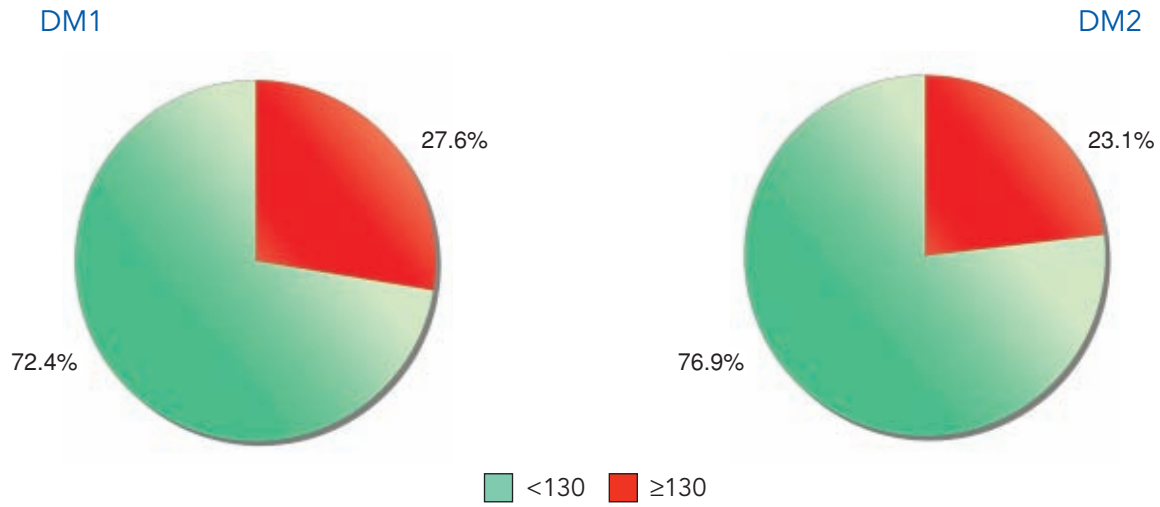
DM2



Yes No

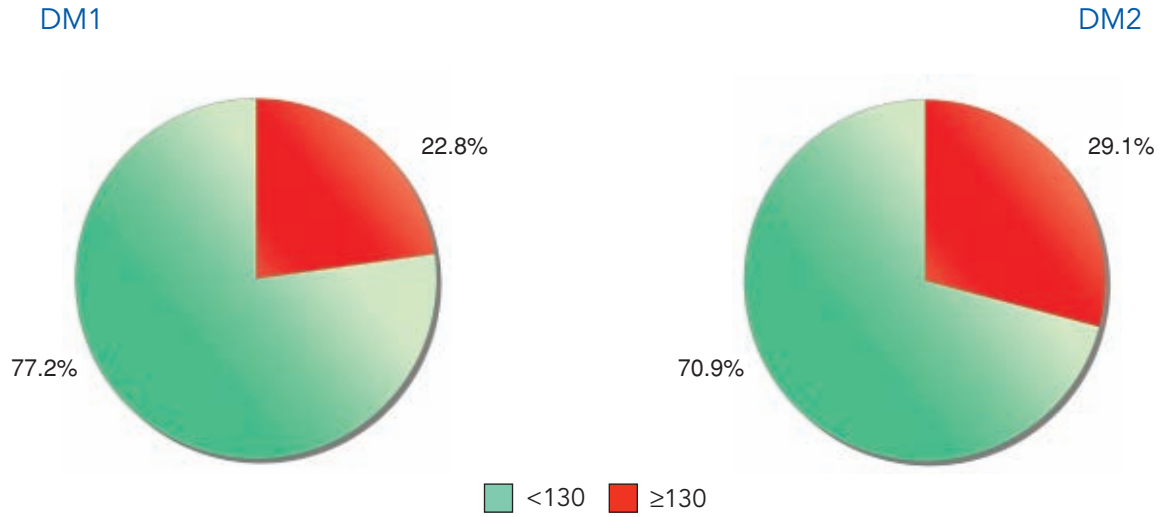
The elevated cardiovascular risk is further documented in this set of diagrams which shows that less than 40% of patients, both DM1 and DM2, had LDL cholesterol levels <100 mg/dl.

Subjects Receiving Lipid-lowering Treatment with LDL Cholesterol ≥130 mg/dl



Overall, 24.7% of DM1 patients and 43.7% of DM2 patients were treated with lipid-lowering drugs. Of them, 3/4 had LDL cholesterol <130 mg/dl, demonstrating the efficacy of therapy in achieving adequate treatment targets. This evidence highlights the need for more aggressive intervention in the remaining subjects with high LDL.

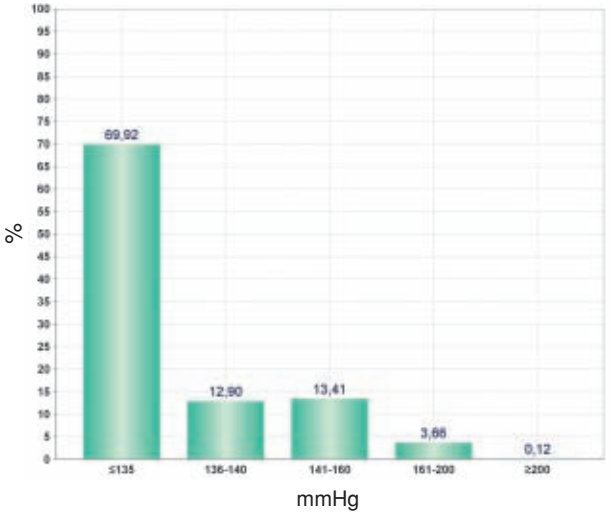
Subjects Not Receiving Lipid-lowering Treatment with LDL Cholesterol ≥130 mg/dl



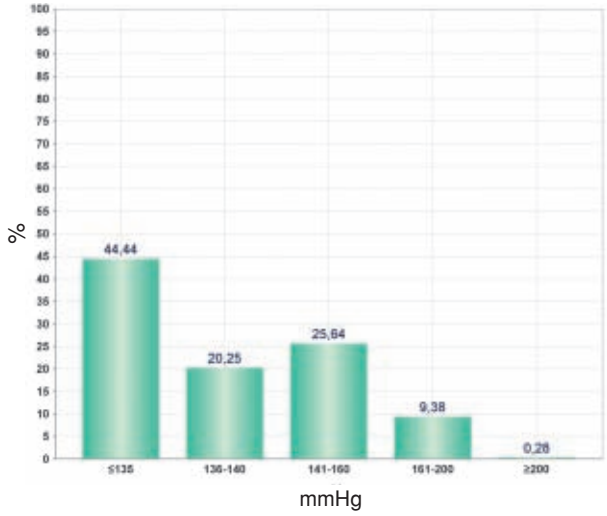
Among the subjects who were not treated with lipid-lowering drugs, about 1/4 of those with DM1 and less than 1/3 of those with DM2 had LDL ≥130 mg/dl, and could therefore benefit from treatment. These figures show that a significant margin for improvement exists in the control of lipid profiles.

Trend by Class of Systolic Blood Pressure

DM1



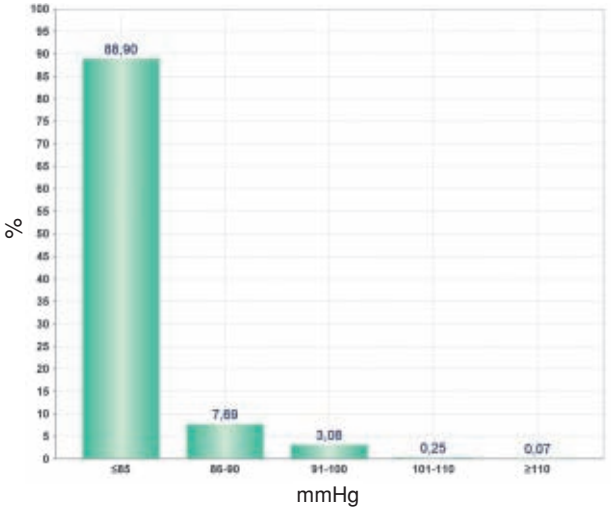
DM2



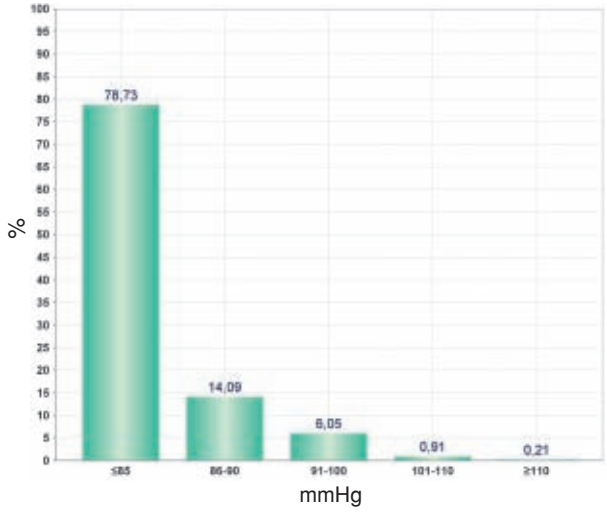
The trend for the class of systolic blood pressure shows extremely high values in 10% of DM2 patients and a small proportion of DM1 patients.

Trend by Class of Diastolic Blood Pressure

DM1

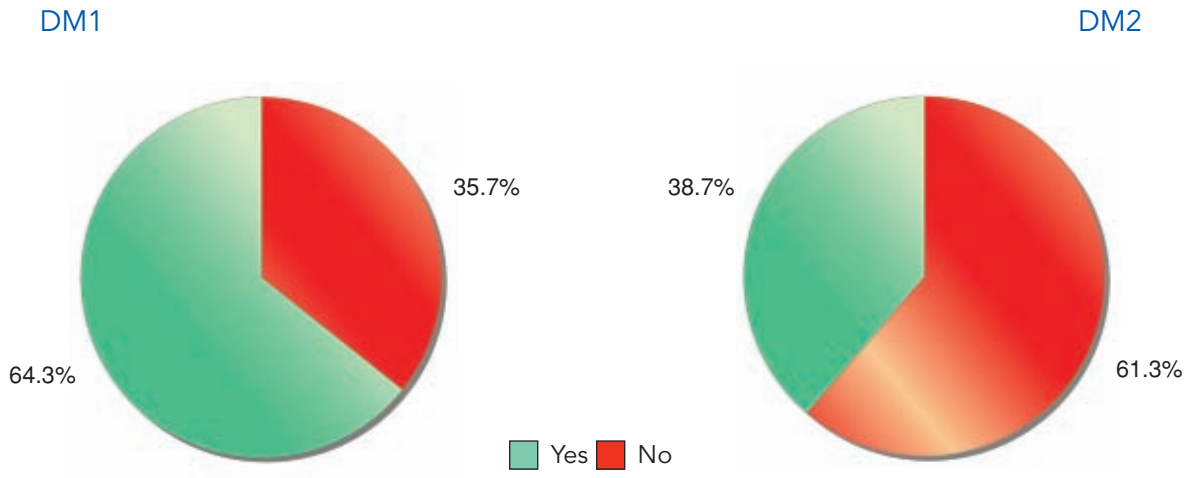


DM2



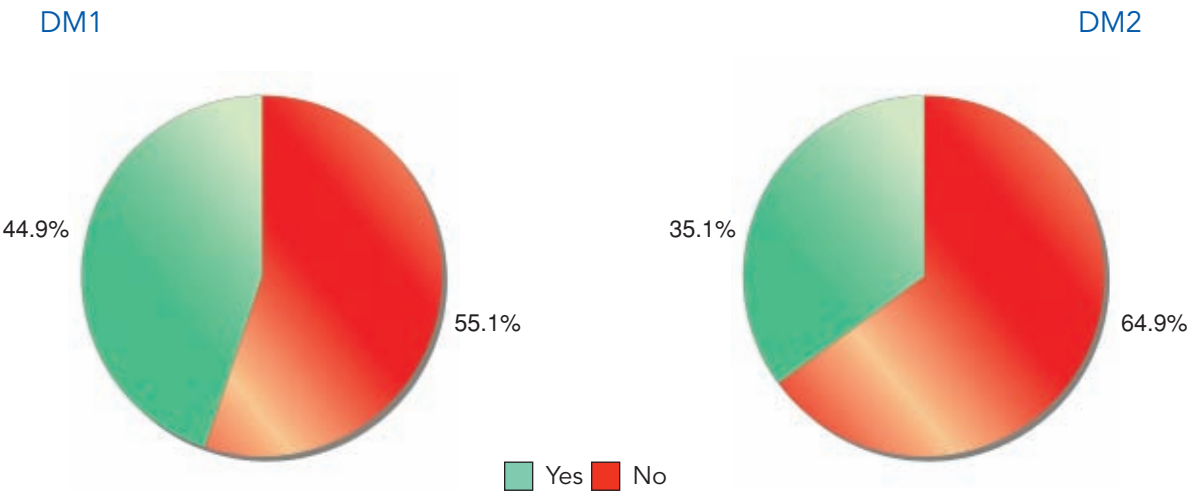
On the other hand, good diastolic blood pressure values (≤85 mmHg) were present in most DM1 patients and in 79% of DM2 patients, indicating that the unsatisfactory blood pressure levels in a high percentage of cases is chiefly attributable to high systolic pressure.

Subjects with Blood Pressure ≤130/85 mmHg



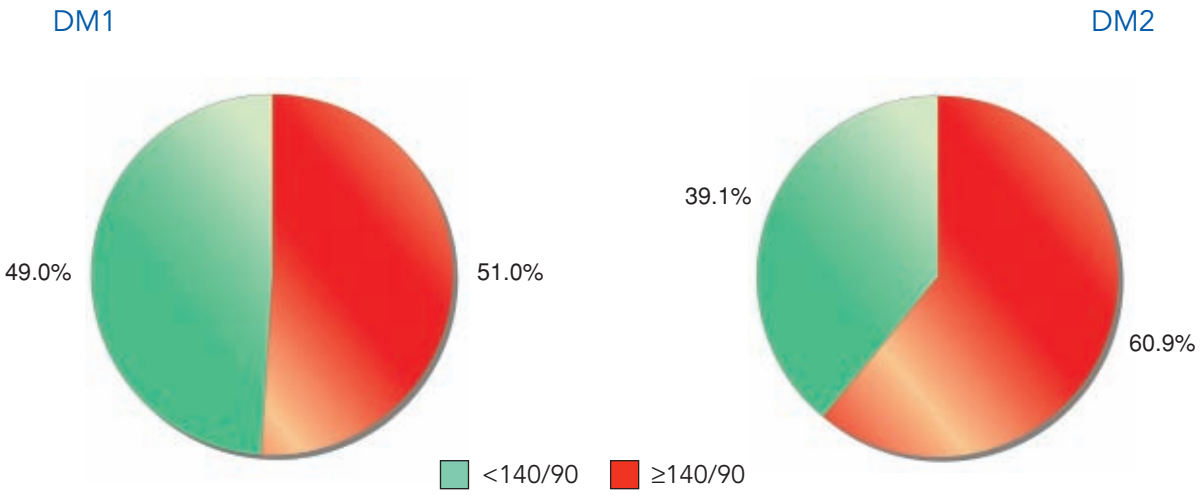
The figures show that 2/3 of DM1 patients, but only 1/3 of DM2 patients, had acceptable blood pressure levels.

Hypertensive Subjects with Blood Pressure ≤130/85 mmHg



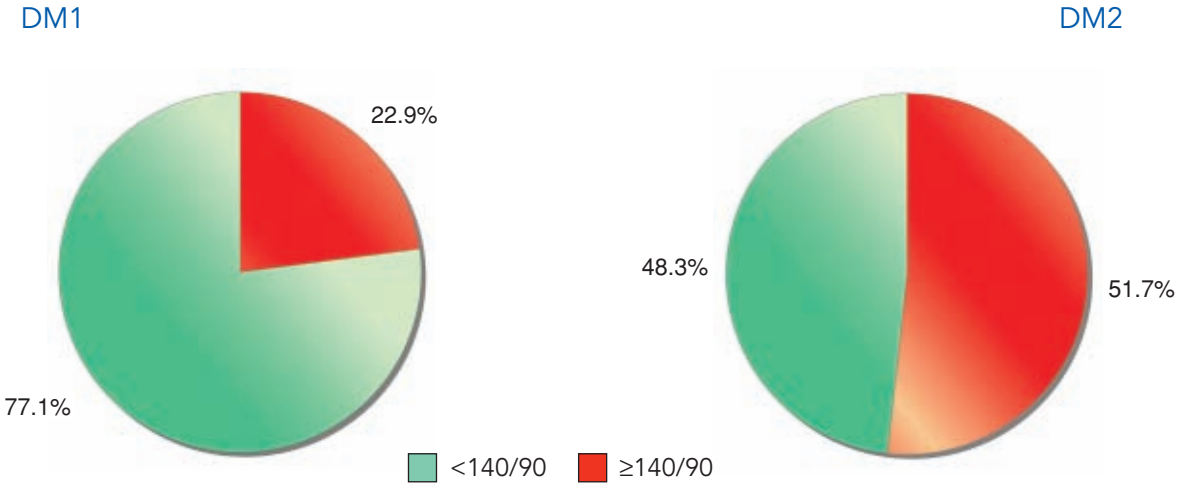
Of the hypertensive subjects in antihypertensive treatment, 31.8% were DM1 patients and 61.9% DM2 patients.
Among these patients, as well, 45% of those with DM1 and 2/3 of those with DM2 did not achieve adequate blood pressure control. These data suggest the need for more aggressive pharmacological management to reach the recommended therapeutic targets.

Subjects Receiving Antihypertensive Treatment with Blood Pressure ≥140/90 mmHg



In confirmation of the previous data, over 1/2 of DM1 patients and 60% of DM2 patients had blood pressure ≥140/90 mm Hg, despite antihypertensive treatment.

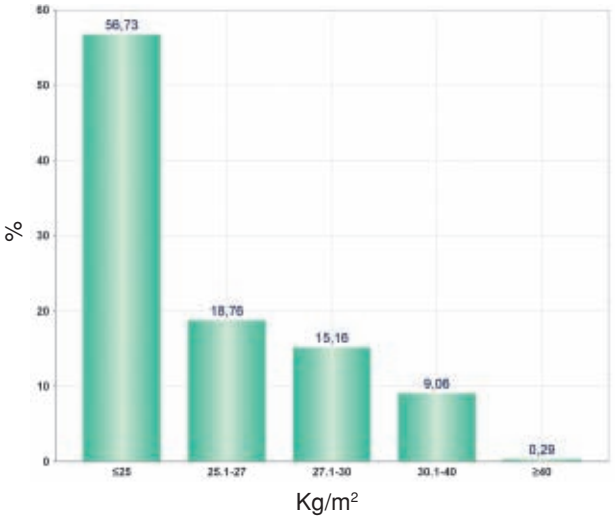
Subjects Not Receiving Antihypertensive Treatment with Blood Pressure ≥140/90 mmHg



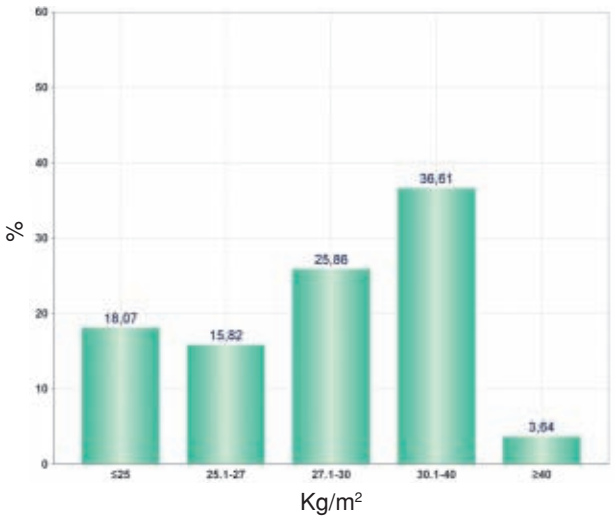
Reluctance towards instituting a sufficiently aggressive approach to this important risk factor is further documented by the high percentage of subjects not receiving antihypertensive treatment, despite their elevated blood pressure values. To be specific, 1/2 of DM2 patients and 1/4 of DM1 patients not receiving specific treatment exhibited blood pressure ≥140/90 mmHg.

Trend by class of Body-Mass Index

DM1



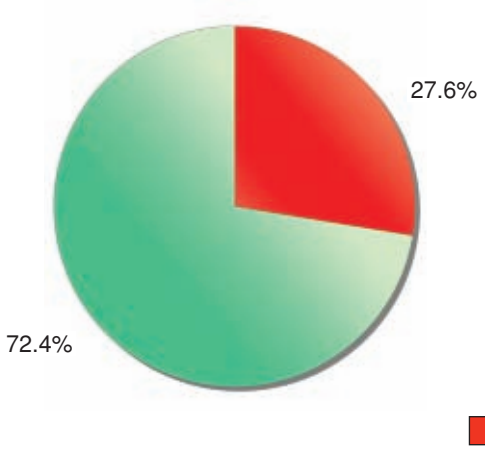
DM2



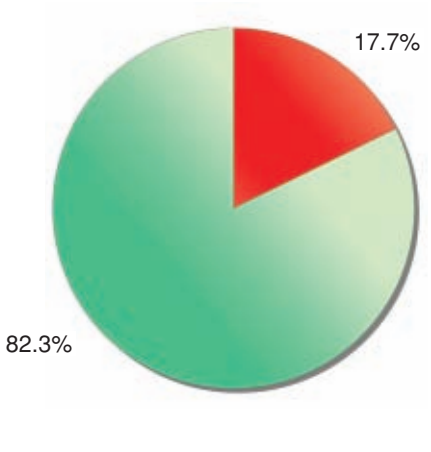
19% of DM1 patients were overweight, while 1/4 were frankly obese. Conversely, over 40% of DM2 patients were frankly obese (BMI >30), and less than 20% had normal body weight.

Smokers

DM1

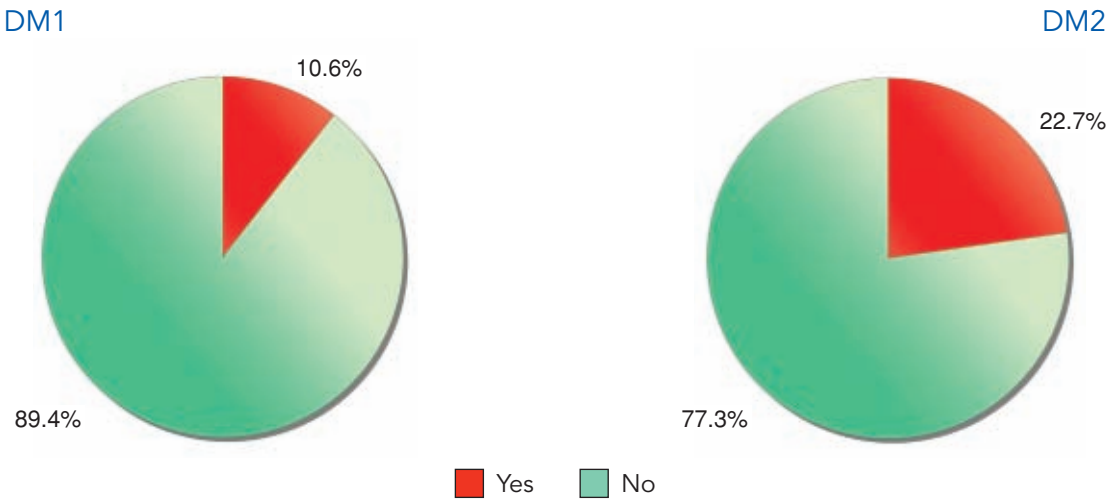


DM2



Nearly 1/3 of DM1 patients and 18% of DM2 patients were smokers. This data is particularly alarming among DM1 patients, given the high risk of microvascular complications associated with smoking.

Heavy Smokers (>20 cigarettes/day) among Overall Smokers

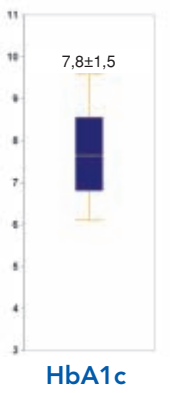


Whereas, proportionately, more DM1 patients were smokers, the percentage of heavy smokers (>20 cigarettes/day) among DM2 patients was twice that of DM1 patients.

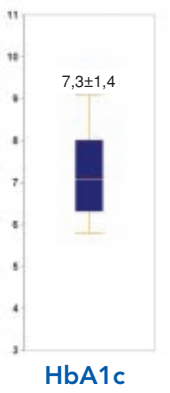
Boxplot of The Mean Levels by Type of Diabetes, Gender and Age

Mean HbA1c and Standard Deviation (SD) (Last Value Normalized to 6.0) Analysed by Type of Diabetes

DM1

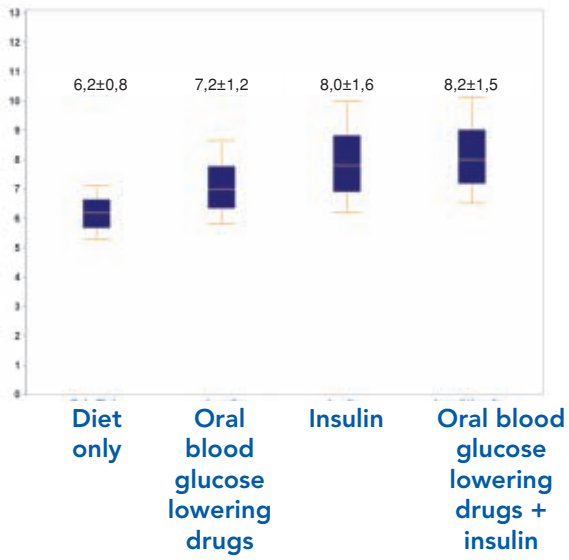


DM2



The mean HbA1c values were 7.8±1.5 for DM1 patients and 7.3±1.4 for DM2 patients. The figures show a considerable variability within both types of diabetes, as well as a marked difference between DM1 and DM2 patients.

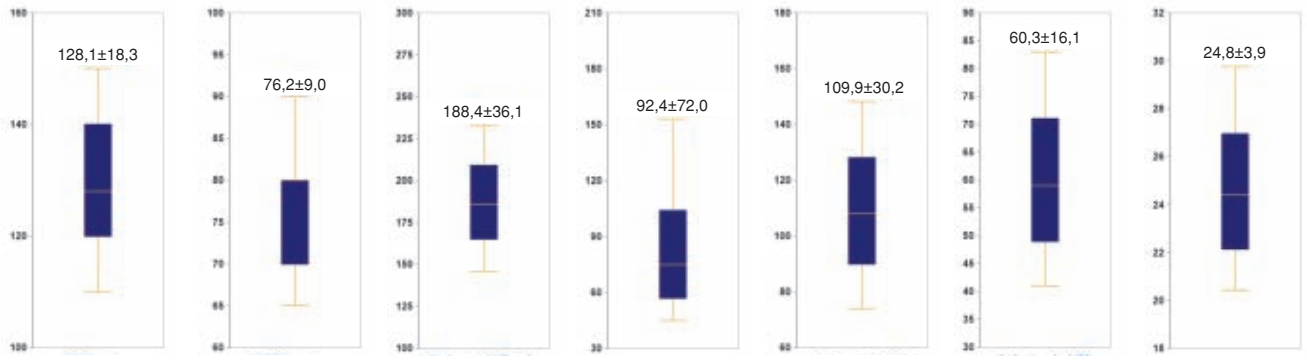
Mean HbA1c and Standard Deviation (SD) (Last Value Normalized to 6.0) Analysed by Type of Treatment in DM2 Patients



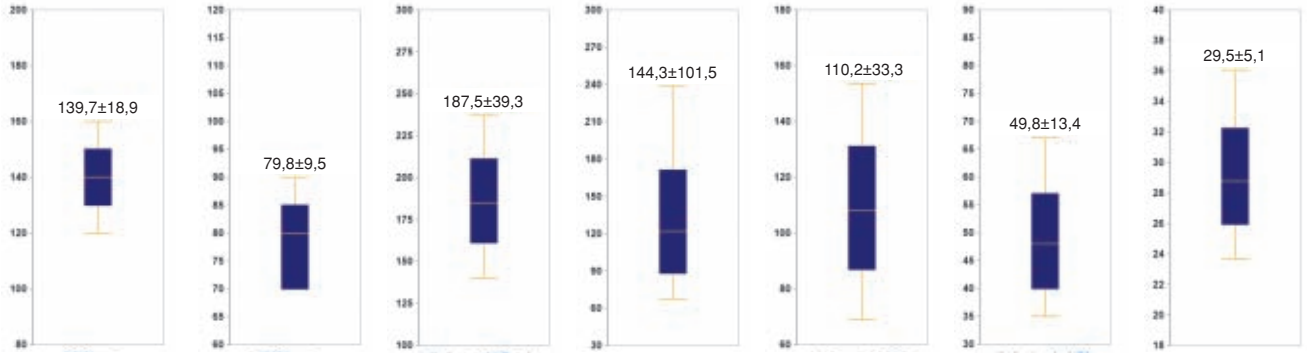
As expected, HbA1c values in DM2 patients were associated with the type of treatment they received. The lowest values were found among subjects on a controlled diet only; whereas, the highest were found among those treated with insulin, especially when associated with oral blood-glucose-lowering drugs.

Mean Values of the Main Clinical Parameters Analysed by Type of Diabetes

DM1



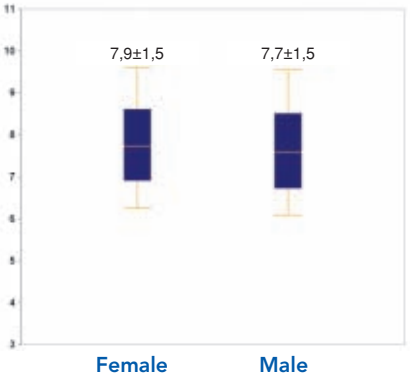
DM2



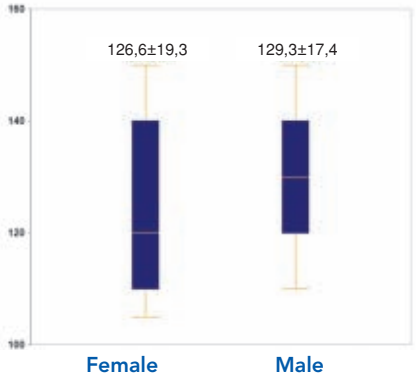
These figures show that DM1 patients, compared with DM2 patients, tended to have a lower risk profile in relation to blood pressure, but a similar risk with reference to lipid profile, especially considering total and LDL cholesterol. In keeping with the typical outline of metabolic syndrome, DM2 patients tended to have higher triglycerides levels and lower HDL cholesterol levels.

Mean Values of the Main Clinical Parameters Analysed by Type of Diabetes and Gender

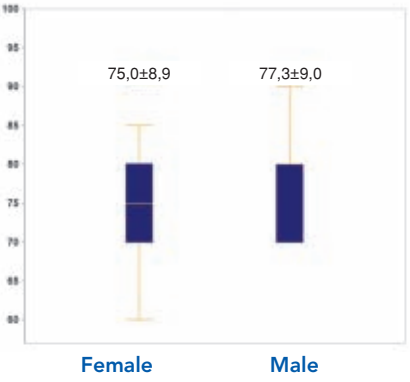
DM1



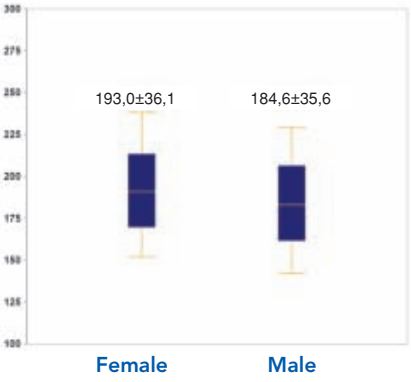
HbA1c



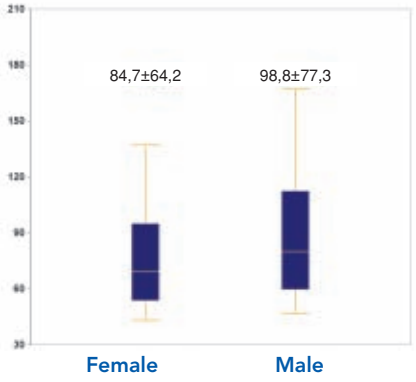
Systolic blood pressure



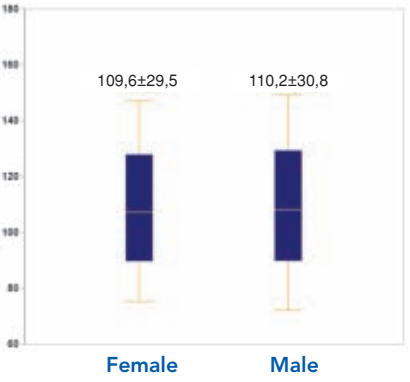
Diastolic blood pressure



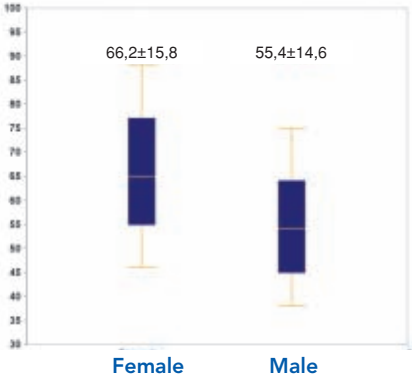
Total cholesterol



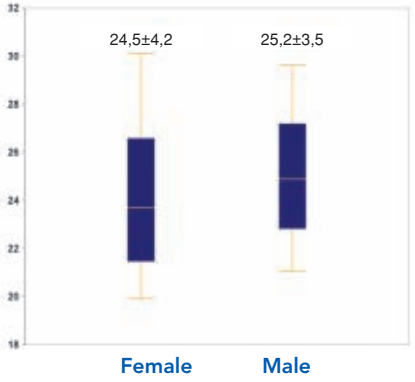
Tryglicerides



LDL Cholesterol



HDL Cholesterol



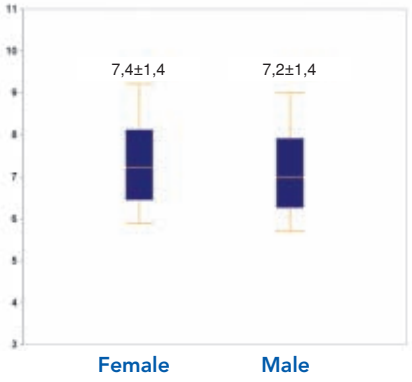
BMI

Among DM1 patients, women tended to have higher HbA1c, total and HDL cholesterol levels than did men, but lower blood pressure, triglycerides and BMI. The gender-specific differences in the lipid profile parameters were similar to mean LDL cholesterol.

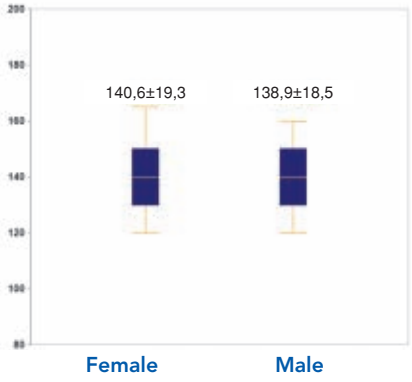
Among the DM2 patients, women tended to have not only higher

Mean Values of the Main Clinical Parameters Analysed by Type of Diabetes and Gender

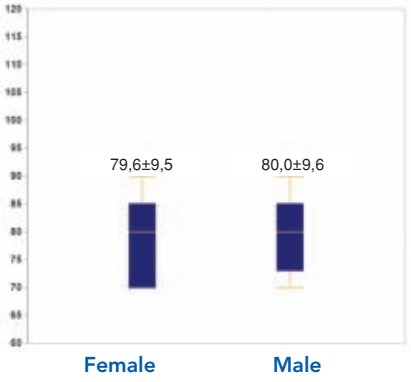
DM2



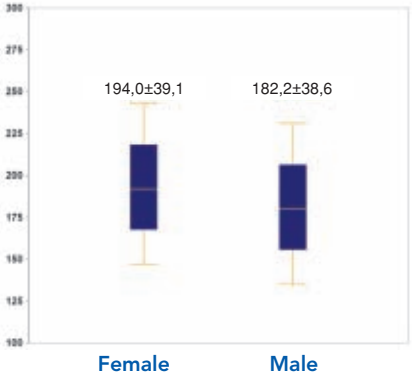
HbA1c



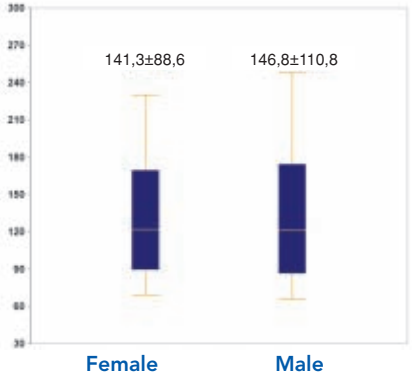
Systolic blood pressure



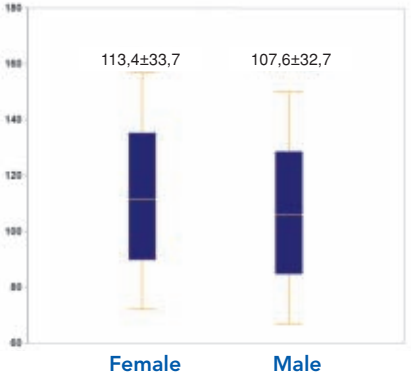
Diastolic blood pressure



Total cholesterol

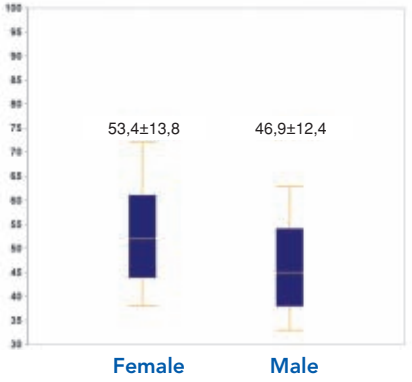


Trygliceride

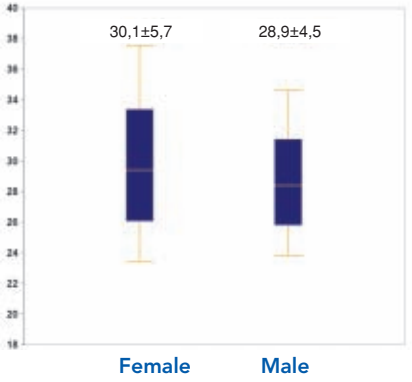


LDL Cholesterol

HbA1c and total cholesterol levels, but also lower systolic blood pressure, LDL cholesterol and BMI than men; whereas, the mean values of triglycerides and diastolic blood pressure were minimally different. As a matter of fact, these data indicate a comparatively poor control of the more relevant cardiovascular risk factors among female DM2 patients.



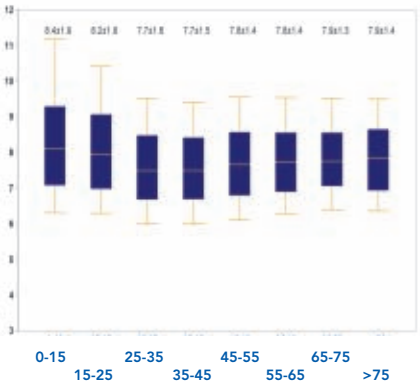
HDL Cholesterol



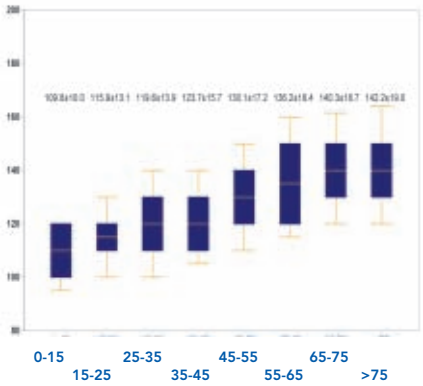
BMI

Mean Values of the Main Clinical Parameters Analysed by Type of Diabetes and Age Group

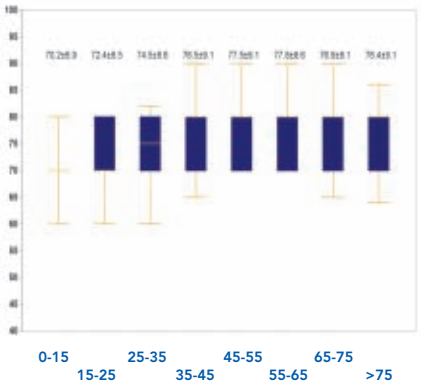
DM1



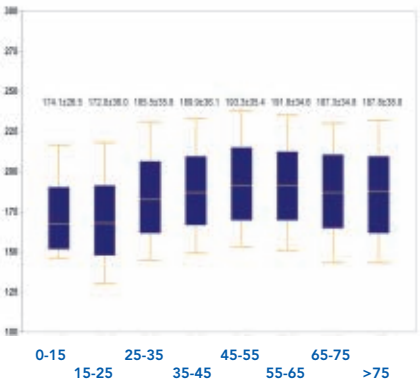
HbA1c



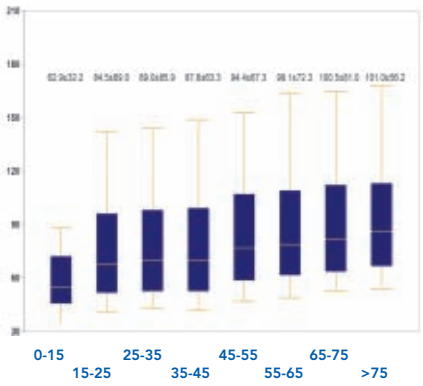
Systolic blood pressure



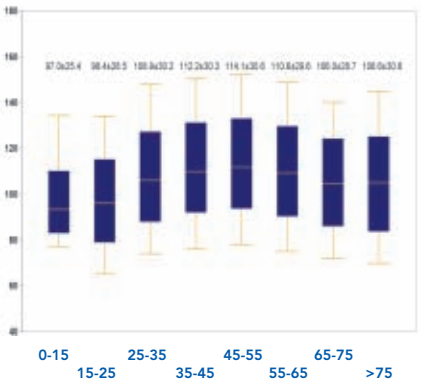
Diastolic blood pressure



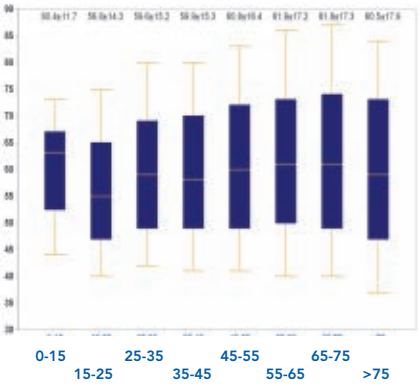
Total cholesterol



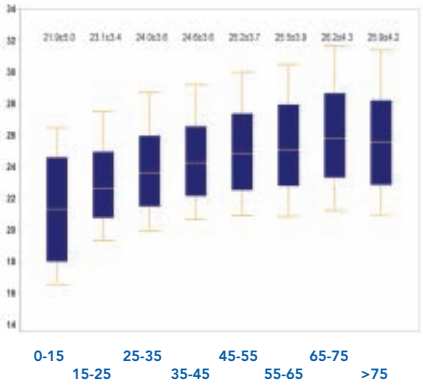
Tryglicerides



LDL Cholesterol



HDL Cholesterol

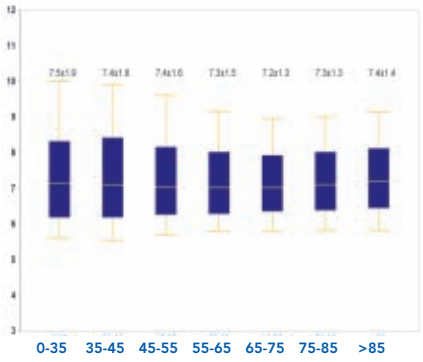


BMI

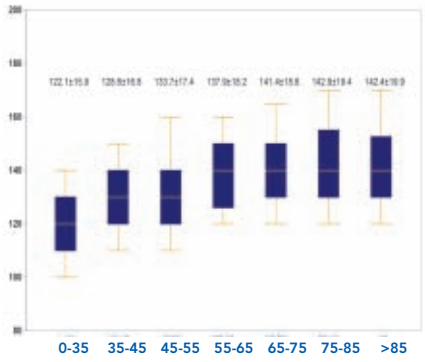
In DM1 patients, the mean HbA1c levels showed minimal variation, with a slight rise and greater variability for those under 25 years of age. There was also a gradual rise in systolic, though not diastolic, blood pressure, tryglicerides and BMI. Total and HDL cholesterol levels tended to increase up to the age of 45 and then plateau, while LDL cholesterol reached the maximum levels in the 45-55 age group.

Mean Values of the Main Clinical Parameters Analysed by Type of Diabetes and Age Group

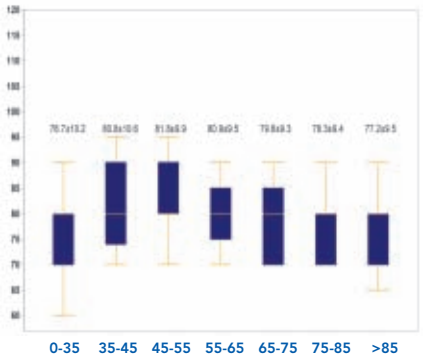
DM2



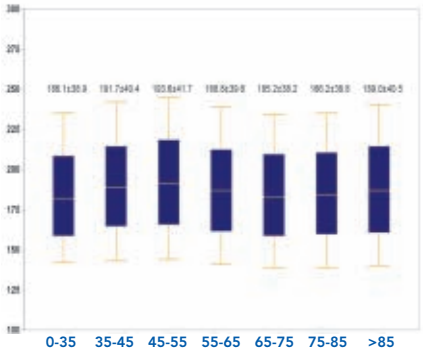
HbA1c



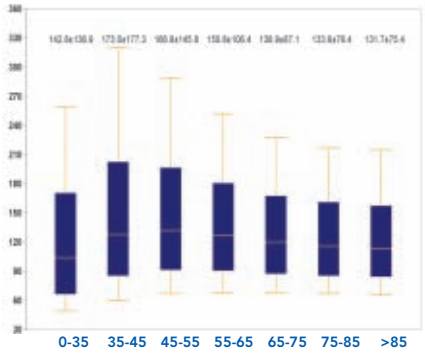
Systolic blood pressure



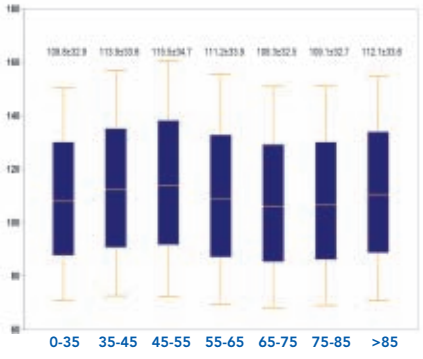
Diastolic blood pressure



Total cholesterol

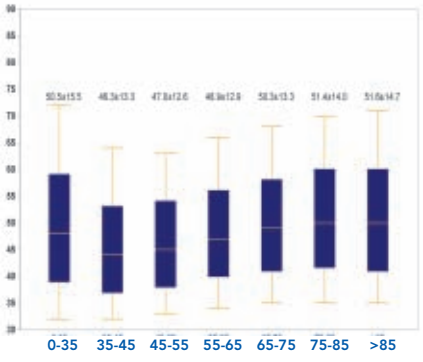


Tryglicerides

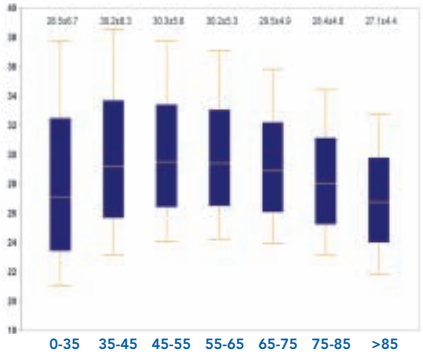


LDL Cholesterol

DM2 patients had minimal variations in mean HbA1c levels. Systolic blood pressure tended to gradually increase up to the age of 55 and then plateau, while diastolic blood pressure tended to diminish with age. The lipid profile was substantially stable. As far as BMI is concerned, on average the highest levels were found in the 35 to 55 age group.

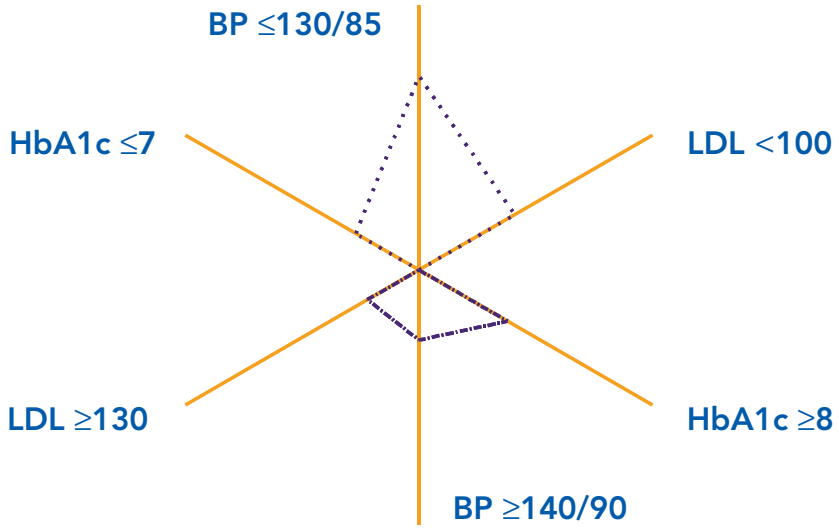


HDL Cholesterol



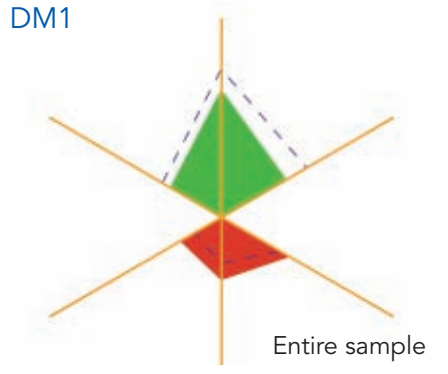
BMI

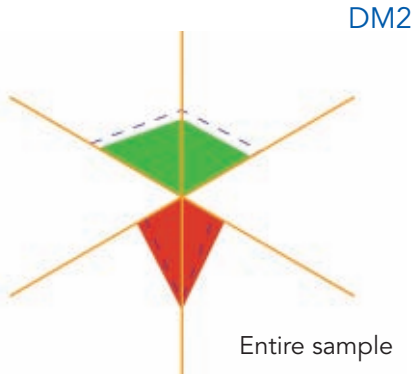
Starplot by Type of Diabetes, Gender, Age and Location



The following starplots concern the intermediate outcome measures. Each polygon is ideally divided into two parts. The three radii in the upper half show the percentage of patients with a favourable outcome for HbA1c, blood pressure and LDL cholesterol. The lower three radii show the percentage of patients with unsatisfactory values (see Methods section). In each starplot, the dashed line border represents the gold standard, while the solid line border refers to the patient group in question. The latter polygon is coloured in green to indicate favourable outcomes, and in red for the unfavourable ones.

Entire Sample Analysed by Type of Diabetes

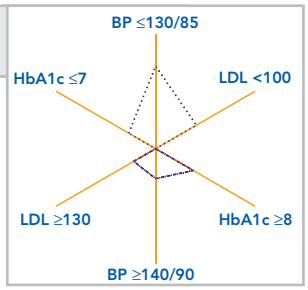




In DM1, the starplot featuring dashed lines indicates that – also in the Centres that contributed to defining the gold standard – a moderate proportion of patients had adequate HbA1c (34%) and LDL cholesterol (50%), while the proportion of patients with adequate blood pressure levels was higher (75%). Conversely, the proportion of patients with particularly high levels for the same parameters was significant (35%, 23% and 16% for HbA1c, blood pressure and LDL cholesterol, respectively).

Compared with DM1, in DM2 the percentage of patients with adequate levels was higher for HbA1c

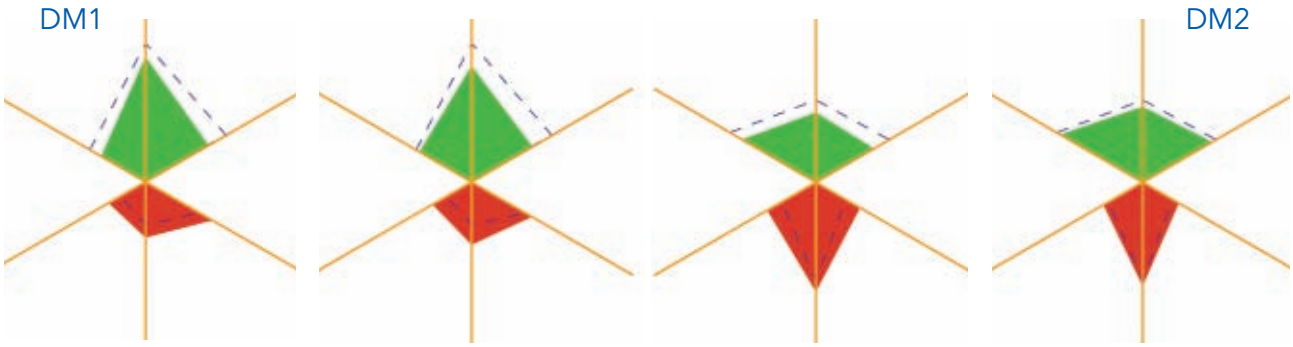
Starplot by Type of Diabetes, Gender, Age and Location



(53%), much lower for blood pressure (44%), and similar for LDL cholesterol (46%). The percentage of patients with particularly high levels for the same parameters were 19%, 53% and 21%, respectively.
Unlike process measures, there was not a large gap between the total sample and the gold standard for either type of diabetes.
In fact, considering the entire sample, the percentages of DM1 patients reaching adequate levels were: HbA1c, 30%; blood pressure, 64%; LDL cholesterol, 38%. On the other hand, the percentages of patients with unfavourable outcomes were: HbA1c, 39%; blood pressure, 32%; LDL cholesterol, 24%.

As far as the entire sample of DM2 patients is concerned, the percentages of DM2 patients reaching adequate levels were: HbA1c, 48%; blood pressure, 39%; LDL cholesterol, 40%. Conversely, the percentages of patients with unfavourable outcomes were: HbA1c, 25%; blood pressure, 57%; LDL cholesterol, 26%.

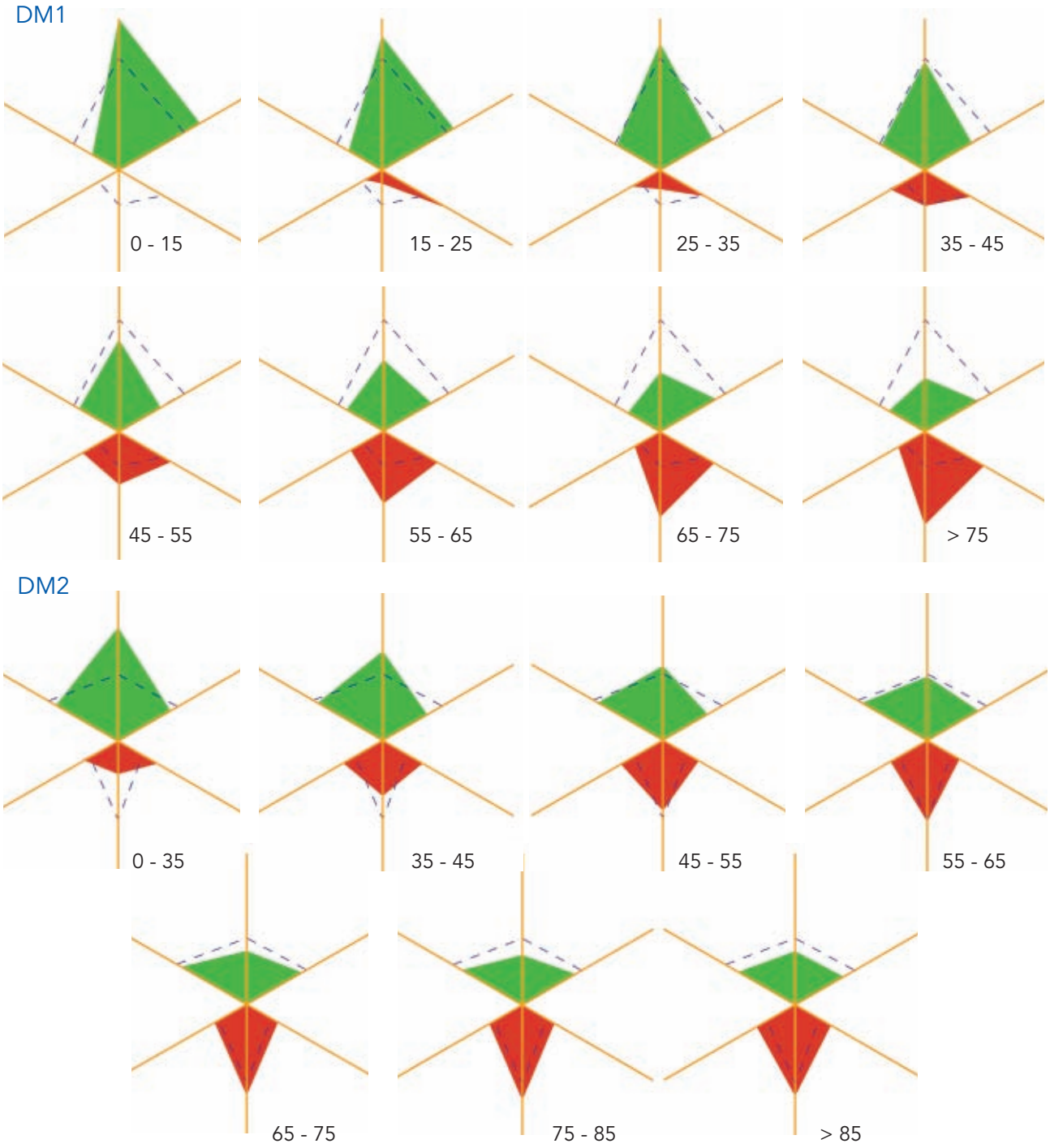
Sample Analysed by Type of Diabetes and Gender



In DM1, the results obtained on LDL cholesterol were similar among men and women. As far as HbA1c and blood pressure were concerned, instead, the latter category systematically featured a lower percentage of patients with adequate levels and a higher percentage of patients with high levels.
In DM2, the men's levels were very similar to the gold standard, while women systematically featured a lower percentage of patients with adequate levels and a higher percentage of patients with high levels.

On the whole, it appears that less attention is directed at achieving target values in female DM1 and DM2 patients.

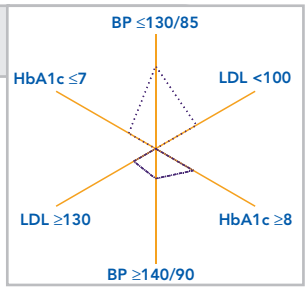
Sample Analysed by Type of Diabetes and Age Group



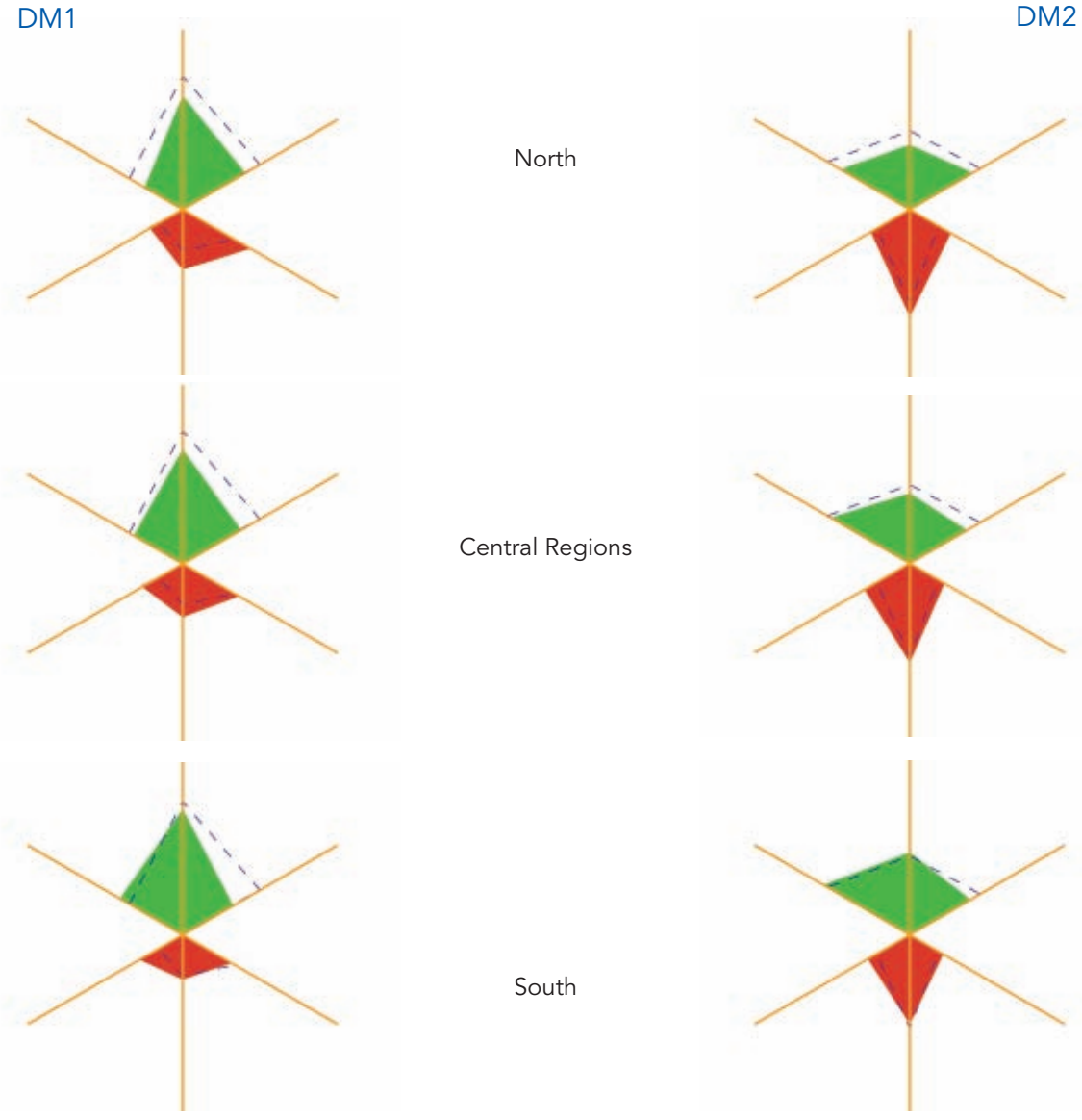
Among the DM1 patients, it is evident that, as age increases, the green area (favourable outcome) gradually becomes smaller; whereas, at the same time, the red area (unfavourable outcome) increases, indicating a progressively greater difficulty in achieving adequate values.

The trend was similar among DM2 patients, but somewhat more limited.

Starplot by Type of Diabetes, Gender, Age and Location



Sample Analysed by Type of Diabetes and Geographic Location

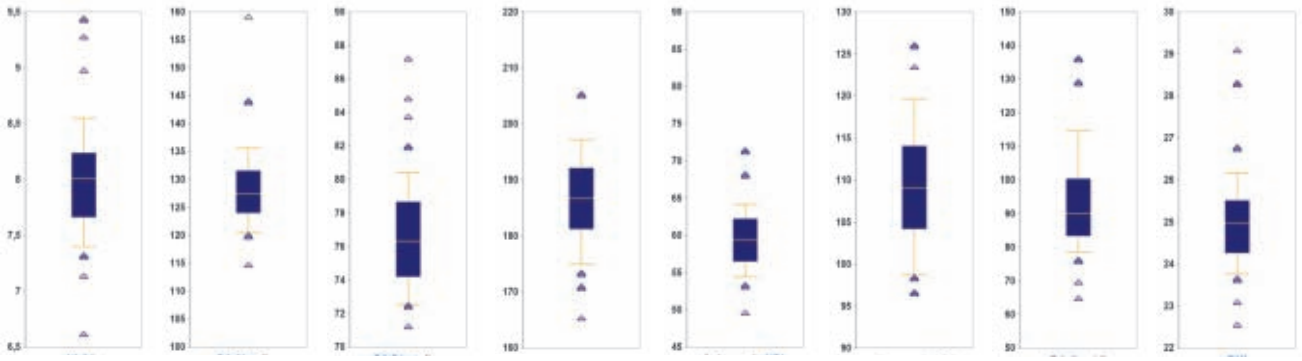


In DM1, the situation varies significantly in relation to geographic location. In fact, the proportion of patients with adequate HbA1c and blood pressure values increased progressively moving down from the North, to the Central regions and the South, while the opposite occurred with reference to the percentage of patients with adequate LDL cholesterol levels. The trend of unfavourable outcomes mirrors the same geographic trend. In DM2, the outcome obtained in the South does not wander much from the gold standard, with the exception of the percentage of patients with adequate LDL cholesterol levels. The gap between the total sample and gold standard increases in the Central regions, and is even greater in the North.

Boxplot of the Centres' Mean Levels by Type of Diabetes

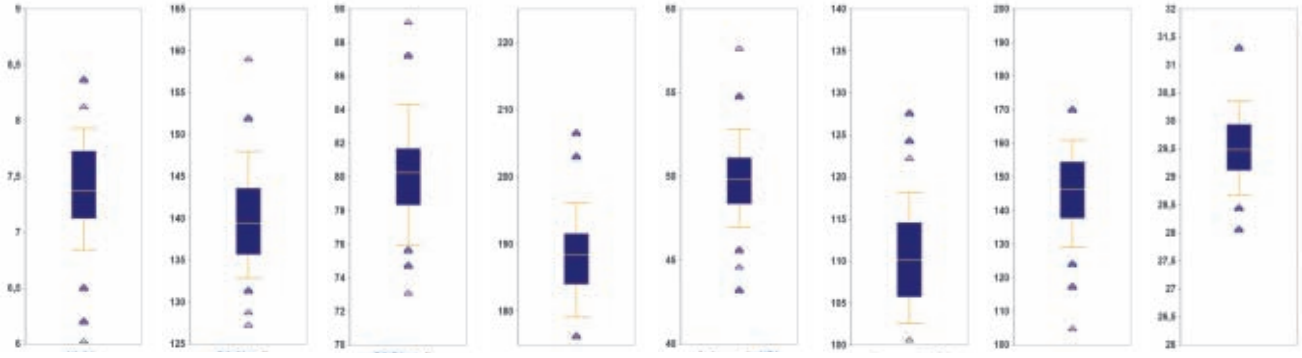
Distribution of the Mean Values of Main Clinical Parameters Analysed by Centre and Type of Diabetes

DM1



HbA1c | Systolic blood pressure | Diastolic blood pressure | Total cholesterol | HDL Cholesterol | LDL Cholesterol | Tryglicerides | BMI

DM2



HbA1c | Systolic blood pressure | Diastolic blood pressure | Total cholesterol | HDL Cholesterol | LDL Cholesterol | Tryglicerides | BMI

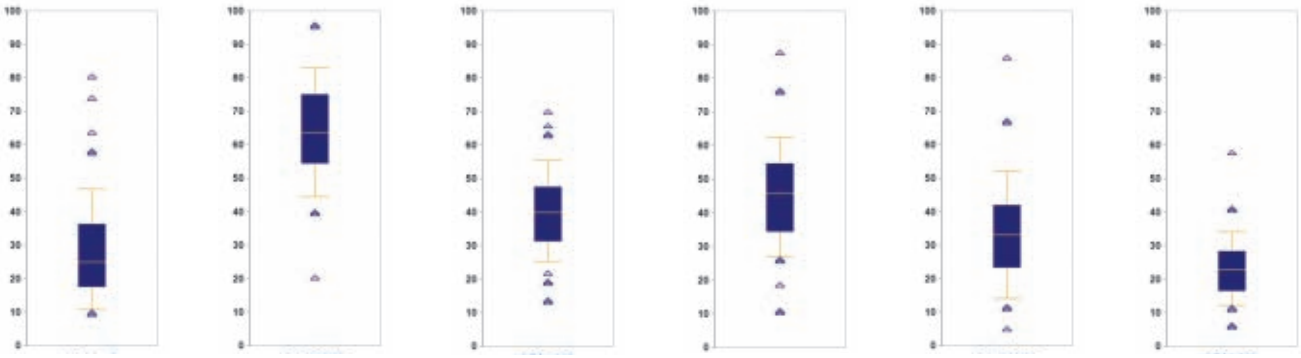
This set of diagrams shows, for each Centre, the distribution of mean values regarding the parameters in question. Among DM1 patients, a marked variability was detected in all parameters. As far as glycaemic control was concerned, for instance, the mean HbA1c (normalized to 6.0) ranged between 7.7% and 8.2% in 50% of the Centres. However, there were also Centres with much lower (down to 6.6%) and much higher (up to 9.4%) levels. A similar interpretative criterion can be applied to all parameters under examination.

In DM2, as well, a marked variability was confirmed among Centres in terms of the mean values of various parameters.

It is noteworthy that, with reference to all parameters, there exists a significant number of outlier Centres whose mean values were well above or below the mean of the other Centres. These data demonstrate pronounced heterogeneity in the outcome of care, and highlight the need to align therapeutic approaches with available scientific evidence.

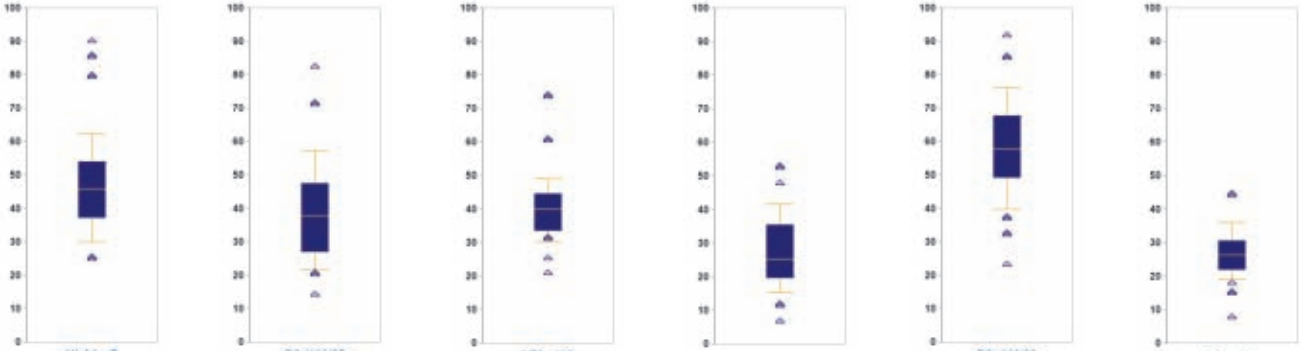
Intermediate Outcome Indicators by Centre based on Type of Diabetes

DM1



HbA1c ≤7 | BP ≤130/85 | LDL <100 | HbA1c ≥8 | BP ≥140/90 | LDL ≥130

DM2



HbA1c ≤7 | BP ≤130/85 | LDL <100 | HbA1c ≥8 | BP ≥140/90 | LDL ≥130

In DM1, HbA1c levels ≤7.0% were reached in a relatively low proportion of patients in most Centres. Few Centres, in fact, achieved a percentage of patients exceeding 40%. Similarly, in most Centres the percentage of patients with LDL <100 mg/dl was less than 40%, while the percentage of patients with adequate blood pressure values, given the low mean age, was much higher. The difficulty in attaining adequate glycaemic control in DM1 patients is further highlighted by the percentage of patients with HbA1c ≥8.0%. However, this generally high level tended to vary considerably among Centres ranging between 10 and 88%. A similar consideration can be made for the percentage of patients with high blood pressure, while the outcomes in LDL cholesterol control tended to be more uniform among different Centres.

In DM2, the proportion of patients with good HbA1c levels was tendentially higher, despite a still marked degree of variability. Moreover, this patient group tended to show a lower percentage of subjects with adequate blood pressure levels, which in most Centres, did not exceed 45%. Similarly, in nearly all Centres about 40% of patients had adequate LDL cholesterol levels. The margin for improvement in care outcome is further highlighted by the generally very high percentages of patients with high levels, especially with reference to blood pressure.

A Comment on Intermediate Outcome Indicators - 1

An analysis of this group of indicators provides interesting information on the degree of metabolic function and the main cardiovascular risk factors (lipid profile, blood pressure, body-mass index, smoking) in the study population.

Glycometabolic Control

Glycosylated Haemoglobin

HbA1c is universally recognized as the best parameter for evaluating glycometabolic function.

The *Italian Standards for Diabetes Mellitus* and several other sets of guidelines suggest that diabetes care should be promptly adapted, in each patient, so as to achieve blood sugar levels close to normal, and a target value of HbA1c steadily <7%. These values serve to prevent the incidence and progression of micro and macrovascular complications (evidence level 1, recommendation strength A).

Stricter targets for glycaemic control (HbA1c <6.5%) can be taken into consideration for individual patients (evidence level 3, recommendation strength B).

The results collected from the different Centres show how difficult it is, with the therapeutic means currently at our disposal, to achieve these outcomes in daily clinical practice.

In fact, HbA1c was suboptimal (>7%) in a very high percentage of DM1 patients (70.2%), as well as about half (51.8%) of DM2 patients.

Unsurprisingly, the percentage of HbA1c in DM2 patients rose as the complexity of treatment increased (from 6.2% of patients on a controlled diet alone to 8.2% of patients treated with combined insulin-oral blood glucose lowering drugs).

However, when comparing the data obtained with results coming from other international surveys, the overall level of glycometabolic function in the treated population was fair.

It should also be noted that patients with HbA1c >8% represent 37.5% of people with type 1 diabetes and 24.3% of people with type 2 diabetes, progressively diminishing with respect to previous AMD Annals collections.

Perhaps the introduction of new classes of drugs and more effective treatments might improve these outcomes further.

Cardiovascular Risk Factors

LDL-cholesterol

According to the aforementioned *Italian Standards*, in patients with diabetes below 40 years of age and without additional cardiovascular risk factors, a therapy with statins together with a modified lifestyle is recommended in case of LDL-cholesterol levels >130 mg/dl. The goal of the therapy is to reach LDL-cholesterol levels <100 mg/dl (evidence level 5, recommendation strength B).

In patients at high risk (with one or more cardiovascular risk factor), lipid lowering therapy should be started regardless of their LDL-cholesterol levels. The goal of the therapy is to reach LDL-cholesterol levels <100 mg/dl (evidence level 1, recommendation strength A).

In patients suffering from cardiovascular disease and having multiple cardiovascular risk factors which cannot be improved, LDL-cholesterol levels <70 mg/dl can represent a therapeutic goal (evidence level 6, recommendation strength B).

Levels <130 mg/dl were achieved by 76.3% of DM1 patients and 73.5% of DM2 patients.

However, LDL-cholesterol optimal levels <100 mg/dl were only achieved by 38.4% of DM1 patients and 39.7% of DM2 patients.

The data concerning pharmaceutical therapy indicate that the number of patients who required treatment (LDL >130 mg/dl) but were not receiving it was still high (22.8% in DM1 and 29.1% in DM2), as was the number of those who, despite being treated, did not achieve the target (27.6% in DM1 and 23.1% in DM2).

It should be underlined that these figures also show a trend towards improvement with respect to previous Annals collections.

Blood Pressure

According to the *Italian Standards*, antihypertensive treatment in patients with diabetes aims at achieving

levels of systolic blood pressure <130 mmHg (evidence level 3, recommendation strength B) and of diastolic blood pressure <80 mmHg (evidence level 2, recommendation strength B).
A blood pressure target <125/75 mmHg is recommended in diabetes patients with proteinuria >1 g/die (evidence level 2, recommendation strength B).
Blood pressure data showed a substantial difference between the two patient groups: they were generally satisfactory for DM1 patients, 64.3% of whom had acceptable blood pressure values, but less so for DM2 patients, among whom said levels are only achieved by 38.7%. This is primarily due to the levels of systolic blood pressure.
Data on pharmacological treatment indicate the need for more aggressive intervention in hypertensive patients, by both improving the outcome among those receiving treatment (51.0% of DM1 and 60.9% of DM2 patients failed to reach the target), as well as by increasing the number of patients receiving treatment (22.9% DM1 and 51.7% DM2 were not treated, despite having blood pressure levels out of target).

It should be noted that, unlike metabolic control and lipid profile, these data were substantially unaltered with respect to previous Annals collections.

Obesity
The body-mass index (BMI) is obviously almost only altered among DM2 patients. It should be noted that less than 1 patient out of 5 has normal body weight. However, it should also be underlined that 43.3% of DM1 patients are overweight and 9.3% are obese.

Smoking
Data on smoking has indicated that far too many patients still ignore the added burden of smoking in regard to cardiovascular risk. DM1 patients, in particular, require targeted education about the risk smoking carries.

Gender-specific Differences
An analysis of gender-specific differences showed, in particular, that in women with DM2 more aggressive treatment is required to reduce cardiovascular risk.

Antonino Cimino and Illidio Meloncelli

A Comment on Intermediate Outcome Indicators - 2

Glycosylated Haemoglobin Analysed by Type of Diabetes and Treatment

This extremely recent picture of this sector of the Italian healthcare system shows a mean HbA1c of 7.8% in DM1 and 7.3% in DM2. Especially when considering the greater number of patients and Centres involved, we can appreciate the slight yet significant improvement with respect to the data previously collected in the Annals. At this point, it would be interesting to make a comparison with the final results of the EUCID study (www.eudic.eu): a data collection funded by the European Union to start monitoring the indicators of diabetes and its complications in Europe. The comparison should be conducted on the percentage of surveyed patients having HbA1c levels out of target; i.e., >7%.

In the Annals 2008, the aforementioned data can be found on page 26, where it is given as 51.8% in type 2 diabetes. In the European standings (which we should consider with some reservation, since the reliability of the information provided by the different countries remains to be fully verified), Italy would rank 4th, as only Ireland (32%), Holland (48%) and France (50%) achieved better outcomes, while other countries – that have a highly organized healthcare system, such as Denmark (64%), Germany (54%) and Belgium (69%), and reported data from diabetes Centres similar to the AMD Annals – clearly show a less favourable situation.
A comparison with the U.S.A. seems even more comforting. Extremely authoritative surveys, such as the NHANES promoted by the NIH or the data from the NCQA (National Committee for Quality Assurance),

report that 20 to 40% of people with diabetes in the U.S. have HbA1c levels >9.5%, and 40 to 50% have HbA1c levels >8%. In 2005, Grant et al. published that the 66% of people with diabetes treated by U.S. academic centres had HbA1c >7, despite very good process indicators (97.6% had performed at least one HbA1c check a year).

However, the Annals 2008 show the work done by the diabetes Centres, which, through therapeutic education and with the pharmacological tools currently available – still not as effective as those at disposal for lipids and pressure – have managed to achieve good overall results in this delicate sector.

The analysis of the mean HbA1c value by type of treatment, useful due to the information it provides on the promptness of the therapeutic intervention, appears substantially unaltered with respect to previous editions. There continues to be a progression of the HbA1c mean value from diet to insulin and blood glucose lowering drugs, a progression which follows a criterion of severity and, likely, disease duration. These diagrams show – with the exception of difficulties due to the type of patient – the well-known phenomenon of therapeutic inertia, whereby a subject is long left with inadequate control before the treatment is modified.

In type 1 diabetes, HbA1c is, on average, worse, thus confirming the greater mean complexity of patients and the lack of patients treated through diet alone – usually in good control, who tend to reduce the mean value in type 2 diabetes.

Cardiovascular Risk Factors Analysed by Type of Diabetes and Gender

Blood Pressure

Mean systolic blood pressure is 128.1 mmHg in DM1 and 139.7 mmHg in DM2; whereas, mean diastolic blood pressure is 76.2 mmHg in DM1 and 79.8 mmHg in DM2.

The difference in mean values between DM1 and DM2 is especially relevant in terms of systolic blood pressure. It is, therefore, confirmed that a DM2 patient is, above all, systolic hypertensive. This should be kept in mind with regard to prevention, since this is the condition that correlates more strongly with the risk of cardiovascular events. This data is certainly affected by mean age, but, as far as prevention is concerned, its relevance does not change.

In this case, too, it is possible to compare the data collected with those found in the EUCID study. The comparison should be conducted on the percentage of surveyed patients having blood pressure levels out of target; i.e., >135/95 mmHg. In the Annals 2008, the relevant data can be located on page 30, where it is given as 64.9% in type 2 diabetes. Even taking into account the more generous 140/90 mmHg cutoff used in the EUCID, Italy does not shine in the area of blood pressure control, since in Europe the percentage of patients out of target ranges from 17% in France to 46% in Sweden. Perhaps this could be read as a call, directed at Italian diabetologists, to better monitor this particular risk factor.

In type 2 diabetes, the greater disadvantage of women is confirmed, with higher mean values of systolic blood pressure. It is not clear to what extent this is due to a different genetic predisposition, or to a different treatment approach. However, this warns of the need to engage in better antihypertensive treatment, especially with female patients.

Lipid Profile

The LDL-cholesterol mean level is 109.9 mg/dl in type 1 diabetes, and 110.2 mg/dl in type 2 diabetes. It is confirmed that the cholesterolaemia levels of Italian diabetes patients are not particularly high, and certainly lower than those reported in other surveys. The comparison with the EUCID study data on lipid profile should be made in regard to the percentage of surveyed patients whose LDL is >100 mg/dl. In the Annals 2008, the said data can be found on page 27: given as 60.3% in type 2 diabetes. Italy ranks 8th and is in an intermediate position between the best countries, such as Ireland (16%) and Denmark (33%), and the worse, such as Cyprus (84%) and Scotland (84%).

Even though it is still too high, the LDL mean value has been gradually decreasing with respect to the Annals 2008. This shows the recent effect of an increasingly widespread use of statins. As far as HDL cholesterol is concerned, the difference between DM1 and DM2 is considerable: 10 mg/dl less in the latter, confirming the basic insulin-resistance.

As in the case of blood pressure, the worse levels of both total and LDL cholesterolaemia are found among women with type 2 diabetes: a difference that cannot be ignored, is difficult to explain, and can have repercussions in terms of cardiovascular complications.

Obesity

The mean BMI (kg/m^2) is 24.8 in type 1 and 29.5 in type 2, with 40% of obese patients (BMI >30) in the latter. In this case, as well, Italy finds itself at an intermediate level in Europe. In the EUCID study, it is in 6th position: after Finland (38%), Cyprus (39%), Austria (36%), Denmark (36%), Belgium (35%); but before France (47%), Sweden (47%), Holland (47%), Scotland (47%), England (45%), Germany (45%) and Ireland (49%). At least in terms of adult population with diabetes, Italy is not among the highest in Europe.

The BMI is considerably higher in type 2 diabetes and among women, as expected.

Age Effect

In type 1 diabetes, ageing affects systolic blood pressure and BMI, as in the general population. In type 2, conversely, we can see that the BMI follows a curve which peeks at around 40-50 years of age: it might be possible to sense the concomitant role of body weight in causing the onset of diabetes in that age group.

While in DM1 the systolic blood pressure is stable over time, in DM2 there is clearly a nadir at around 50 years of age, further confirming this age group's critical situation with reference to risk factors typical of insulin-resistance.

In type 2 diabetes, lipid levels and body weight reach a maximum peek of severity at around 55 years of age. Then they tend to reduce slightly, providing us with the picture of a diabetes patient in geriatric age whose lipid factors are less pressing than systolic hypertension.

Starplot by Type of Diabetes, Gender, Age and Location

This diagram – which by now has become a classic, thanks to the AMD Annals – enables us to highlight the strengths and weaknesses of diabetes care with respect to the internal gold standard.

It is evident that the critical point of diabetes care in DM1 is represented by the attainment of good glycaemic control, as the HbA1c <7% radius is the poorest.

In DM2, the difficulty in controlling blood pressure, in particular, almost invariably prevails over the attainment of the other positive targets. These figures seem to generally worsen both as age increases, and among women. As in the past, the analysis by location shows that there is a greater difficulty pursuing optimal targets among the Centres in the North, especially with reference to controlling metabolism and blood pressure. This might also depend on a less frequent recourse to drugs with respect to the South.

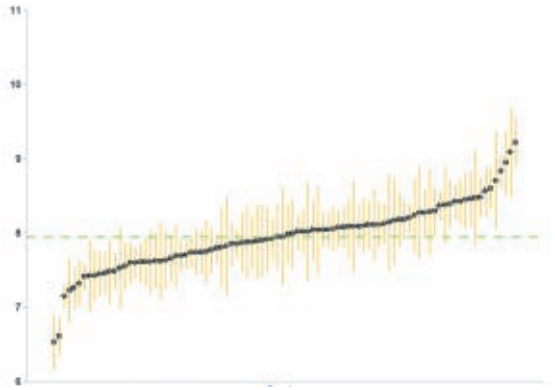
Carlo Giorda

Diagrams of the Variability among Centres, with Case-mix and Clustering Adjustment

Variability among Centres: Mean Levels Adjusted by Age, Gender, Diabetes Duration and Clustering Effect

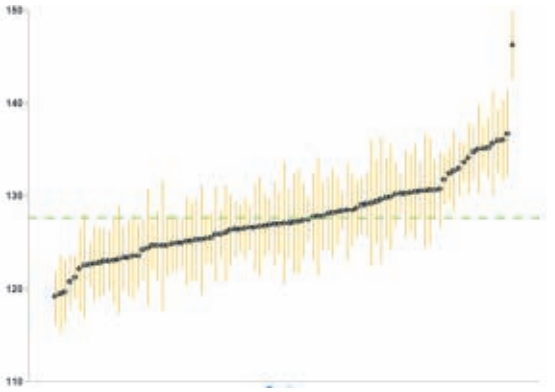
DM1

HbA1c



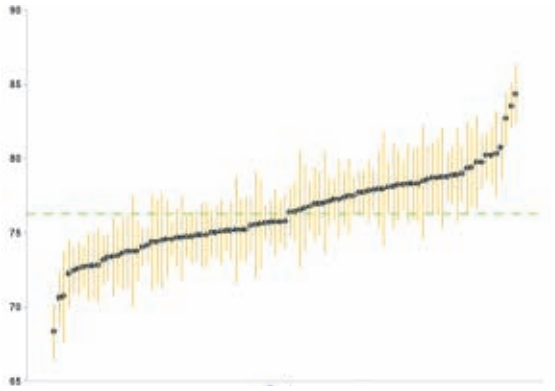
Centre

Systolic blood pressure



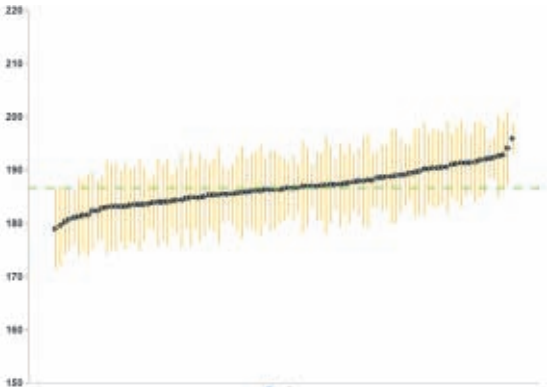
Centre

Diastolic blood pressure



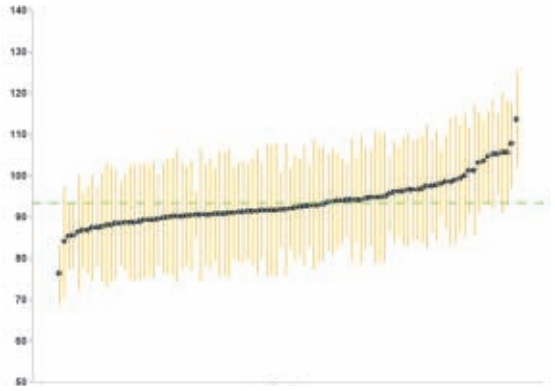
Centre

Total cholesterol



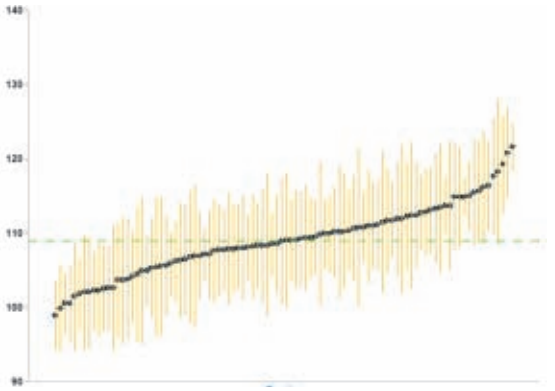
Centre

Tryglicerides



Centre

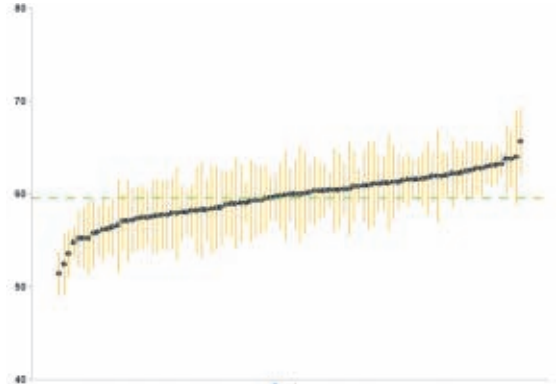
LDL Cholesterol



Centre

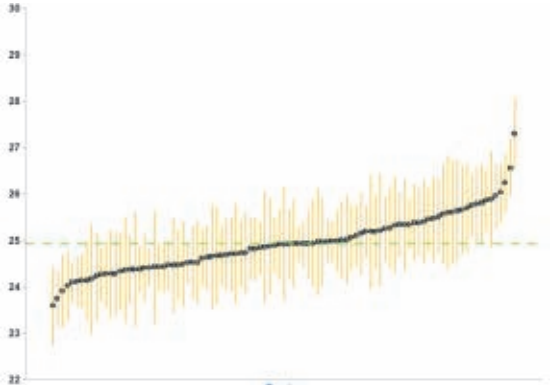
DM1

HDL Cholesterol



Centre

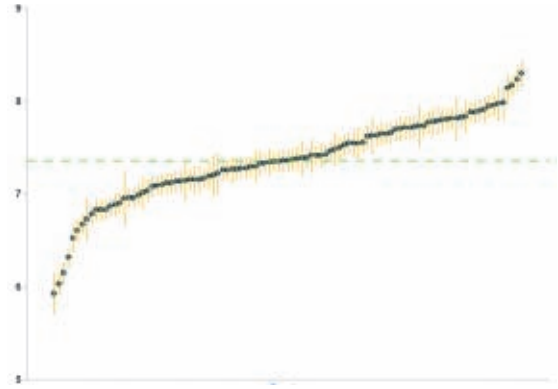
BMI



Centre

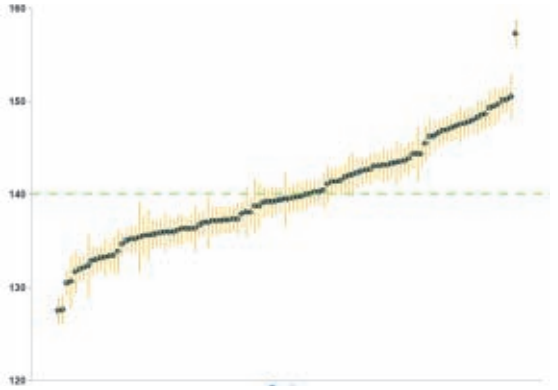
DM2

HbA1c



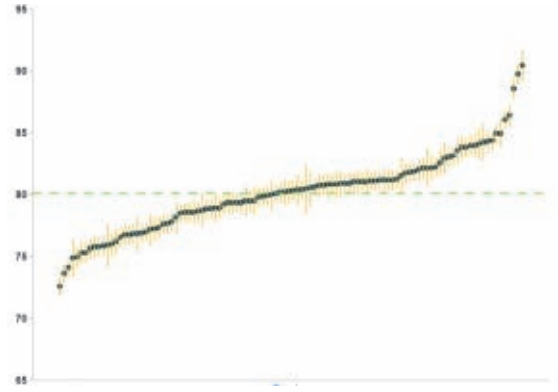
Centre

Systolic blood pressure



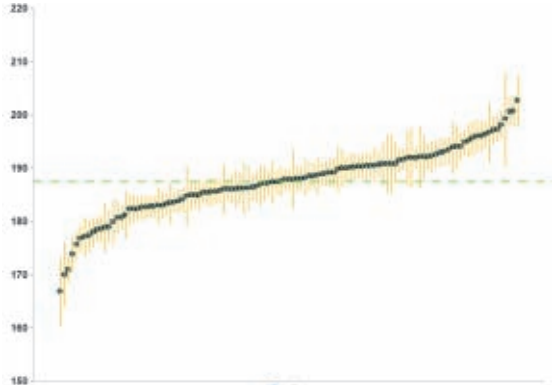
Centre

Diastolic blood pressure



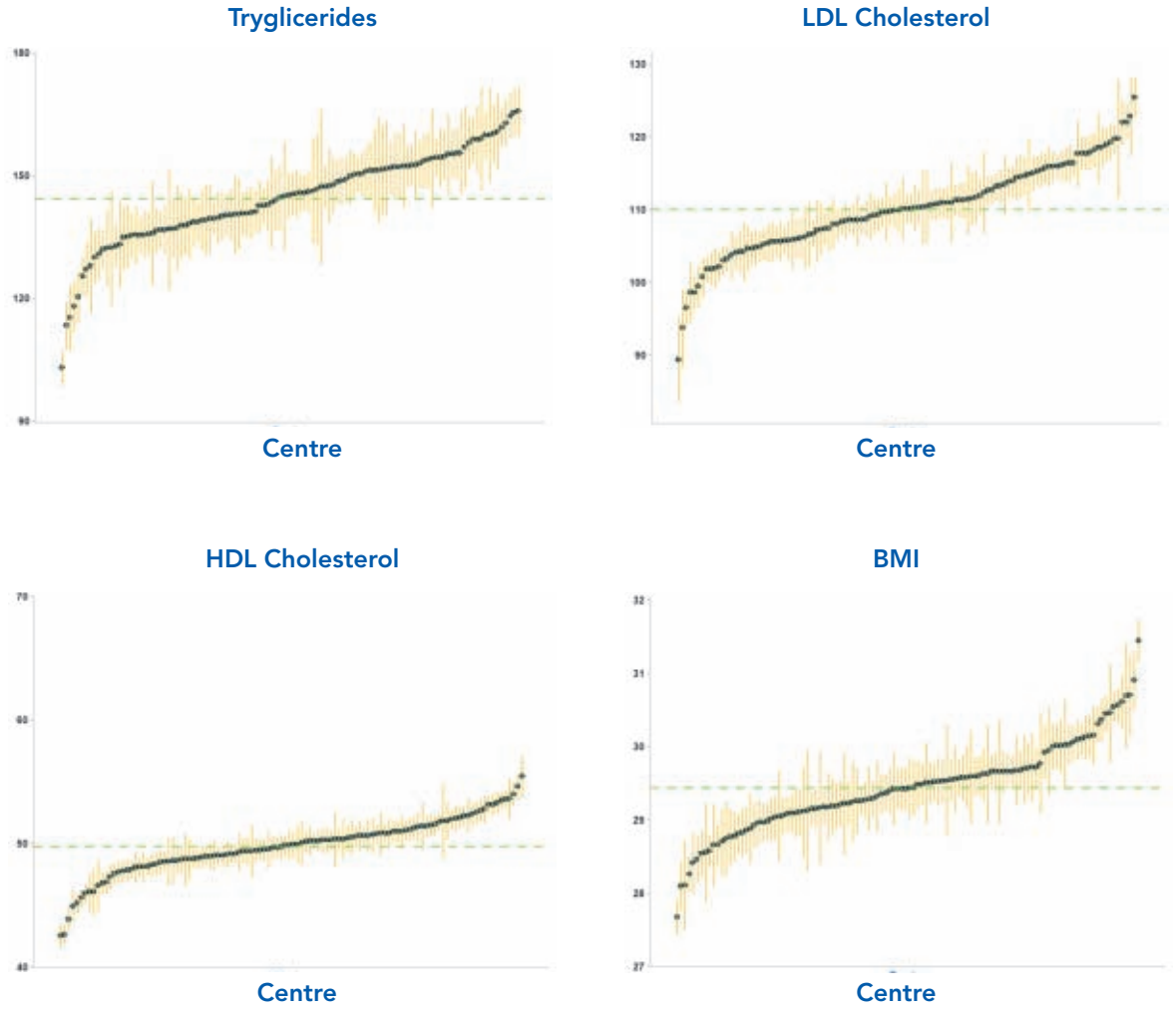
Centre

Total cholesterol



Centre

DM2



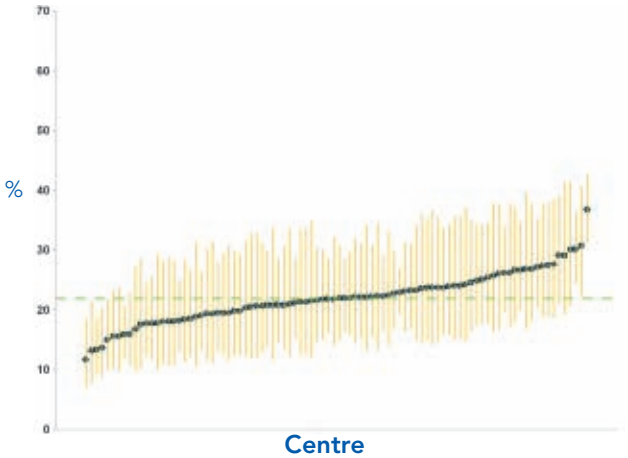
As discussed in the methods section, the variability in process measures and intermediate outcome measures among Centres may partly have resulted from differences in patient population, as well as clustering problems.

For this reason, the inter-centre variability shown in these figures was adjusted for the effect of clustering, patient age and sex, and diabetes duration. Even after these potential confounders were considered, however, the figures show that in both DM1 and DM2 a variability in the mean values of the parameters in question remained, with some Centres located well below or above the estimated mean value for the entire population. The picture for DM1 and DM2 is similar, even if in the former estimates have wider confidence intervals owing to the fewer cases reported per Centre.

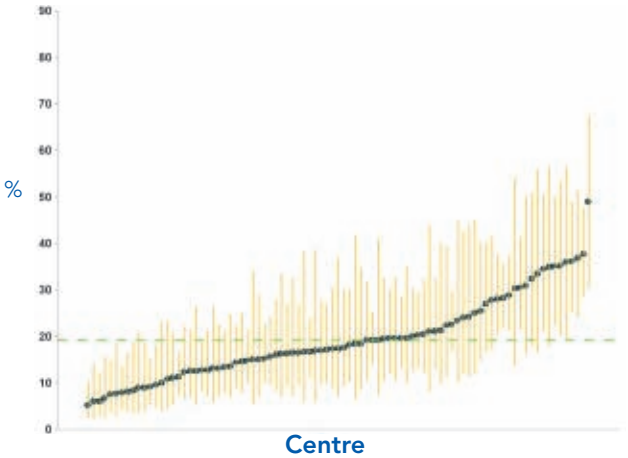
Variability in the Tendency to Prescribe Lipid-lowering and Antihypertensive Treatment

DM1

Subjects not receiving lipid-lowering treatment with LDL-C ≥130 mg/dl

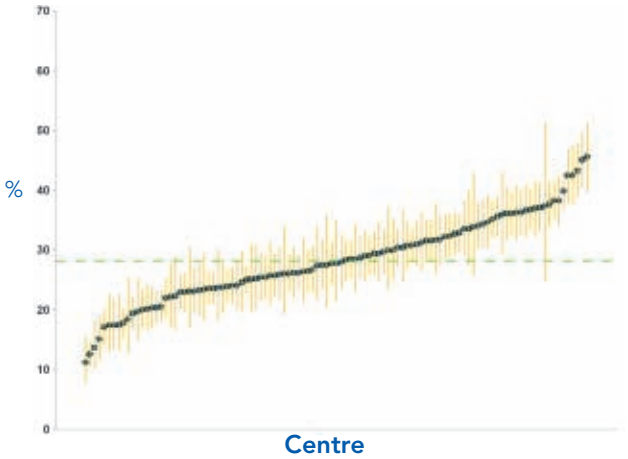


Subjects not receiving antihypertensive treatment with BP ≥140/90 mmHg

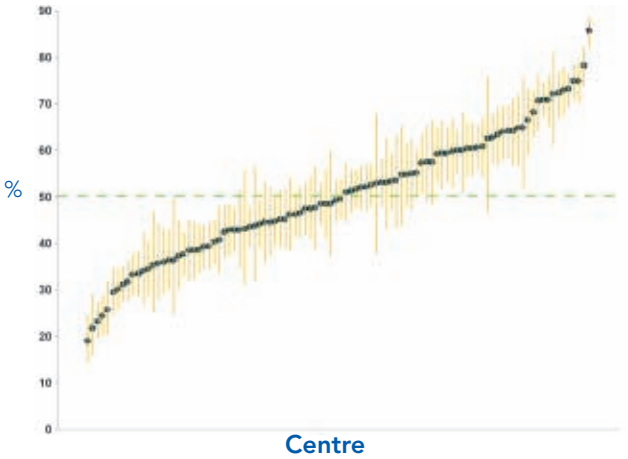


DM2

Subjects not receiving lipid-lowering treatment with LDL-C ≥130 mg/dl



Subjects not receiving antihypertensive treatment with BP ≥140/90 mmHg



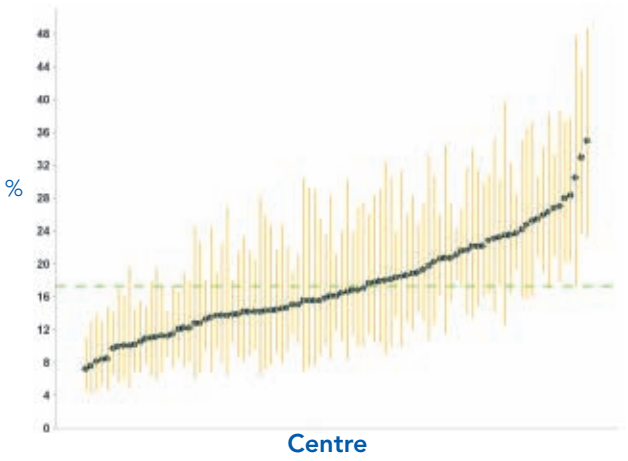
The same approach to statistical analysis was adopted to evaluate the tendency of Centres to treat subjects with LDL cholesterol ≥130 mg/dl or blood pressure ≥140/90 mmHg.

The diagrams show that the percentage of potential candidates for statin therapy, but not treated, varied among Centres from 12% to 35% in DM1 patients and from 11% to 45% in DM2 patients. Similarly, the percentage of hypertensive patients not receiving antihypertensive treatment ranged between 5% and 48% among DM1 patients and between 19% and 87% among DM2 patients.

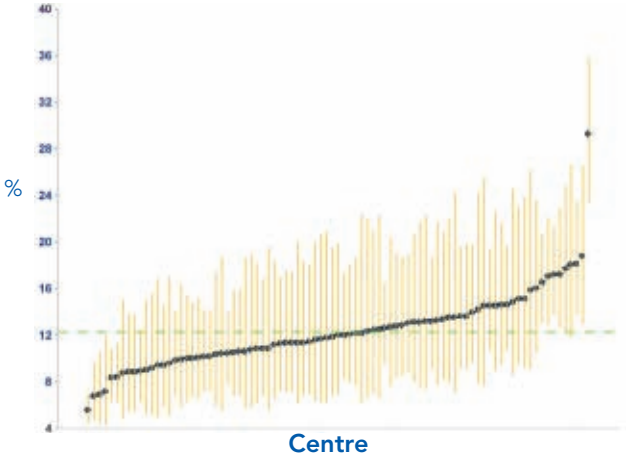
Variability in the Use of Specific Drug Classes

DM1

Statins

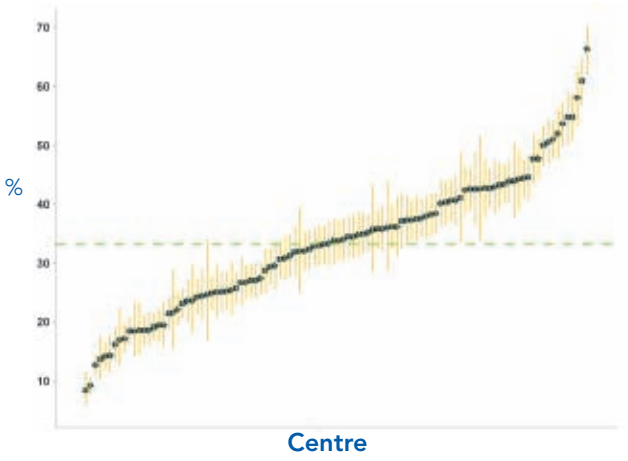


ACE-inhibitors

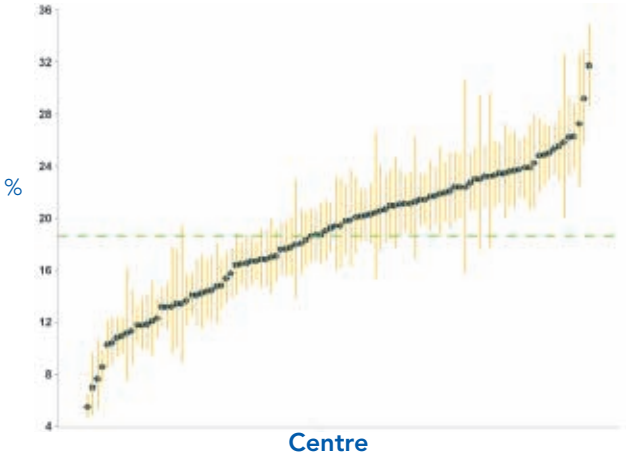


DM2

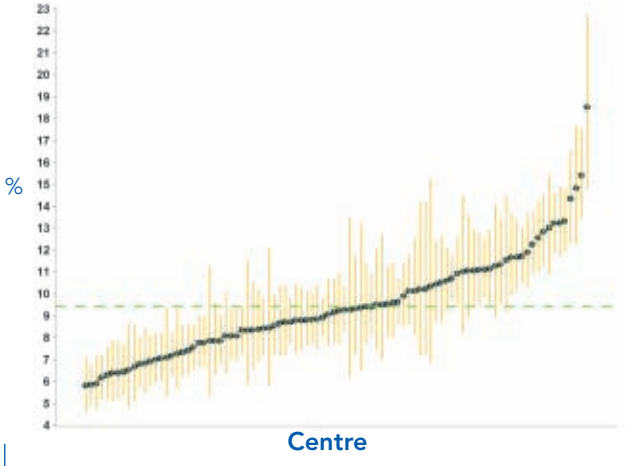
Statins



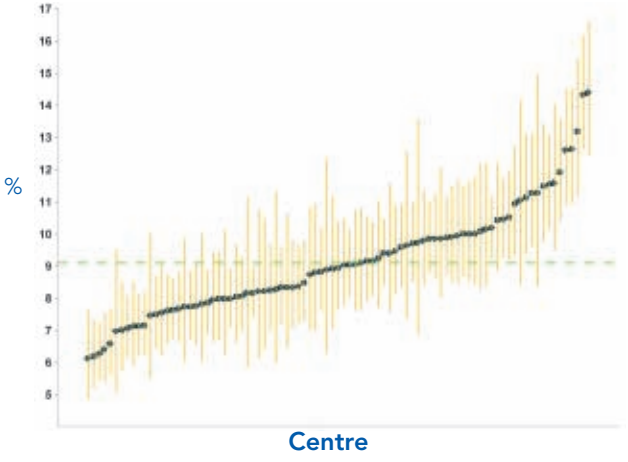
ACE-inhibitors



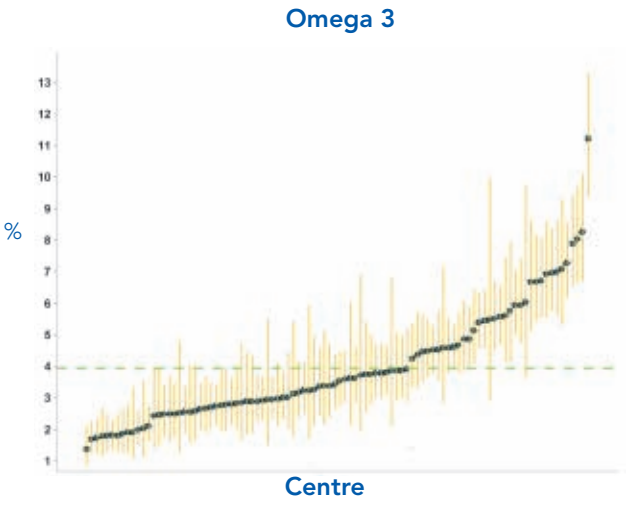
Sartans



Beta-Blockers



DM2



In DM1 patients, variability in the use of specific drug classes was evaluated only with respect to statins and ACE inhibitors; for all other drug classes, the percentage of use was too low for analysis. The figures show that, when matched for age and sex, the percentage of statin-treated patients varied between slightly over 7% and 35%, while the percentage of those receiving ACE inhibitors ranged from 5% to 29%.

Wider variability was found in the treatment of DM2 patients. The mean percentage of those treated with statins was 33% (range, 8-67%), while the mean percentage of those treated with ACE inhibitors was 18% (range, 5-31%). Lower levels of variability were found in the use of sartans (range, 6-19%), beta-blockers (range, 6-14%), and omega-3 (range, 1-11%).

A Comment on the Diagrams Representing the Variability among Centres

The phenomenon of variability in the results obtained – by now well-known and described for several years, starting from the published analyses of DAI and QuED studies – continues to dominate the scene in diabetes care. The analyses concerning the tendency to prescribe various treatments deserve a special comment. However, with respect to previous years, a lower degree of data dispersion is evident. In fact, the forestplots related to HbA1c, blood pressure and lipids, tend to become "more horizontal", conforming to a greater extent to the line of the mean value. This certainly might depend on a greater treatment intensity in Centres which were previously insufficient; but, in all likelihood, it is due to greater accuracy in recording data (or, at least, this component plays a relevant role). The training campaigns promoted by the AMD, and the sense of responsibility among doctors working at the Centres supplying data to the Annals, have doubtlessly affected the quality of the data collected. We should always remember that several outcome research analyses show the best results in terms of care effectiveness were obtained at those Centres that registered data with greater precision.

As far as the tendency to prescribe treatment is concerned, it is still clearly evident – represented in a clear and immediate manner – that not all Centres respond in the same way, when facing the given levels of blood pressure or LDL. Dispersion concerns drug classes whose effectiveness is proven, and is greater in DM2.

We reiterate once again that this phenomenon is by no means particular to diabetes care, nor to Italian healthcare in general. Similar variability can be found in cardiology and internal medicine throughout Europe and the United States, and has been widely reported in the literature. The factors which somehow influence a correct therapeutic outcome – such as patient age, total number of tablets to be taken, cost of medication, control of expense appropriateness on the part of healthcare administrators, the AIFA notes, the physician's beliefs and cultural background, patient compliance – continue to play a decisive role in treatment intensity.

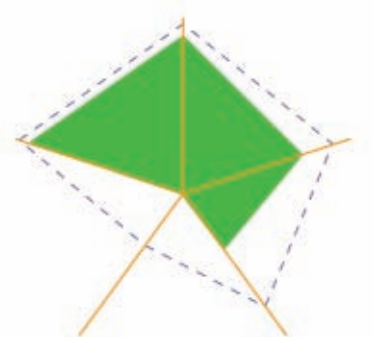
Carlo Giorda

Analyses by Region

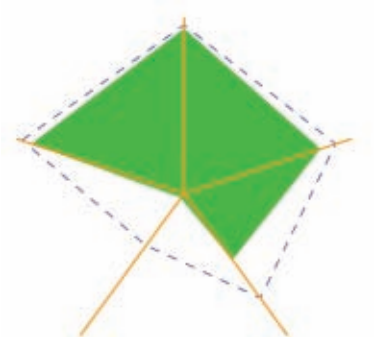
Starplot of Process Indicators

DM1

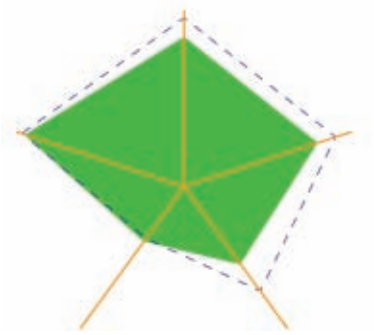
DM2

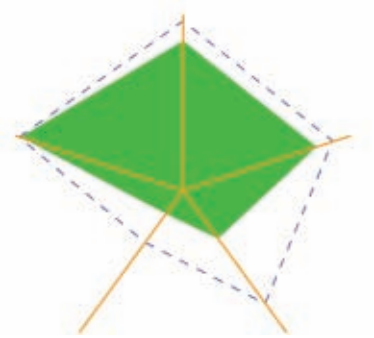


Piemonte

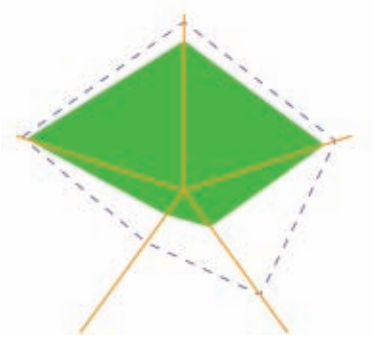


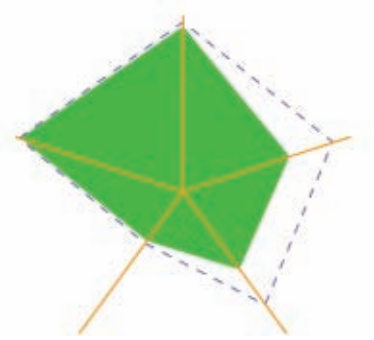
Lombardia



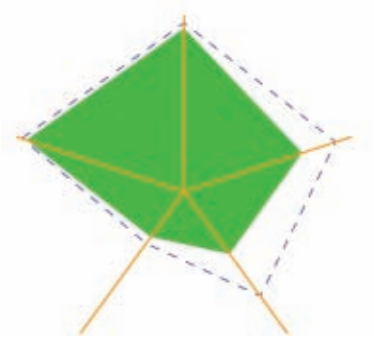


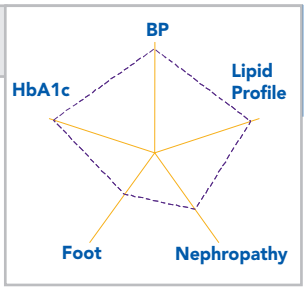
Veneto





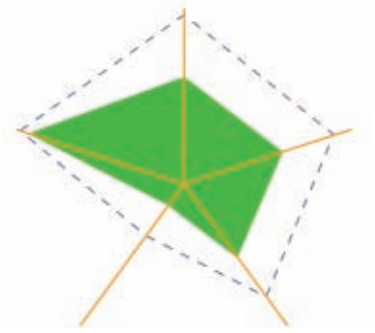
Friuli Venezia Giulia



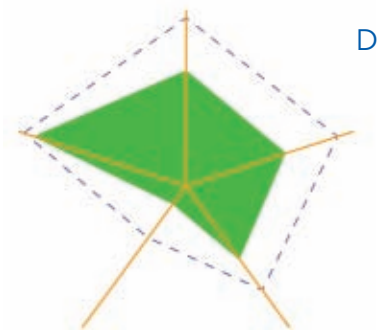


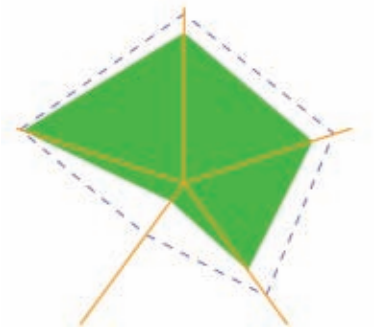
DM1

DM2

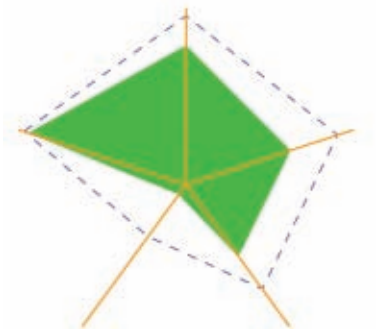


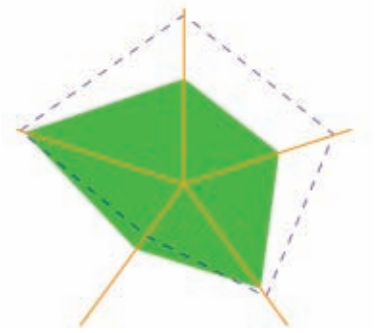
Emilia Romagna



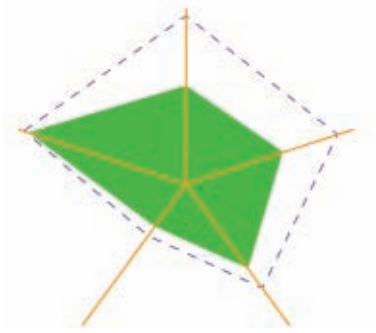


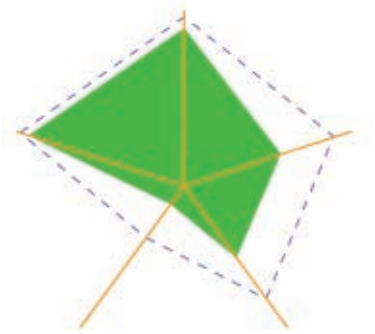
Toscana



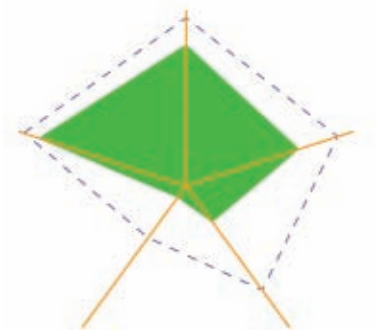


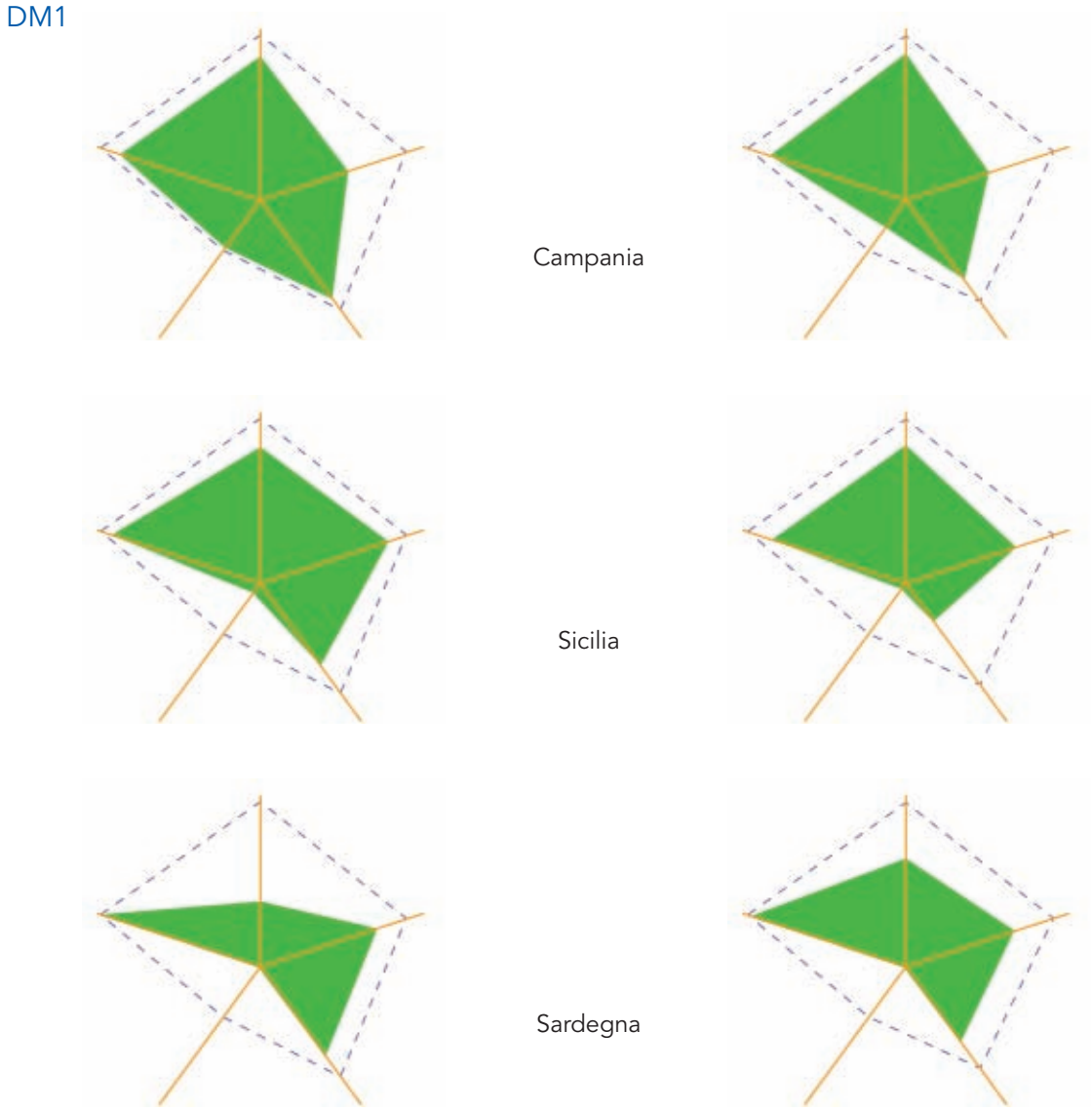
Marche





Lazio





A comparison of the data from different regions, in both DM1 and DM2, shows substantial variability in all indicators, as highlighted by the different form and size of the green area.

HbA1c monitoring is the only satisfactory parameter in all of the regions without exception. Among the other indicators, the recording of blood pressure comes closest to the gold standard in many regions, with the exception of Emilia Romagna, Marche, and Sardegna.

Conversely, only a few regions near the gold standard data in measuring the lipid profile and monitoring kidney function. The most varied parameter – which probably suffers from the way data was recorded – is foot examination, which is very close to the gold standard in a few regions, but nearly absent from the others.

Overall, Lombardia is the region that comes closest to the golden standard for all indicators under examination.

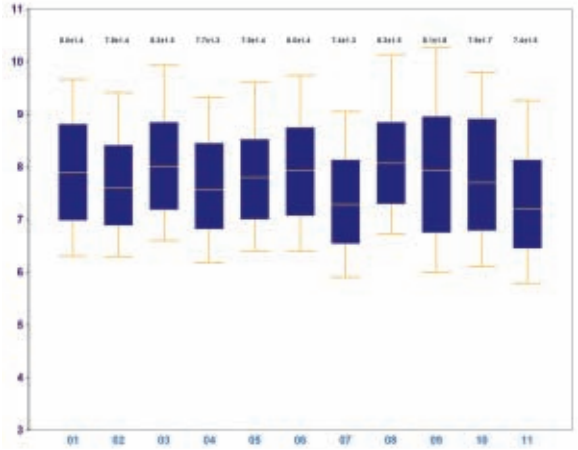
Boxplot of Some Intermediate Outcome Indicators Analysed by Type of Diabetes

In DM1, the HbA1c mean levels obtained in different regions show marked differences, ranging between 7.4% (Marche and Sardegna) and 8.3% (Lazio). In general, the mean levels are around 8% in most regions, while the intra-region variability is quite similar from region to region, even though it is more marked in Campania and Sardegna.
Compared to DM1, the mean HbA1c levels in DM2 are generally lower, ranging between 6.9% (Marche and Sardegna) and 7.9% (Lazio). The outcomes obtained across regions, as well as the intra-region variability, tend to be more homogeneous than in DM1.

Region Code - Region

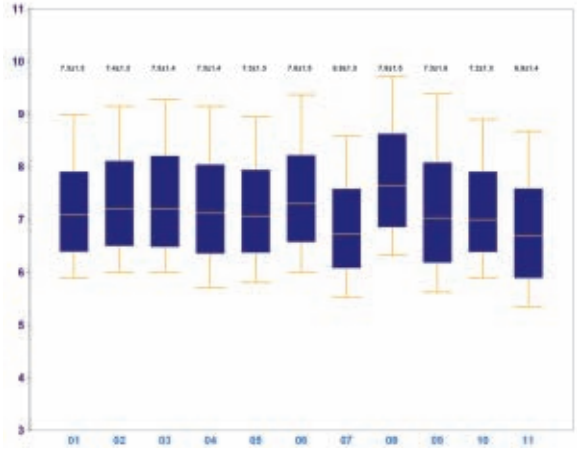
- 01 = Piemonte
- 02 = Lombardia
- 03 = Veneto
- 04 = Friuli Venezia Giulia
- 05 = Emilia Romagna
- 06 = Toscana
- 07 = Marche
- 08 = Lazio
- 09 = Campania
- 10 = Sicilia
- 11 = Sardegna

DM1

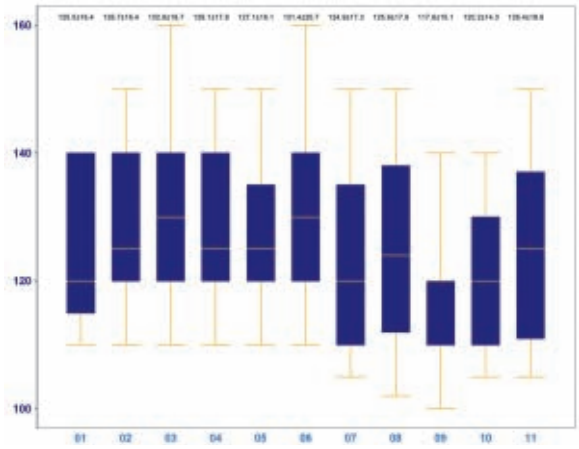


HbA1c (normalized to 6.0)

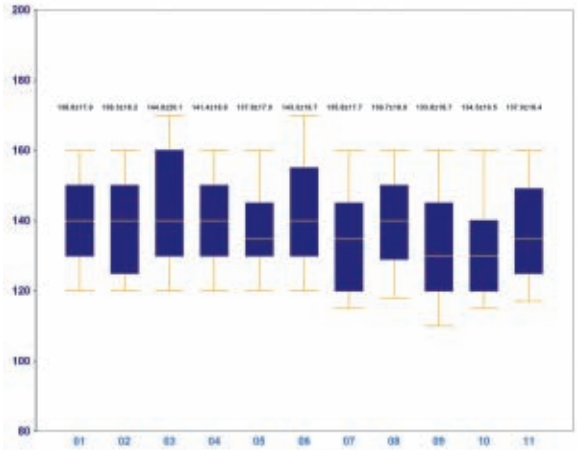
DM2



HbA1c (normalized to 6.0)



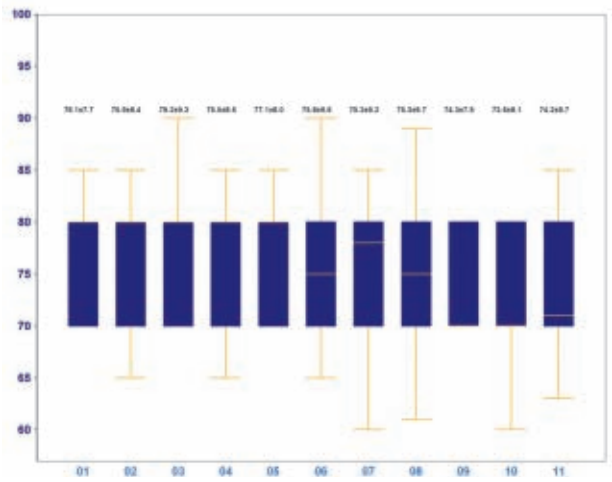
Systolic blood pressure



Systolic blood pressure

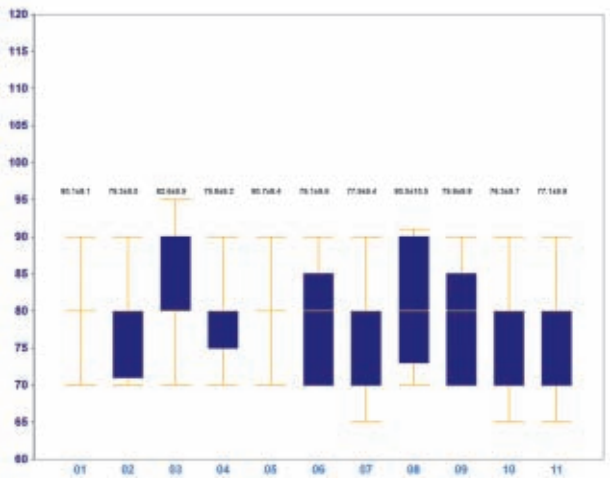
In both DM1 and DM2, the systolic blood pressure levels tend to be lower in the Southern regions. In this case, as well, a certain degree of variability is evident among regions, with mean levels ranging between 118 mmHg (Campania) and 133 mmHg (Veneto) in DM1, and between 134 mmHg (Campania) and 145 mmHg (Veneto) in DM2. Levels of intra-region variability also are significant, as shown by the different height of the boxes.

DM1



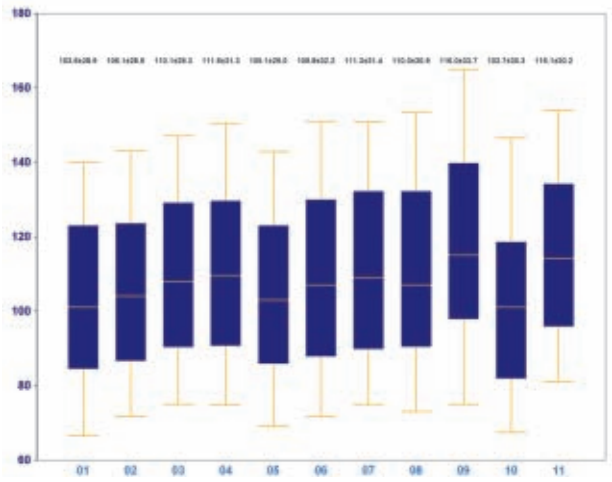
Diastolic blood pressure

DM2

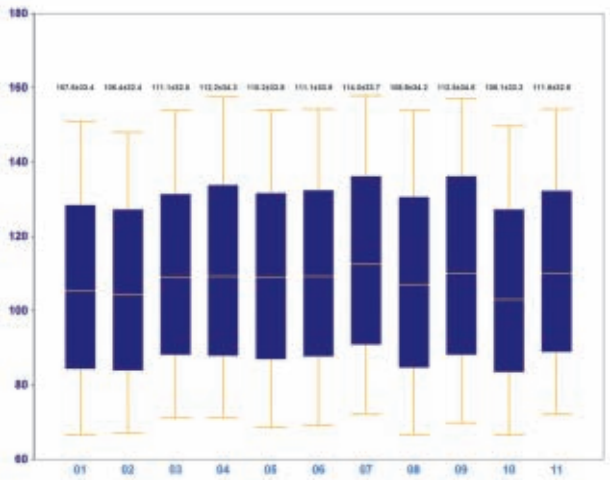


Diastolic blood pressure

On the contrary, the diastolic blood pressure levels are extremely homogeneous. In DM1, 50% of the values are between 70 and 80 mmHg in all regions. In DM2, the mean values range between 76 mmHg (Sicilia) and 83 mmHg (Veneto). In two regions (Piemonte and Emilia Romagna), the intra-region variability is so small that 50% of values coincide with the median. As a result, the blue area of the boxplot is not visible.



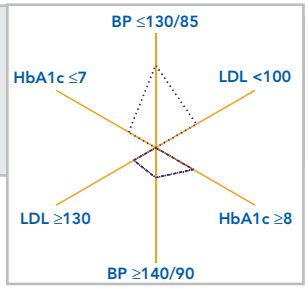
LDL Cholesterol



LDL Cholesterol

As far as LDL cholesterol is concerned, the regional mean values range between 103 mg/dl (Sicilia) and 116 mg/dl (Campania and Sardegna) in DM1, and between 106 mg/dl (Lombardia and Sicilia) and 114 mg/dl (Marche) in DM2. All regions feature high intra-region variability.

Starplot of the Intermediate Outcome Indicators



DM1

DM2

Piemonte

Lombardia

Veneto

Friuli Venezia Giulia

DM1

DM2

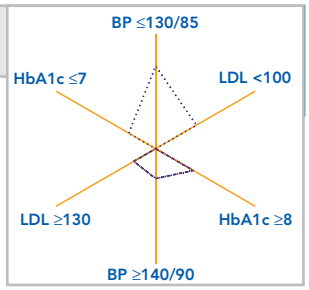
Emilia Romagna

Toscana

Marche

Lazio

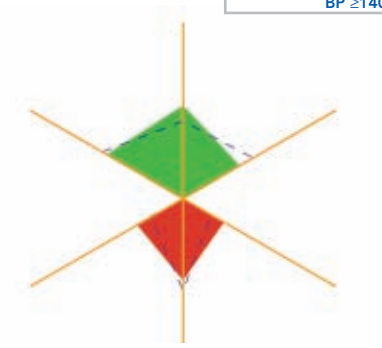
Starplot of the Intermediate Outcome Indicators



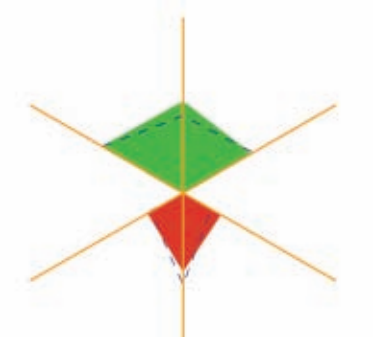
DM1

DM2

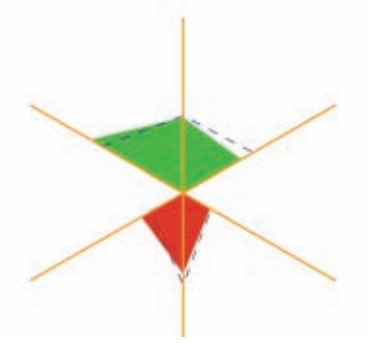
Campania



Sicilia



Sardegna



As in the case of the process starplots, a comparison between data from different regions shows some variability in all indicators, as highlighted by the different size and shape of both the green and red areas. Such variability is greater in DM1 than DM2. In DM1, the region closest to the golden standard levels is Lombardia, followed by Emilia Romagna and Piemonte.

In DM2, aside from the aforementioned regions, Sicilia also features a very similar profile to the gold standard, together with better blood pressure control. In Marche and Sardegna, instead, only the lipid profile outcomes are less satisfactory, with respect to the gold standard.

Regional Variability in the Use of Specific Drug Classes: Mean Levels Adjusted by Age, Gender, Diabetes Duration and Clustering Effect

Inter-region variability in the prescription rates of different drug classes is, in general, limited.
In DM1, the rate of statin prescription ranges between 13% (Lazio) and 22% (Emilia Romagna), with a mean value of 17%. The rate of ACE inhibitor prescription is more varied, ranging between 8% (Sardegna) and 22% (Toscana), with a mean value of 13%.
In DM2, the rate of statin prescription ranges between 25% (Campania) and 37% (Emilia Romagna), with a mean value of 33%. The rate of ACE inhibitor prescription ranges between 14% (Marche and Sardegna) and 21% (Veneto and Emilia Romagna), with a mean value of 13%. As for the other drug classes, the rates of prescription are generally low, and feature less significant inter-region differences.

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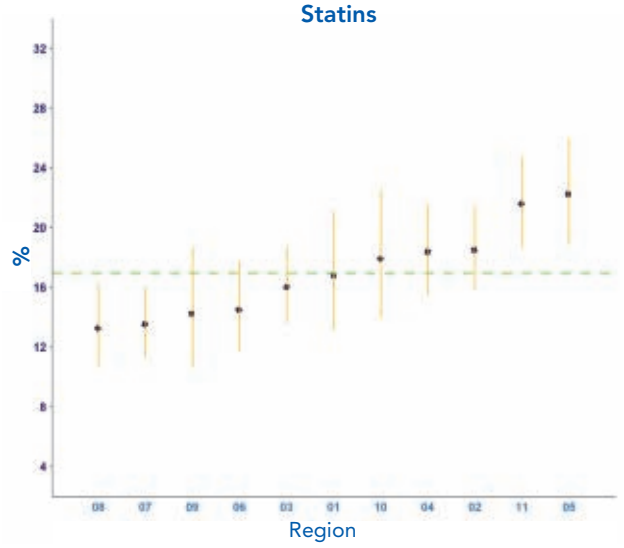
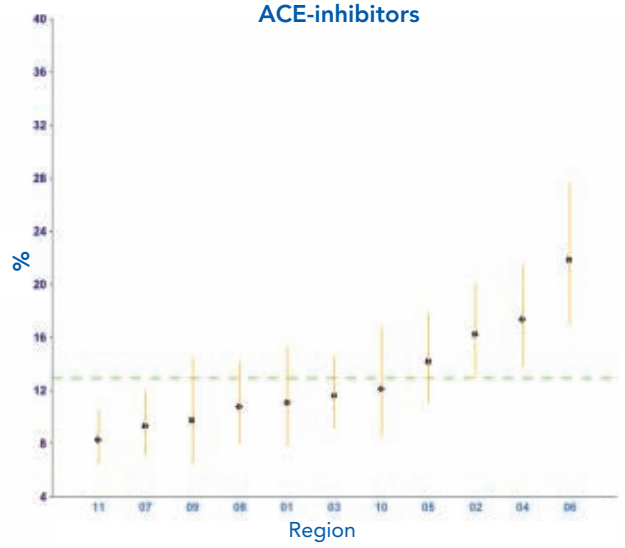
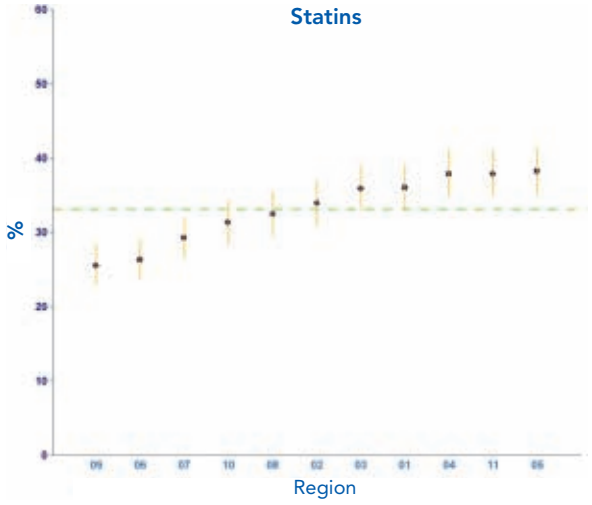
- 07 = Marche
- 08 = Lazio
- 09 = Campania
- 10 = Sicilia
- 11 = Sardegna

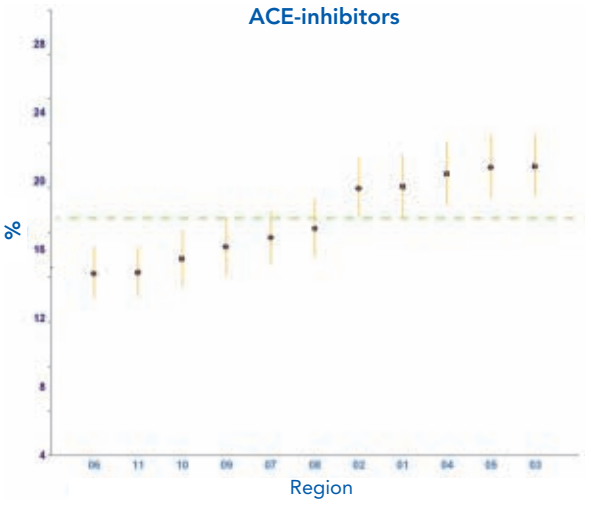
DM1

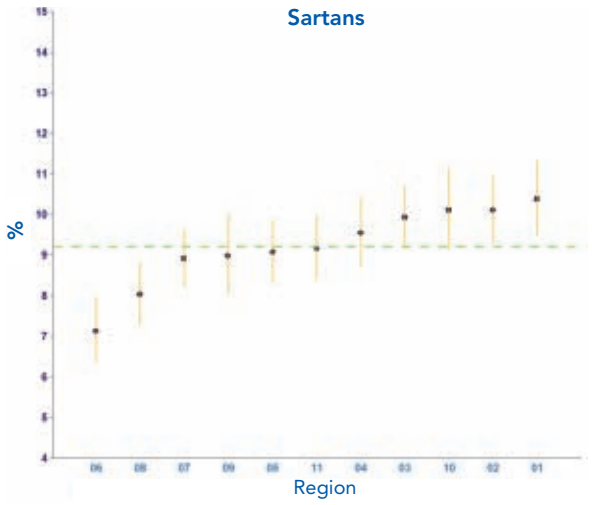




DM2


Statins
%
Region


ACE-inhibitors
%
Region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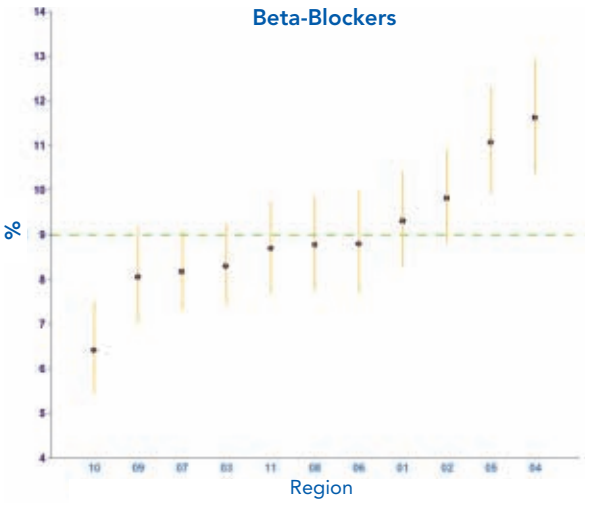
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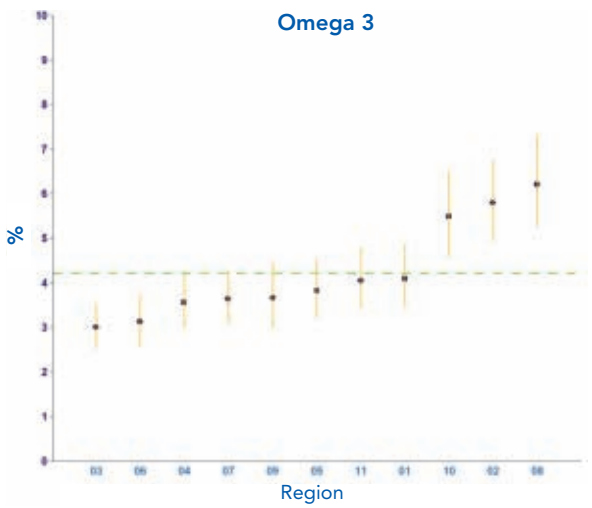
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Region

A Comment on the Analyses by Region

The analysis of the regional data offers a picture of diabetes care in Italy which provides us with more uncertainties than certainties.
Consequently, the Editorial Board long discussed whether we should limit ourselves to merely suggesting functional interpretative principles to readers, or if we should, on the basis of the mentioned principles, also examine the situation in terms of different regions.
Once again, our aim is not to give marks or list rankings, but rather to make reading the Annals easier for those who do not specialize in this scientific field.
We chose the second option, but would like to strongly emphasize the speculative nature of the indications we provide here.
One of the few points we can be sure of is that tremendous variety exists among organizations and care delivery in Italy. Moreover, this confirms the need for greater homogenisation, which should be implemented on the basis of the examples of best practice showed by the Annals themselves, but also taking the local conditions into account.
A really thorough and objective utilization of the data should make it possible to compare the indicators related to the process (system's efficiency) and intermediate outcome (effectiveness) of the diabetes Centres, with identical indicators provided by General Medicine, and those deriving from integrated management.
As a result, we could objectively assess the quality of care delivered under different modes, including the "integrated system" everybody would like to see implemented today.
It would not be a bad idea, for once, to design a new organization based on objective indicators, and not only personal intuition or models drawn from abroad.
Today the data at our disposal only come from the diabetes care sector, but we hope that, as soon as possible, they will be integrated with homogeneous information coming from General Medicine doctors.
The longitudinal analysis which the AMD will carry out in the AMD Annals 2009 will certainly contribute further useful information.
On the basis of the data made available now from diabetes Centres, and by comparing both the process starplots, which show the organization's efficiency, as well as the intermediate outcome starplots, which show the effectiveness of the interventions, we can identify the concordances and discordances.
On the basis of these results, we are able to formulate hypotheses relating to the targets for improvement which are to be pursued in each region. We should always remember, however, that the services recorded are most likely less numerous than those actually provided, and that this important variable is difficult to estimate.
Another limitation is due to the fact that the data came from a small number of Centres within every region: consequently, information might not reflect the situation of regions as a whole.

Positive Concordances: Lombardia, Piemonte and Emilia Romagna feature the shortest distance between the mean value (green areas) and the gold standard in the starplots referring to both intermediate outcome and process.
This means that efficiency and effectiveness combine together in a balanced relationship.
However, that the data from these regions only cover 5-10% of the total should be taken into consideration. Therefore, this positive concordance might actually only relate to the few Centres involved, and not to the entire regional organization.
In any case, the organizational models of the participating Centres can certainly be viewed as a reference.

Negative Concordances: In Lazio and Toscana, a significant distance exists between the mean levels and the gold standard in the starplots relating to both process and intermediate outcome.
A possible reading of this negative concordance might be the disproportion between very high demand and the limited ability to respond on the part of the Centres. This situation would entail the impossibility to ensure an optimal organization able to guarantee that all the services necessary to people with diabetes who contact a Centre are delivered; thereby, making the care targets very difficult to reach.

Positive Discordances: In Marche, Sicilia, Campania, and Sardegna, a significant distance exists between the mean levels and the gold standard in the starplots which relate to process. This indicates that the organization is suboptimal.
At the same time, the intermediate outcome indicators show good performance (short distance from the gold standard in the green area).
A possible reading might be that, despite the disproportion between very high demand and limited ability to respond on the part of the Centres, the outcome of care is still good due to unknown factors possibly related to genetics or diet.
We should not underestimate the possibility that the information was not systematically recorded; if that were the case, only the deficit of the process indicators would be apparent.

Negative Discordances: In Friuli and Veneto, a very small distance exists between the mean levels and the gold standard pertaining to process indicators (indicating good organization); however, at the same time, a significant distance from the gold standard in the green area and the surpassing of the red area are shown in the starplots relating to intermediate outcome indicators (indicating suboptimal performance).
A possible reading is that the Centres are well structured and organized, but patients are not visited on a continual basis. Otherwise, we might conjecture that case outcomes worse than expected are caused by other unknown factors, including genetics or diet. A further possible interpretation is that these Centres, being Centres of regional excellence, predominantly treat the most complex cases.

It goes without saying that this schematization is only an initial interpretative hypothesis, not supported by the real indicators of performance; i.e., the final outcome indicators that are to date not yet available.
The purpose of the schematization is to start a debate on the topic, and any judgement or creation of rankings is not intended. It should, therefore, be considered and assessed for what it is: a working hypothesis.
We also believe that these regional analyses might stimulate Centres that have not so far participated in the data collection to do so. Obviously, the greater the number of participating Centres within a region, the higher the relevance of the indications provided. This remains true in view of their value for making political and administrative decisions in the field of diabetes.

Giacomo Vespasiani and Illidio Meloncelli

The Annals 2008 represent the conclusion of a journey in quality of care initiated several years ago, as well as the beginning of a new research horizon.
They provide a picture of diabetes care over the last four years, and the data they present warrant some thought. Even though the longitudinal analysis will not be completed until May 2009 (AMD National Annual Meeting, in Rimini), we are already able to highlight a positive evolution in the quality of care as expressed by the different indicators. The participating Centres have been showing greater attention to collecting data correctly, as well as to performing the surveys that make it possible to monitor a complex disease like diabetes. This fact represents a cultural growth and an increase in awareness made evident by the Annals 2008. It also reflects the "spirit" which first originated the Annals, whose aim has always been – through the collection and analysis of data – to disseminate a culture of quality in healthcare, and the comparison and exchange between peers in order to improve performance and organization.
The collection and analysis of data are the indispensable first steps of clinic governance in diabetes, and are to be followed by the knowledge of the guidelines and Standards of Care, the assessment and optimisation of the organizational system, and the construction of an actual "path of care" whose protagonist is the patient, made aware and empowered through effective educational measures. The Annals, therefore, are not only a unique scientific product, but also a clinical tool we can use to reflect and take action.
The inclusion of the regional data constitutes a further step forward in line with the change undergone by the healthcare system already. The healthcare system has in fact been regionalized, hence it is necessary and useful that each Centre is able to compare and exchange experiences with counterparts inside and outside its region. This is not meant to ascertain who is "the best," but rather so that we can all improve: our sole interest being the people who suffer from diabetes and metabolic diseases. The AMD will take care to enable a debate and exchange at a regional level, not only among those who helped produce the data, but among all diabetes specialists, so as to promote a serene and free, as well as scientifically correct reflection on the initiatives needed to improve the quality of care. This will make it possible for our Scientific Society to plan specific actions in each region, putting at everybody's disposal the instruments we have for training, scientific information, research, quality, as well as the definition and implementation of care paths.
The Annals 2008 are, for the AMD and all Italian diabetes specialists, a resource to plan future actions.
The AMD intends to further develop the Annals, rendering them a subject for independent scientific research. Monitoring the different care indicators – over time and in a controlled and scientifically correct manner – is a duty for a Scientific Society that has always been committed to improve the quality of care for the people suffering from diabetes and metabolic diseases. This is why we want to develop the Annals in the field of research, involving as many Centres as possible, without ever neglecting the aim of encouraging cultural exchange and growth. Together with the *Italian Standards*, they will be the indispensable instrument for translational research, helping identify what prevents us from covering the divide between standards and outcome, and promote effective measures to make change possible, in a perspective of continuous improvement.
Finally, I would like to extend my gratitude to all the people who, in different ways, contributed to the realization of the Annals 2008, and to Novo Nordisk and Lifescan that made their publication and circulation possible.

Adolfo Arcangeli
AMD National President