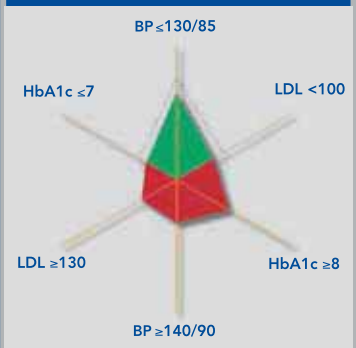
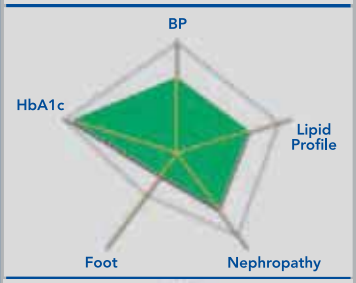
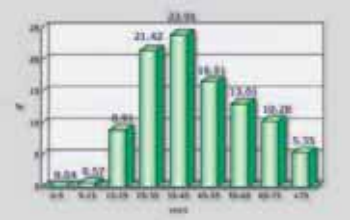
AMD 2006 Annals







Quality Indicators in Diabetes Care in Italy

Antonino Cimino, Carlo Giorda, Illidio Meloncelli, Antonio Nicolucci, Fabio Pellegrini, Maria Chiara Rossi, Giacomo Vespasiani

English version edited by Carlo Giorda

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Associazione Medici Diabetologi

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AMD
Associazione Medici Diabetologi

Viale Carlo Felice, 77 - 00185 Roma, Italy
Tel. +039 06.700.05.99 - Fax +039 06.700.04.99
E-mail: amdass@tiscalinet.it
http://www.aemmedi.it

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AMD 2006 Annals

Quality Indicators in Diabetes Care in Italy

The Diabetes Annals edited by the AMD derive from a project started in 2000, when the Group for Computerization of Italian Diabetes Care (GIDI) was founded. One of the Group's objectives was to produce a data set that could be extracted automatically by all computerized diabetes medical records in a uniform electronic format.
This data set, although collected from various electronic medical records, was intended to have a shared standard that would enable the assembly of clinical information, regardless of the electronic medical record at the source.
The first step was to identify the clinical information that the data was to contain. An analysis was conducted to determine the reasons for the failure of past attempts and to learn from these lessons.
The critical points identified from an examination of previous data set collections were:

1. a complete lack of specific computer capabilities in the electronic structure of the clinical data to be collected;
2. the collected data could be processed only by a central owner and only according to the owner's interpretation. In other words, once the data were collected, it was difficult to render them useful to individual users for separate use.

For this reason, we decided that the basic objective on which to calibrate the entire project, along with the information content of the data set, was to identify those quality indicators that could help make the delivery of clinical diabetes care more efficient. Starting from this objective, the single items required for calculating the indicators were identified. The items were then linked to specific data entry functions to standardize the data file in the system.
In this way, the AMD 2002 Data File was created and published on the AMD web site. At the same time, the commercially available electronic medical records had to be configured so as to produce this data set. The new configuration was implemented by Eurotouch, Metadiainf, Millenium and Perseo, the first two of which are clinical diabetes records and the second two are interfaces used by the Association of General Practitioners. Each record, to document proper alignment with the AMD standards, sent an automatically extractable data file which was then controlled and validated by the AMD.
At this point, each diabetologist could have processed his/her own data in a standardized fashion; however, it was noticed that very few diabetologists had access to a system with which they could independently calculate the indicators. To overcome this drawback, an AMD indicator software package was developed that could automatically calculate pre-selected indicators for each user.
On calculation of the indicators, several items were found to be missing and that not all the desired indicators could be calculated. For this reason, from 2003 to 2004 the AMD Quality Group reviewed the list of items making up the 2002 Data File and published a new list under the name of Data File 2004.
This time, an AMD indicator software processing program was developed and made available to all members.

The Eurotouch record, the Metadiainf record and the Brescia diabetologia record were aligned with the 2004 update. In this way, the first important target was achieved: to enable diabetes treatment centers to employ an electronic medical record of quality indicators for improving services and/or conducting internal audits.
The second target within the capability of this system was to prepare a national data file for the creation of a clinical database from which indicators could be calculated.
This target was reached with the collaboration of 87 Italian diabetes centers which delivered to the AMD, under the norms of privacy, their 2004 data files. One of the 87 centers sent data that were illegible due to problems with the electronic support, so that the calculation was made on 86 centers. Thanks to an unconditioned contribution from LifeScan Italia, which in this effort demonstrated solid partnership with Italian diabetes care, the data were incorporated and processed by the Consorzio Mario Negri Sud and then commented by the AMD. The ***AMD 2006 Annals of quality indicators in diabetes care in Italy*** is the result of this joint collaboration.
Not all the indicators processed in this national database are those that could theoretically be extracted because a huge gap remains between what is actually done and what is coded (generally much less).
However, the data file system and the processing of the AMD indicators is operative and automated. With improved quality of the data collected, information will become more accurate and complete with less effort.
To this end, the AMD Quality Group has developed courses on how to obtain clean data; this nationwide intervention will undoubtedly lead to better results.
It is our intent to publish an annual extract of the data collected by the diabetes centers. We are certain that the improved quality of the findings and the ever greater involvement of centers will make our Annals a useful document for health care and social assistance in diabetes.
I wish to thank all our friends and colleagues who helped edit the Annals: Antonino Cimino, Carlo Giorda, Illidio Meloncelli, Antonio Nicolucci, Fabio Pellegrini and Chiara Rossi. Special thanks go to the Executive Board, the Study and Research Center and the AMD Quality Group for having provided their support during project design and development.
As arduous as it was challenging, this undertaking would not have been possible without the enthusiasm of the 87 diabetes centers across the country that furnished their data. This document will provide a stimulus to continuing collaboration and a signal to all AMD members to become involved in so positive an experience for improving Italian diabetes care.

Giacomo Vespasiani
Director of the AMD Study and Research Center

Centers List

AUTHORS	INSTITUTION	UNIT	TOWN
Giuseppe Reina	U.O. Lungodegenza Adrano P.O. Biancavilla	Ambulatorio di Diabetologia e Malattie del Ricambio	Adrano, CT
Antonino Pipitone	Ospedale Civile di Adria	Servizio di Diabetologia	Adria, RO
Paolo Fumelli, Rosa Anna Rabini, Massimo Boemi, Roberto Giansanti, Pierluigi Sorichetti	INRCA	U.O. Diabetologia	Ancona
Mario Velussi	Casa di Cura - Pineta del Carso	Servizio di Diabetologia	Aurisina, TS
Carlo Rinaldi	Ospedale Fatebenefratelli Benevento	U.O.S. Medicina d'Urgenza e O.B.	Benevento
Umberto Valentini, Antonino Cimino	A.O. Spedali Civili di Brescia	U.O. di Diabetologia	Brescia
Luciano Carboni, Maria Grazia Murtas, Alessandro Delogu, Mirella Floris, Maria Pia Turco	Ospedale S.S. Trinità	Servizio di Diabetologia	Cagliari
Mario Manai, Francesca Spanu	Ospedale Civile S. Giovanni di Dio	Diabetologia	Cagliari
Marco Songini, Giampiero Piras	Azienda Ospedaliera G. Brotzu	Struttuta Complessa di Diabetologia - Dipartimento di Medicina Interna	Cagliari
Antimo Aiello, Maria Rosaria Cristoforo, Simonetta Di Vincenzo, Lorenzo Cocco	Ospedale Regionale Cardarelli Campobasso	U.O.C. Diabetologia - Endocrinologia - Malattie Metaboliche	Campobasso
RiccardoTrifirò	ASL 1 - Ospedale di Carrara	U.O. di Diabetologia	Carrara, MS
Juliette Grosso, Antonietta Sciulli, Brunella Di Nardo, Loredana Rossi, Antonio Lorizio	Presidio Ospedaliero Castel di Sangro	U.O. di Diabetologia	Castel di Sangro, AQ
Loris Confortin, Narciso Marin, Mario Lamonica	Ospedale Civile S. Giacomo Apostolo	S.S.D. Diabetologia	Castelfranco Veneto, TV
Maurizio Di Mauro, Rosario Battiato	Ospedale Garibaldi	Ambulatorio di Diabetologia e Medicina Interna	Catania
Ignazio Lorenti	Azienda Ospedaliera di Cannizzaro	Servizio di Diabetologia	Catania
Andrea Nogara, Angelo Boscolo Bariga, Stefano De Boni	Ospedale di Chioggia	Servizio di Diabetologia di Chioggia	Chioggia, VE
Anna Chiambretti, Riccardo Fornengo, Elena Mularoni	Ospedale Civico di Chivasso	Servizio di Diabetologia	Chivasso, TO
Graziano Santantonio	Ospedale San Paolo	U.O. di Diabetologia	Civitavecchia, RM
Giosuè Ghilardi, Patrizia Fiorina	Ospedale S. Biagio	Servizo Diabetologico	Clusone, BG
Dario Gaiti	Ospedale Civile San Sebastiano	Servizio di Diabetologia	Correggio, RE
Alfonso Longobucco	Azienda Sanitaria n. 4 - Poliambulatorio di Cosenza	Servizio di Diabetologia e Endocrinologia	Cosenza
Nicoletta Musacchio, Augusto Lovagnini Scher, Annalisa Giancaterini	A.O. S. Gerardo	Centro Integrazione Territoriale Centro di Attenzione al Diabetico	Cusano Milanino, MI
Massimo Lepri, Giuseppe Placentino	Ospedale S. Biagio	U.O. di Diabetologia	Domodossola, VB
Donata Richini, Stefano Molinari	Ospedale di Vallecamonica Esine	U.O.S.S. di Diabetologia e Malattie del Metabolismo	Esine, BS
Luisella Cotti, Gabriella Garrapa	ASUR Marche Zona Territoriale n. 3	U.O. di Diabetologia	Fano, PS
Paolo Foglini, Claudio Bedetta, Sandra Di Marco, Paola Pantanetti	Ospedale di Fermo	U.O. S. di Diabetologia e Malattie del Metabolismo	Fermo, AP
Anna Leopardi	Ospedale di Comunità Camerata		Fiesole, FI

Cristiana Baggiore, Anna Leopardi, Tiziana Pedone, Paolo De Carlo, Cassandra Crescenti	ASL 10 Ospedale Nuovo San Giovanni di Dio	U.O.S. Diabetologia e Malattie Metaboliche	Firenze
Mauro Cignarelli, Angela Caroleo Angela, Olga La Macchia	Azienda Mista Universitaria Ospedaliera	Cattedra di Endocrinologia e Malattie del Metabolismo	Foggia
Costanzo Mastrangelo	Ospedali Riuniti di Foggia	U.O. di Pediatria	Foggia
Alfredo Carducci Artenisio, Gaspare Stabile	Policlinico Universitario G. Martino	U.O. Diabetologia, Dipartimento Clinico-Sperimentale di Medicina e Farmacologia	Gazzi, ME
Claudio Taboga, Barbara Catone	Ospedale S. Michele - ASL 3	Ambulatorio Diabetologico	Gemona del Friuli, UD
Guglielmo Ghisoni, Francesca Fabbri, Marina Torresani, Roberto Crovetto	Ospedale di Nervi	Servizio di Diabetologia	Genova
Giuseppe Sanfilippo	AZ 3 Distr. Giarre	Centro Diabetologico	Giarre, CT
Giuseppe Campobasso	ASL BARI 5 - Distretto sociosanitario 2	Servizio di Diabetologia	Gioia del Colle, BA
Marina Merni, Brunato Barbara	Presidio Ospedaliero di Gorizia	Ambulatorio di Diabetologia	Gorizia
Ezio Bosi	Area Nord AUSL RE Gustalla - Correggio	Servizio di Diabetologia	Guastalla, RE
Cecilia Marino, Augusta Micheletti, Michela Agostinelli, Annarita Petrelli	Ospedale di Gubbio	Servizio di Diabetologia	Gubbio, PG
Angelo Corda, Luisa Pisano, Giacomo Guaita	Ospedale Santa Barbara	Servizio di Diabetologia	Iglesias, CA
Mario Pupillo, Angelo De Luca	Ospedale Renzetti ASL Lanciano Vasto	U.O.S. di Diabetologia	Lanciano, CH
Albino Massidda, Gisella Meloni	Ospedale Nostra Signora della Mercede	Modulo di Diabetologia	Lanusei, NU
Rosa Maria Meniconi	USL 12 Viareggio - Ospedale Versilia	U.O. di Diabetologia e Malattie Metaboliche	Lido di Camaiore, LU
Mario Balsanelli, Mauro Fetonti, Andrea Rotolo, Paola Sambo	ASL Roma D	U.O.C. per la prevenzione e cura della Malattia Diabetica, Dismetabolismi ed Endocrinopatie	Lido di Ostia, RM
Francesco Giannini, Alberto Di Carlo, Ilaria Casadidio	Ospedale Campo di Marte	Servizio Autonomo di Diabetologia e Malattie Metaboliche	Lucca
Gabriele Maolo	Presidio Ospedaliero di Macerata	Servizio di Diabetologia	Macerata
Cesare Vincenti	Distretto Socio-Sanitario - ASL LE/2 Maglie	Ambulatorio di Diabetologia	Maglie, LE
Luigi Sciangula, Alessandra Ciucci, Erica Banfi, Antonello Contartese	Struttura Ospedaliera di Mariano Comense	U.O.S. di Diabetologia e Malattie Metaboliche	Mariano Comense, CO
Patrizio Tatti, Donatella Bloise, Falvia Costanza, Patrizia Di Mauro, Osvaldo Russo	AUSL RM H - Ospedale San Giuseppe	U.O.C.A. di Diabetologia ed Endocrinologia	Marino, RM
Maria Adelaide Dolci	Ospedale Santi Giacomo e Cristoforo	U.O. di Diabetologia e Malattie del Metabolismo	Massa
Angelo Venezia, Morea Roberto	Ospedale Madonna delle Grazie	U.O. di Diabetologia, Malattie Metaboliche ed Endocrine	Matera
Antonino Di Benedetto, Domenico Cucinotta	Università di Messina	Dipartimento di Medicina Interna	Messina
Pietro Pata, Teresa Mancuso	Ospedale Piemonte	Servizio di Diabetologia	Messina
Giampaolo Testori, Pietro Rampini, Nadia Cerutti	Ospedale Fatebenefratelli e Oftalmico	Struttura Complessa Diabetologia	Milano
Alfredo Zocca	Presidio Ospedaliero Macedonio Melloni	Reparto di Medicina Interna, Ambulatorio di Diabetologia	Milano
Marco Comoglio	ASL 8 Regione Piemonte	Servizio di Malattie Metaboliche e Diabetologia	Moncalieri, TO
Anna Maria Cernigoi, Carla Tortul	Ospedale San Polo	Servizio di Diabetologia e Malattie Metaboliche	Monfalcone, GO

Giuseppe Panebianco	Usl 17		Monselice, PD
Valeria Manicardi, Michelini Massimo, Delfina Dall'Asta	AUSL di Reggio Emilia - Ospedale di Montecchio	Dipartimento di Medicina	Montecchio, RE
Adriano Gatti, Michele Bonavita, Renato Carleo, Eugenio Creso, Raffaele Giannettino, Massimo Gobbo	Ospedale S. Gennaro ASL Napoli 1	Diabetologia	Napoli
Salvatore Turco, Anna Amelia Turco, Iovine Ciro	Università Federico II	Dipartimento di Medicina Clinica e Sperimentale - Diabetologia	Napoli
Annamaria Cicalò	Ospedale Vecchio	Servizio di Diabetologia	Nuoro
Giuseppe Saglietti	ASL14 - Ospedale di Verbania	Servizio di Diabetologia	Omegna, VB
Antonella Schellino	Ospedale Castelli	Struttura Complessa di Diabetologia e Malattie Metaboliche	Pallanza, NO
Orazio Vasta			Paternò, CT
Maria Teresa Tenconi, Federico Roncarolo, Carlo Mazzaro	Università di Pavia	Dipartimento di Medicina Preventiva Occupazionale e di Comunità - Sezione di Igiene	Pavia
Adriano Spalluto, Luigi Maggiulli, Lara Ricciardelli	Azienda Ospedaliera San Salvatore	Servizio di Diabetologia e Malattie Metaboliche	Pesaro
Donatella Zavaroni, Umberto De Johannon	Ospedale Guglielmo da Saliceto	U.O. di Diabetologia	Piacenza
Renzo Gelisio, Patrizia Li Volsi	ASL 10 Veneto Orientale (Ospedale vecchio)	Servizio di Diabetologia	Portogruaro, RO
Paolo Di Bartolo, Francesco Cannatà	Presidio Ospedaliero di Ravenna AUSL Provincia di Ravenna	U.O. di Diabetologia, Dipartimento di Malattie Digestive e Metaboliche	Ravenna
Celestino Giovannini	Polo Sanitario Reggio Calabria Nord ASL 11	Servizio di Diabetologia e Malattie del Ricambio	Reggio Calabria
Emilio Rastelli	Ospedale di Riccione AUSL Rimini	Diabetologia e Malattie Metaboliche	Riccione, RN
Guido Testa, Simonetta Colasanti, Grazia Maria Lombardi	Ospedale Luigi Di Liegro ASL Roma D	Struttura Complessa Malattie del Metabolismo e Diabetologia	Roma
Giuseppe Maraglino	AO Santa Maria degli Angeli	U.O.S. di Diabetologia	Sacile, PN
Giacomo Vespasiani, Illidio Meloncelli, Lina Clementi, Marianna Galetta, Milena Santangelo	ASUR Regione Marche - Zona Territoriale 12	Centro di Diabetologia e Malattie del Ricambio	San Benedetto del Tronto, AP
Stefano Parini, Maria Camilla D'Antonio, Mariaelena Vacchetti	Azienda ASL Bologna - Distretto Nord - U.O. Medicina Interna	Ambulatori Diabetologia San Giovanni in Persiceto e Crevalcore	San Giovanni in Persiceto, BO
Giorgio Arpaia, Silvestre Cervone	Azienda ASL FG1- Stabilimento ospedaliero San Marco in Lamis	U.O. Medicina Interna - Servizio Malattie Metaboliche e Diabetologia	San Marco in Lamis, FG
Maura Gardinali	Casa di Cura S. Maria Maddalena	U.O. di Diabetologia	Santa Maria Maddalena, RO
Silvana Manfrini	Ospedale di Senigallia	U.O. Diabetologia	Senigallia, AN
Italo Tanganelli	Azienda Ospedaliera Universitaria Senese	Biotecnologie Applicate alle Malattie del Ricambio	Siena
Giuseppe Felace, Elena Tortato	Ospedale San Giovanni dei Battuti di Spilimbergo	Medicina ambulatorio di Diabetologia	Spilimbergo, PN
Giovanni Divizia	Ospedale Generale San Matteo degli Infermi	Servizio di Diabetologia e Malattie Metaboliche	Spoleto, PG
M. Bruna Diodati	Ospedale Civile SS. Annunziata	U.O. di Diabetologia	Sulmona, AQ
Massimo Veglio	Ospedale Evangelico Valdese	U.O. Autonoma di Malattie Metaboliche e Diabetologia	Torino
Mario Vasta, Maurizio Sudano, Maria Grazia Pronti, Gigliola Martinelli	Ospedale Civile di Urbino	Servizio di Diabetologia	Urbino
Silvio Sposito	Ospedale Civile V. Colombo	U.O.S. Diabetologia	Velletri, RM
Francesco Cervellino, Armando Zampino, Rosa Sinisi	Ospedale San Francesco ASL 1	Unità Speciale di Diabetologia	Venosa, PZ
Alfonso Basso, Marco Strazzabosco	Ospedale San Bortolo	Servizio di Diabetologia	Vicenza

Methods

The AMD Annals are the result of a joint collaboration among 86 Italian diabetes centers that use computerized systems (electronic medical record) in routine patient management and standardized extraction of information in the AMD Data File. This file is the basic tool since it provides all the necessary information for describing process and outcome indicators.
A fundamental premise for correct data interpretation concerns the inevitable overlap between the quality of care delivered and the quality of data collected. In other words, a reliable evaluation of the quality of delivered care cannot be separated from a correct use of the electronic medical records. Partially completed data on services delivered make it impossible to distinguish between whether a certain procedure was not performed (e.g. fundus inspection) or not recorded on the chart. As discussed elsewhere, this problem has made using certain indicators impossible and influenced the selection of centers in the analysis.

Selection of Centers

To ensure a representative level of clinical practice, centers 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 77 centers were eligible for care profile analysis. Similarly, centers 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 because in some centers the computerization of clinical data was activated only recently and regarded only a part of the patients receiving care.

Selection of Population

All analyses regard active patients in the year 2004, i.e. all DM1 or DM2 patients who underwent at least one examination, measurement of glycosylated hemoglobulin or fasting glycemia or were prescribed a diabetes drug during the index year.

Definition of Gold Standard

For the selected process and intermediate outcome measures, the total performance and that of the single centers were evaluated in relation to a gold standard. These reference values were calculated from those centers that had complete information about:

Variable	Threshold value (≥)
Sex	90%
Age	90%
Type of diabetes	90%
HbA1c	70%
blood pressure	70%
Body-mass index	70%
Lipid or LDL-cholesterol profile	50%
Indication of diabetes therapy	85%

This process led to the selection of 30 centers. To define the gold standard, the 75th percentile of the distribution of the values of these centers was used. This value represents the best performance obtained by 25% of the centers with the highest values. For example, the gold standard of the process indicator "measurement of HbA1c in DM2" is 97%. In other words, 25% of the selected centers measured HbA1c in at least 97% of their patients during the study period. In the remaining

75% of centers the percentage of those which measured HbAc1 was lower.
In the measurement of positive intermediate outcomes (e.g. percentage of patients with HbA1c <7%), the analysis was the same. When intermediate outcomes were negative (e.g. percentage of patients with HbA1c ≥8%), the gold standard was based on the 25th percentile (e.g. the value obtained by 25% of centers with the lowest percentage of patients with HbA1c ≥8%).

General Descriptive Data

Except for certain descriptive aspects furnished for the entire sample (123,863 subjects), the characteristics of the study population were reported separately for DM1 patients (6999 subjects) and DM2 patients (114,249 subjects). The data concern socio-demographic characteristics (age, sex) and clinical parameters (body-mass index [BMI], HbA1c, blood pressure, triglycerides, total cholesterol, HDL and LDL). When not recorded on the medical chart, the LDL levels were calculated using the Friedwald formula. LDL cholesterol was calculated only when the medical chart also showed total cholesterol, HDL and triglycerides measured at the same visit.
Since the normal range of HbA1c varied from center to center, to permit comparative analysis, the values were mathematically transformed. In other words, the value of each patient was divided by the upper limit of the normal range at a specific center, thus obtaining the percentage shift of the value from the upper limit of the normal range. This value was then multiplied by 6.0 to permit an interpretation of the data on HbA1c, using 6.0% as the normal reference value.

Selection of Indicators

As mentioned, this report is based partly on the indicators used in the AMD Data File.

Process indicators
Of the selected indicators, those regarding at least once yearly monitoring of:

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

For all indicators the denominator was the number of active patients in the index year, excluding centers that reported fewer than 10 active DM1 patients or fewer than 100 active DM2 patients.
A further process indicator - the mean number of visits grouped by type of treatment - was evaluated only in those centers that had recorded at least one examination in at least 80% of active patients. This selection was necessary because in some centers the electronic medical record was not used to quantify the services delivered and so not all examinations were recorded in the data field needed to create the AMD data file.
Noteworthy is that among the process indicators in the Data File, fundus inspection was not included nor assessment of neuropathy. The test results were often reported on the electronic medical record as free text and so were unusable for statistical analysis.

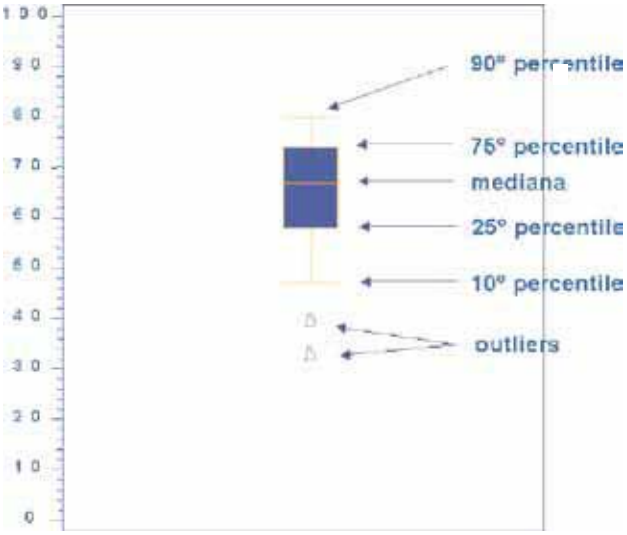
Intermediate outcome indicators
The intermediate outcome indicators were:
- Percentage of patients with HbA1c <7% and ≥8%
- Percentage of patients with LDL cholesterol level <100 mg/dl and ≥130 mg/dl
- Percentage of patients with blood pressure <130/85 mm Hg and ≥140/90 mm Hg
- BMI classes
- Percentage of smokers
- Percentage of patients with LDL ≥130 mg/dl not on statin therapy
- Percentage of patients with blood pressure ≥140/90 mm Hg not on antihypertensive therapy

For all these indicators the denominator was those patients with at least one finding of these parameters during the index year. As mentioned, excluded from the analysis were those centers where these parameters

were measured in fewer than 10 DM1 patients or in fewer than 100 DM2 patients.
The last two indicators were calculated only in those centers with sufficient information about current treatment (at least 5% of patients receiving statin therapy and at least 10% of those receiving antihypertensive treatment).
The percentage of smokers was calculated only in those centers where at least 10% of patients were smokers.

Final outcome indicators
These indicators, although highly important and appropriately contemplated in the Data File, are outside the scope of this report. As with other process measures, information on long-term complications were often reported in free text on the medical records rather than being coded, despite the standard code fields listed on the record.

Boxplot



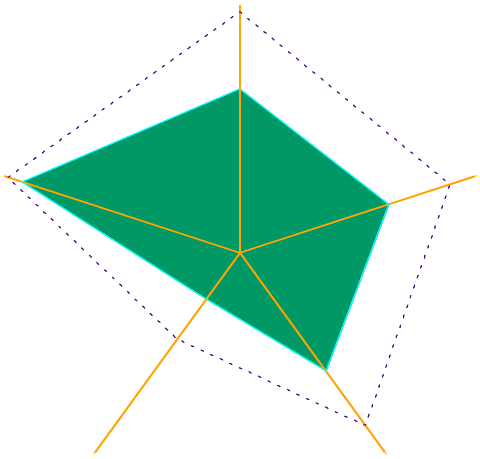
Graphical Representation of Data

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

Prevalence of diabetes by region
This map provides a close idea of the percentage of patients with diabetes within each region of the country. To this end, the estimated diabetes prevalence (4.5%) was used for each region. This prevalence was then applied to each region using the 2002 ISTAT data to quantify the resident population. The intensity of shading of the regions is proportionate to the percentage of patients included in the Data File with respect to the estimated percentage.

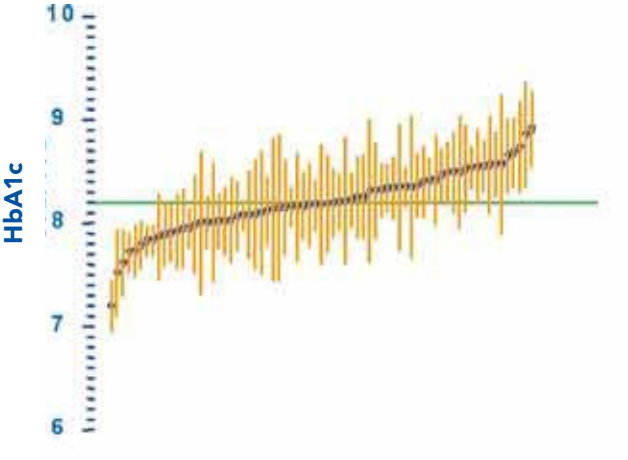
The boxplots give a simple yet complete summary of a variable's distribution. As shown in the figure, a boxplot consists of a rectangle with a center line that indicates the median, while the upper and lower hinges correspond to the 75th and the 25th percentiles, respectively. The bars extending above 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 of the bars graphically indicates the variability of the index in question: a flattened box shows the measure in question 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.

Starplot



Starplots summarize in a single figure multiple variables, 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 center to the border of the starplot. The values on the radii are joined to form a polygon. Each figure contains two starplots, the one with a dashed line border represents the gold standard values calculated as described above; the one with solid lines represents the values obtained on the entire sample or by single center/patient subgroup. The closer the points of the solid line bordered starplot are to those of the starplot with dashed lines, the closer the quality of care in that specific center/patient subgroup matches the desired value (i.e. that obtained by the best centers). In process measures, the wider the polygon, with points close to 100%, the better the care delivered.
A starplot much smaller than the one with dashed lines (on one or more radii) denotes a gap between delivered quality of care and desired quality level. To represent intermediate outcome measures, the starplot is divided into two parts: the upper half (in green) indicates the percentage of patients with a favorable outcome (e.g. HbA1c <7%, blood pressure <130/85 mm Hg, LDL <100 mg/dl), while the lower half (in red) indicates the percentage of patients with unfavorable values (e.g. HbA1c ≥8%, blood pressure ≥140/90 mm Hg, LDL ≥130 mg/dl), so that the larger the green area and the smaller the red area, the greater the number of positive outcomes.

Variability figures

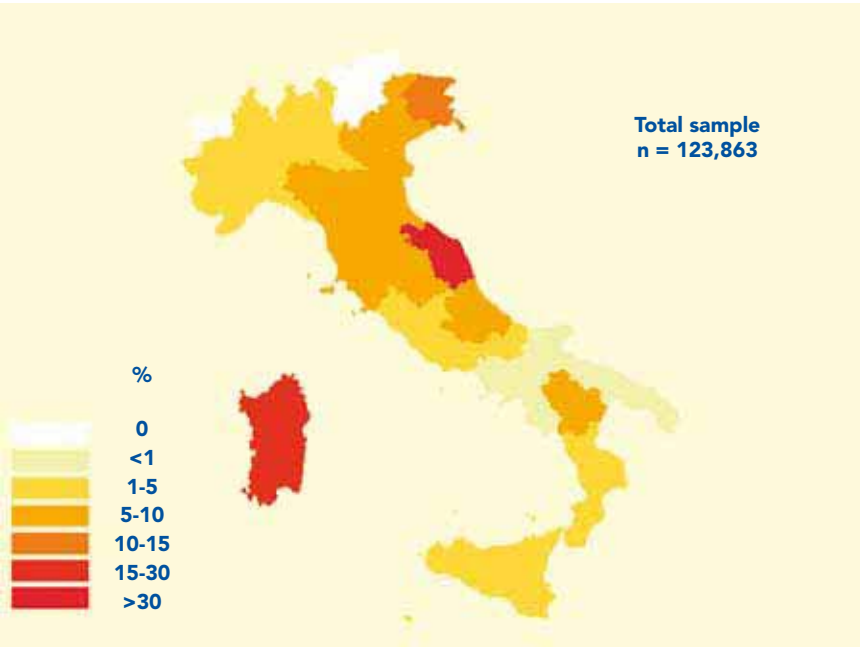


Variability in process and intermediate outcome measures among centers was obtained using multilevel analysis, adjusting the values for patient age and sex and for the clustering effect (patients followed up at the same center cannot be considered independent measures since they tend to receive similar care).
For each center, the mean value or percentage is reported together with the 95% confidence interval estimated in the multilevel model. With this approach the mean HbA1c values can be compared among the centers (or the percentage of patients with HbA1c <7%) matched for sex and age.
The values can be ranked in increasing order to gain an idea of the variability among centers for a certain measure. The center line indicates the mean of the entire study sample, thus allowing a rapid evaluation of how far the values of each center lie outside the mean.

Map and General Descriptive Indicators

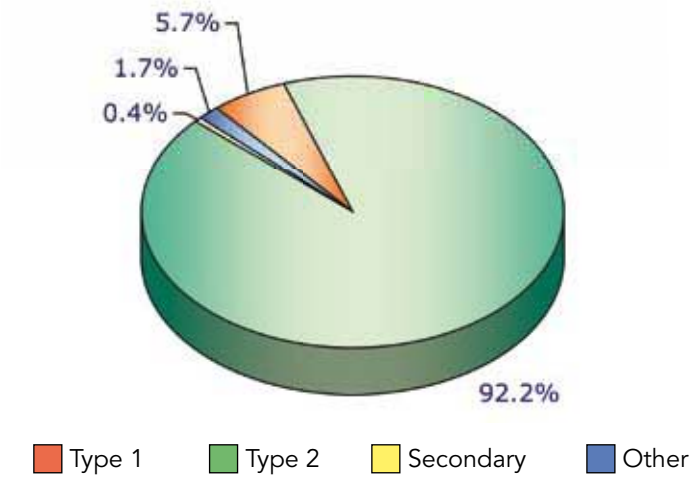
Proportion of Patients in the AMD Data File of the Estimated Total of Diabetic Patients (Prevalence 4.5%)

In all, data were provided on 123,863 patients examined at 86 centers in 2004 (median, 1280 patients per center; range, 149-6076), 121,248 of which presented with a diagnosis of DM1 (6999) or DM2 (114,249).
Of the DM1 patients, 42.5% were recruited from the north, 21.7% from the central regions, and 35.8% from the south. Of the DM2 patients, the number from north to south was 43.8%, 31.9% and 24.4%, respectively.
The map shows the distribution of the study sample by region. In most regions, the percentage of patients was 5-10% of the estimated number of diabetic patients, with a peak of 30% for the Marches.



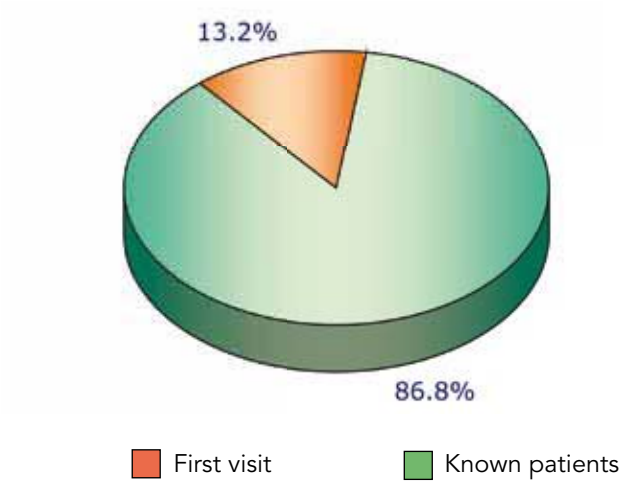
Indicators of the General Population

Distribution by Type of Diabetes



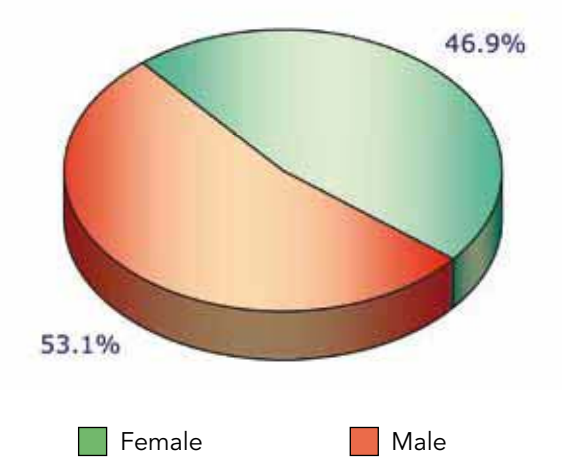
The distribution by type of diabetes shows that care was predominantly delivered to DM2 patients (90%) examined during 2004.

First visit Versus Total Visits During 2004



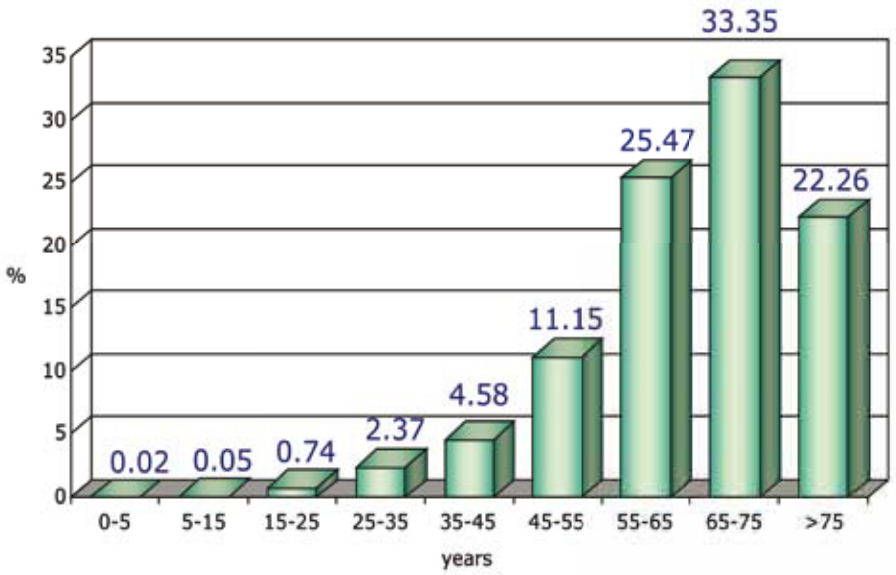
Of a total of 123,863 patients examined in 2004, 16,398 (13.2%) visited a diabetes care center for the first time, suggesting that a considerable number of patients seek specialist consultation.

Distribution by Patient Sex



Slightly more men than women sought specialist consultation.

Distribution of Treated Patients by Nine Age Groups

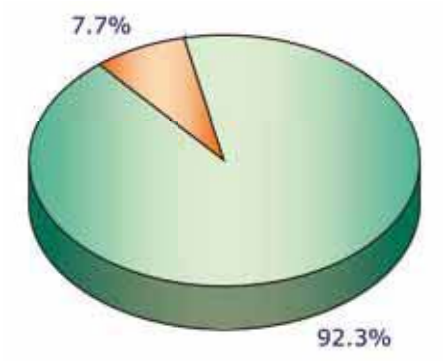


Distribution by age group shows that more than half of treated patients were over 65 years of age, highlighting that an important part of care is delivered to older population segments.

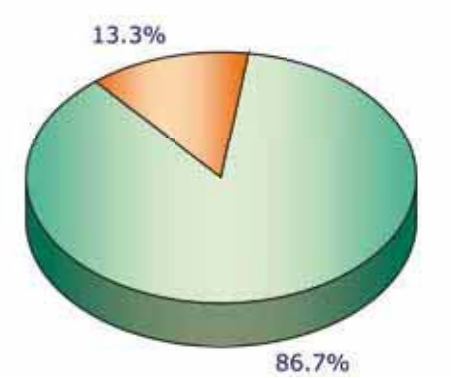
Indicators of Type 1 and 2 Diabetes

First Visit Versus Total Number of Visits During 2004

DM1



DM2

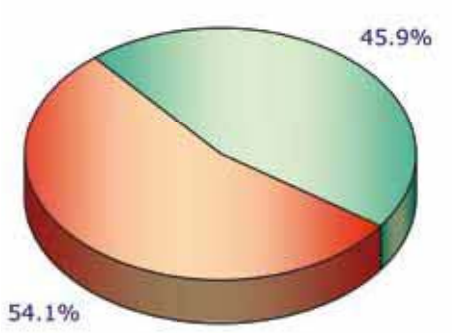


First visit Known patients

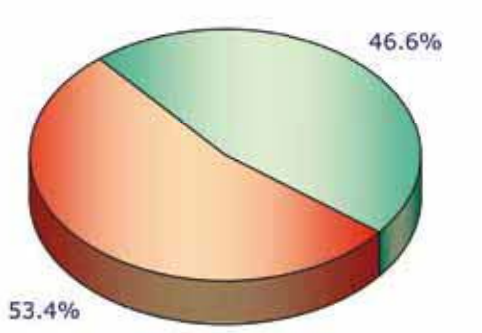
Among the DM1 patients, 536 (7.7%) of 6999 had their first visit during 2004; among the DM2 patients, 15,196 (13.3%) of 114,249 had their first visit. This comparative finding shows that proportionately more first visits are for diabetes type 2.

Distribution by Patient Sex

DM1



DM2

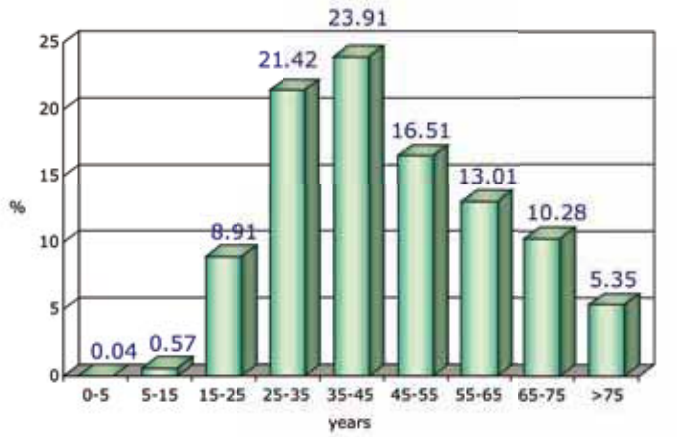


Female Male

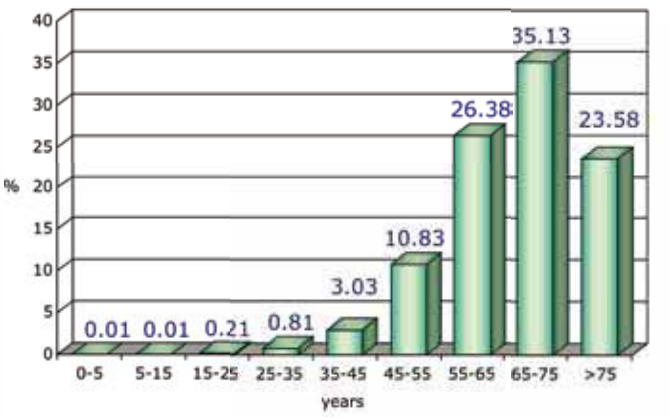
Among both DM1 and DM2 patients there was a slight predominance of men.

Distribution of Population by Nine Age Groups

DM1



DM2



As expected, the distribution by age group differed between the two types of diabetes. DM1 patients were younger; 30% were over 65 years of age; 50% were between 15 and 45 years. DM2 patients were older, but a consistent percentage of patients aged between 45 and 55 years or younger was also present.

Comment on General Indicators

As can be seen from the map on page 6, the entire country was represented, but with different percentages of inclusion. For this reason, we decided not to analyze the data by region, even if in some regions a percentage of inclusion greater than 10% could have permitted a local analysis. Those regions wishing to conduct local analysis should contact the regional AMD president's office.

The distribution of diabetic patients across diabetes centers shows a prevalence of DM1 of 6%, which is lower than the expected 10%. Rather than as an overestimate of DM1 prevalence, this value should be interpreted as the consequence of a sharp increase in DM2 in recent years.

Also noteworthy is that 13.2% of patients (13.3% of DM2 and 7.7% of DM1 patients) sought first consultation at a specialized center in 2004. These figures indicate the huge growth in services diabetes centers must deliver each year to an ever higher number of new patients, with a complete turnover of patients attending a diabetes center that is more rapid than the natural history of the disease. Given a fixed total number of diabetes cases per center, all patients would be replaced by new ones over a span of 7 years. This means that even with other players in diabetes care, and not only internal physicians, the large proportion of diabetics who do not seek treatment until chronic complications develop cannot be underestimated. While the number of persons with type 2 diabetes in Italy is not significantly high as yet, about 4% are between 25 and 45 years of age.

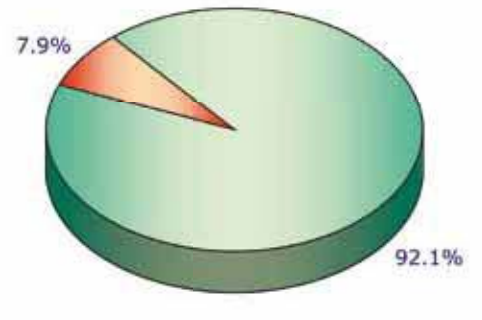
Giacomo Vespasiani

Process Indicators

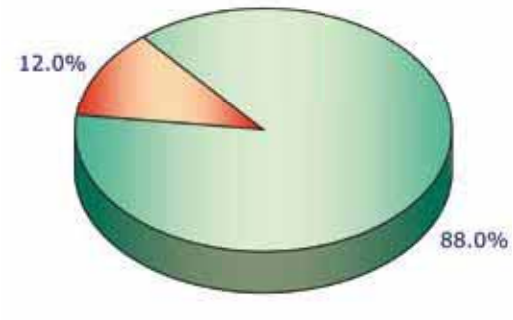
AMD Process Indicators Analyzed by Type of Diabetes

Subjects Who Had Hba1c Measured at Least Once During 2004

DM1



DM2

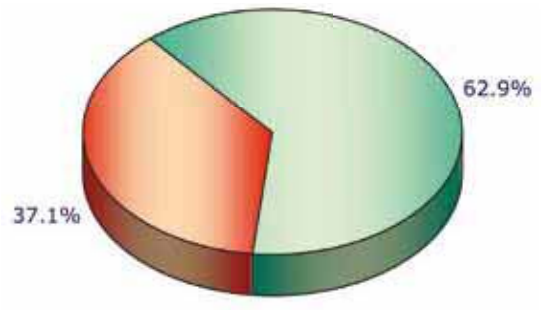


Yes No

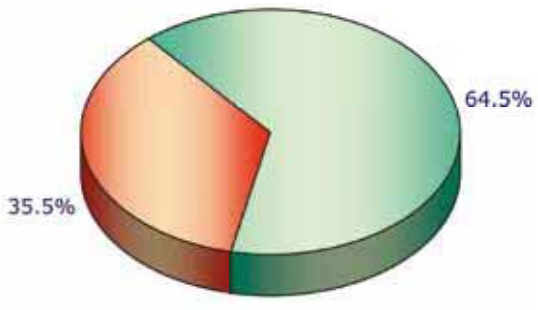
In both types of diabetes HbA1c monitoring represents an integral part of care in nearly all patients.
HbA1c was measured at least once in 2004 and recorded in the database in over 90% of DM1 and 88% of DM2 patients.

Subjects Who Had Lipid Profile Evaluated at Least Once During 2004

DM1



DM2



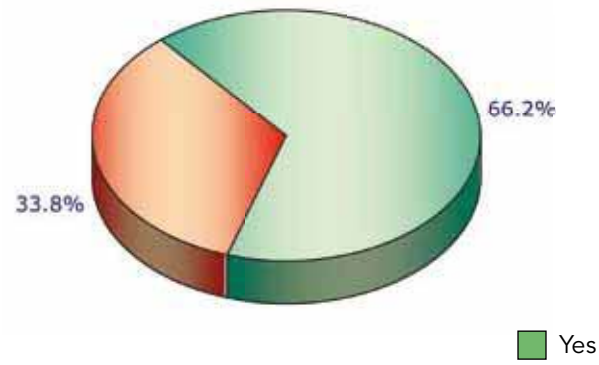
Yes No

Despite the elevated risk of cardiovascular disease, lipid profile monitoring was less consistent than HbA1c monitoring.

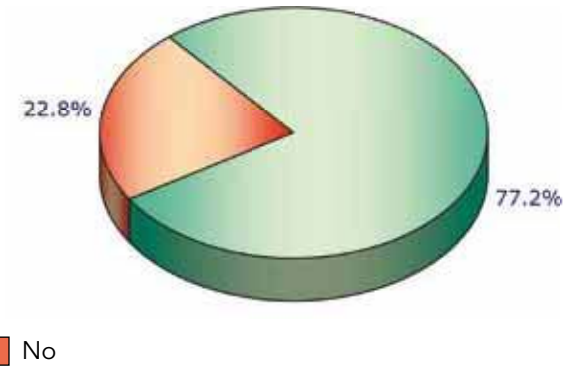
Over one third of patients, both DM1 and DM2, did not have their lipid profile evaluated during 2004.

Subjects Who Had Blood Pressure Measured at Least Once During 2004

DM1



DM2



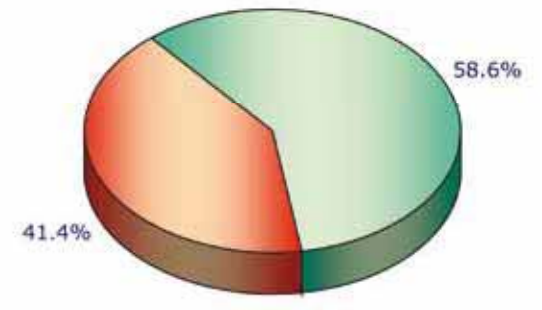
Yes No

As with lipid profile monitoring, blood pressure monitoring was not always consistent according to the medical records.

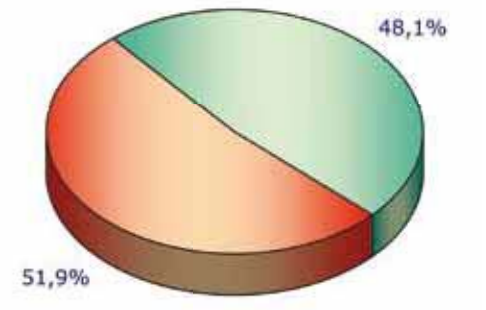
However, there seems to be greater attention directed at DM2 than DM1 patients (75% vs. 66%).

Subjects Assessed for Nephropathy

DM1



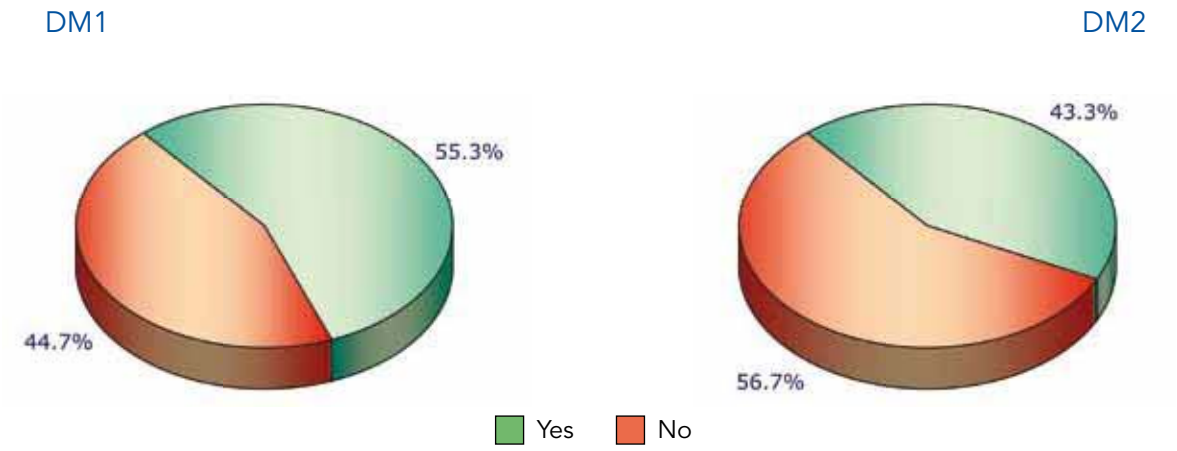
DM2



Yes No

Unlike cardiovascular risk, assessment of renal function seems to be more often performed in DM1 than DM2 patients (59% vs. 50%); nonetheless, renal function assessment was not performed in nearly half of either patient group.

Subjects at Risk of Diabetic Foot



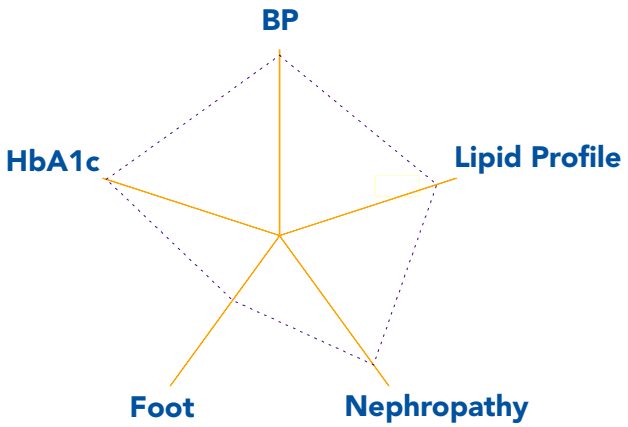
Among the subjects considered at risk (neuropathy, previous trophic lesions or amputations, arteriopathy of the lower extremities), 55% of DM1 patients and less than half of DM2 patients had their feet examined during the index year. This underlines the need to intensify monitoring of one of the most incapacitating complications of diabetes.

Subject Assessed for Diabetic Foot

Poor attention to foot examination is all the more evident from an analysis of the entire sample. Only one fifth of patients, both DM1 and DM2, were recorded as having undergone foot examination during 2004.

Starplot Analysis by Type of Diabetes, Patient Sex and Age, and Region of Country

Process Indicators

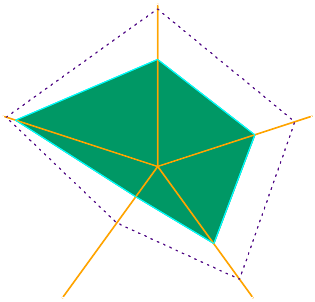


The starplots represent the process measures. In detail, each radius indicates the percentage of patients for which the electronic medical record showed at least one examination during 2004 for the following parameters: HbA1c, blood pressure, lipid profile, renal function, foot examination. For each starplot, the dashed line border represents the gold standard (see Methods section), while the solid line refers to the patient group in question.

Sample Analyzed by Type of Diabetes

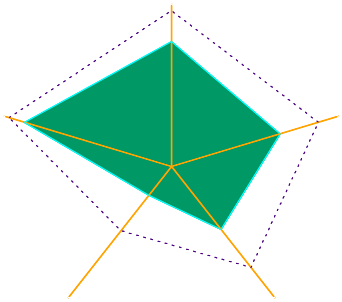
DM1

Entire sample



DM2

Entire sample



As regards DM1, the dashed line starplot shows that extremely satisfying percentages were obtained by those centers that define the gold standard related to monitoring of glycemic control (98%), blood pressure (97%), lipid profile (89%), and renal function (86%), whereas information on foot examination (43%) lies below optimal levels.

An analysis of the entire sample shows, however, a marked gap between the actual values and the gold standard, except for HbA1c monitoring (92%), blood pressure (66%), lipid profile (63%), renal function (59%), foot examination (23%).

As regards DM2, the dashed line starplot shows extremely satisfying percentages for those centers that define the gold standard for glycemic control (97%), blood pressure (96%), lipid profile (88%), a satisfactory percentage of patients monitored for renal function (77%), whereas foot examination (49%) was subopti-

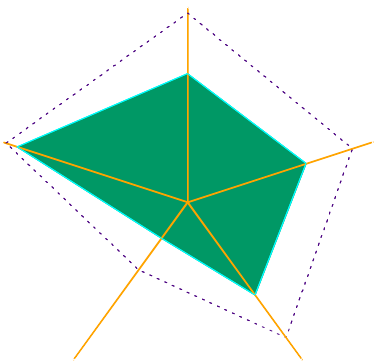
mal. A marked gap between the gold standard and the entire sample was also found for DM2. While the gap for HbA1c monitoring was small (88%), it was much larger for all other parameters, including blood pressure (77%), lipid profile (65%), renal function (48%) and foot examination (22%).

A comparison between the two patient groups shows that HbA1c and renal function were the two parameters most often monitored, while blood pressure was more often reported for DM2. No major differences in monitoring of lipid profile or foot examination emerged from the comparison.

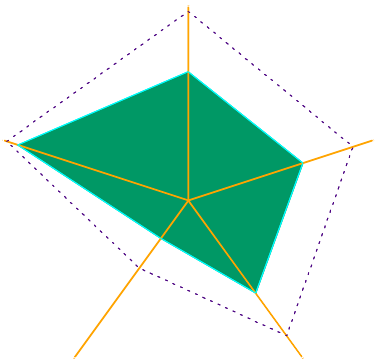
Sample Analyzed by Type of Diabetes and Patient Sex

DM1

Female

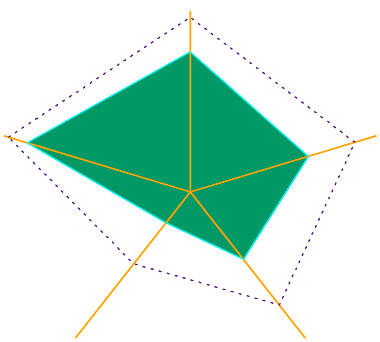


Male

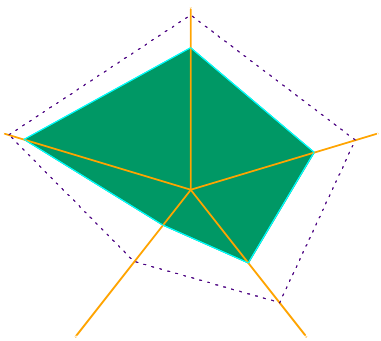


DM2

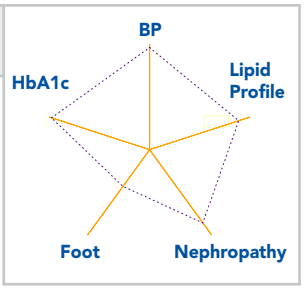
Female



Male

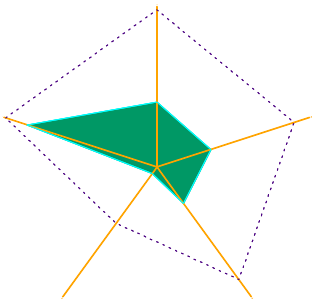


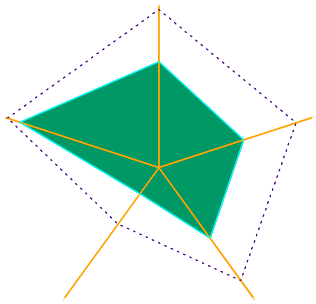
No differences emerged between male and female patients in either DM group for these parameters. The gap between the gold standard and the total sample shows, regardless of the sex of the patient, a real margin for improvement in patient care.

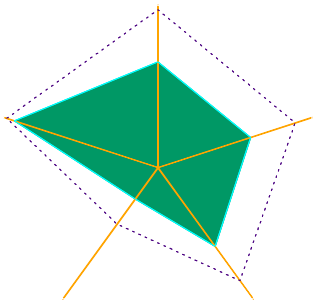


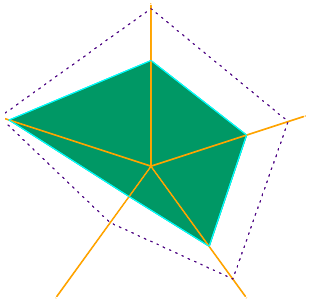
Sample Analyzed by Type of Diabetes and Age Group

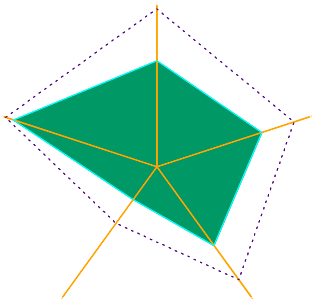
DM1

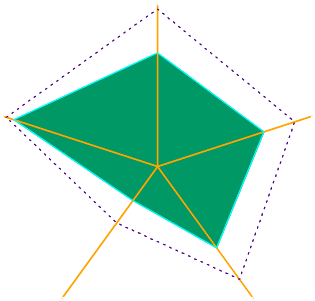

0 - 15

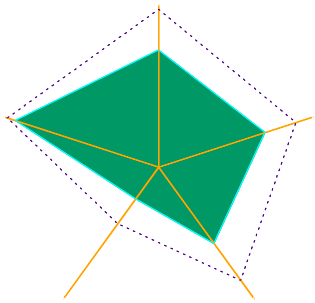

15 - 25


25 - 35


35 - 45


45 - 55


55 - 65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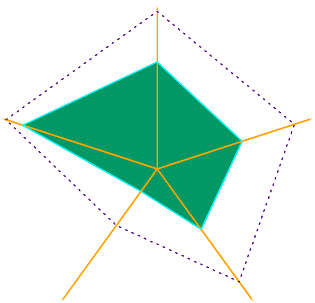
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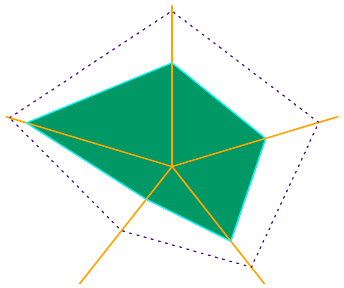
Sample Analyzed by Type of Diabetes and Age Group

DM2



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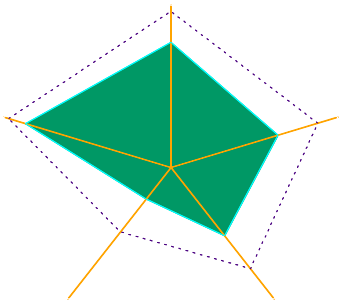

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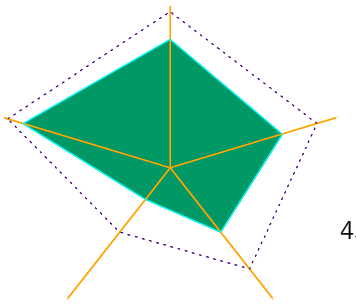

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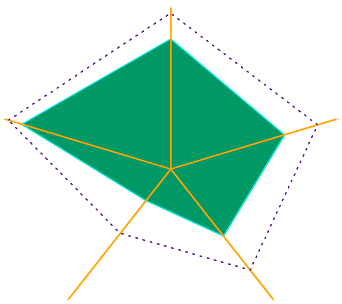

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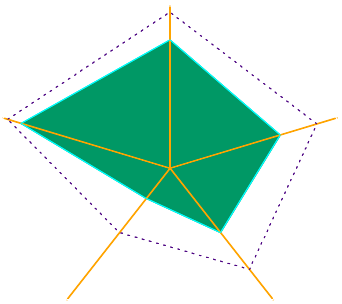

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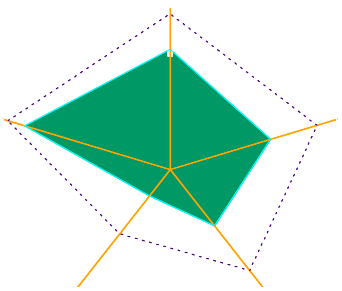

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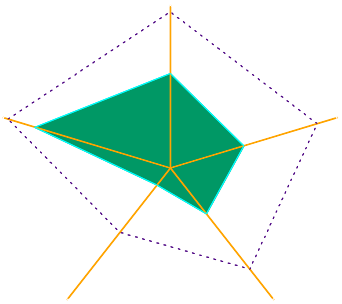
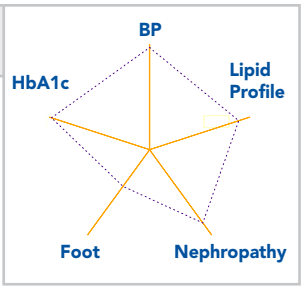


> 85

In DM1, except for younger and older patients in 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 aged over 75 and even more so in those aged over 85 years.

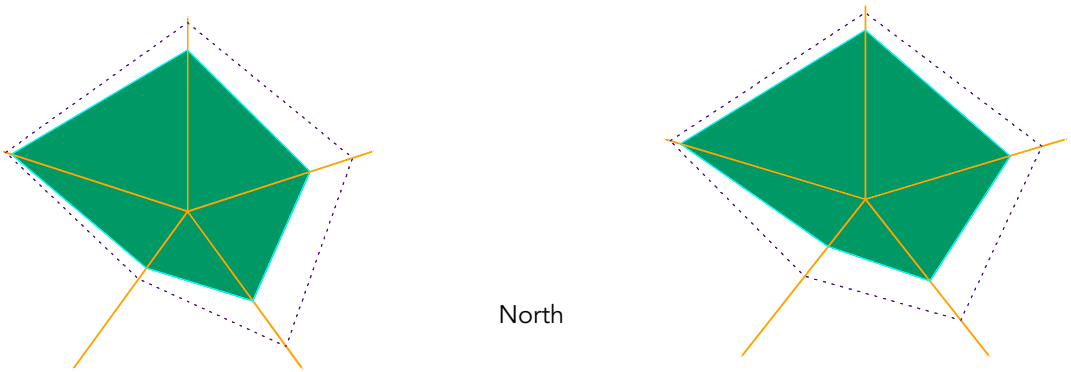
Starplot Analysis by Type of Diabetes, Patient Sex and Age, and Region of Country



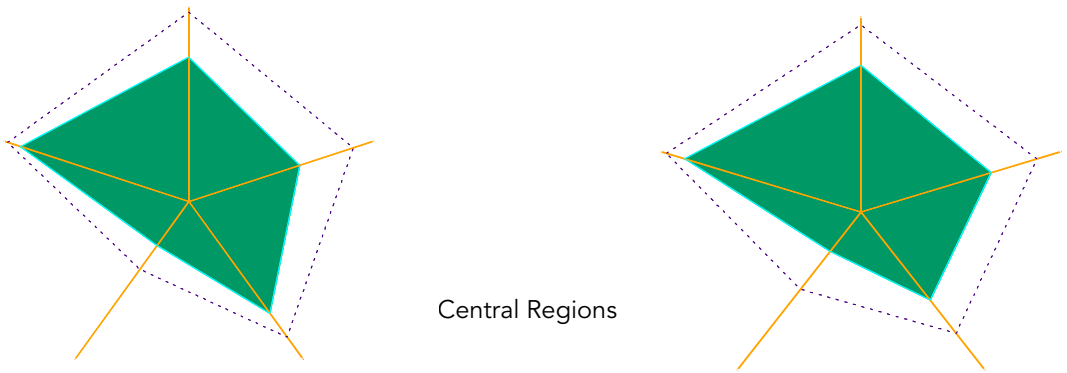
Sample Analyzed by Type of Diabetes and Region of Country

DM1

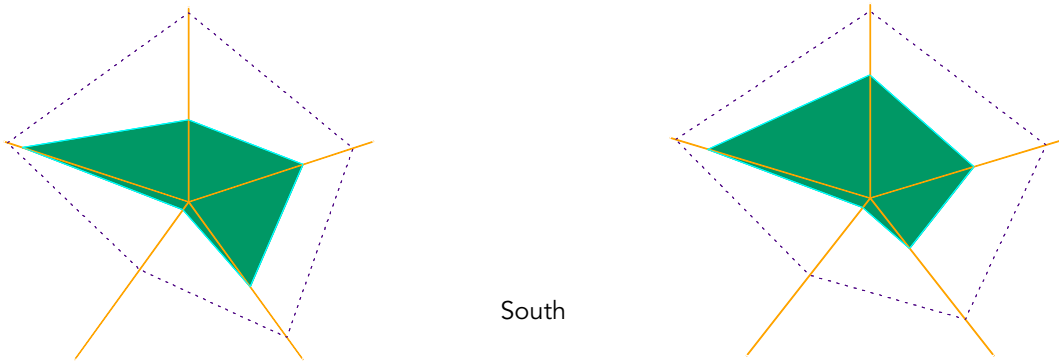
DM2



North



Central Regions



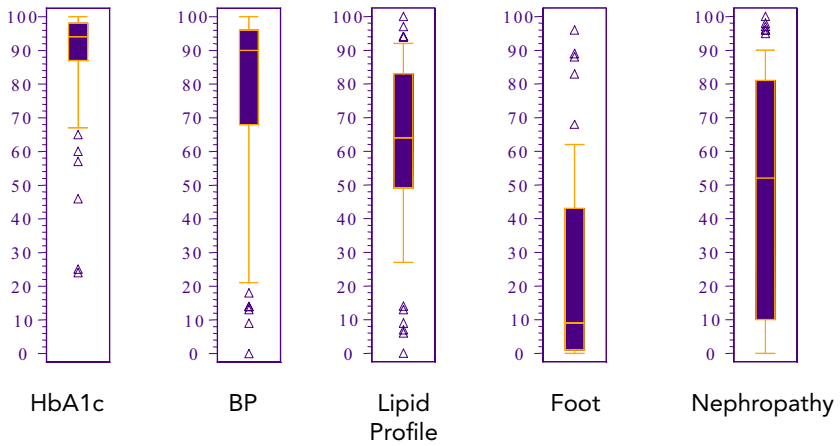
South

Moving from north to south, the information appears less and less complete for all process indicators in question in both types of diabetes.

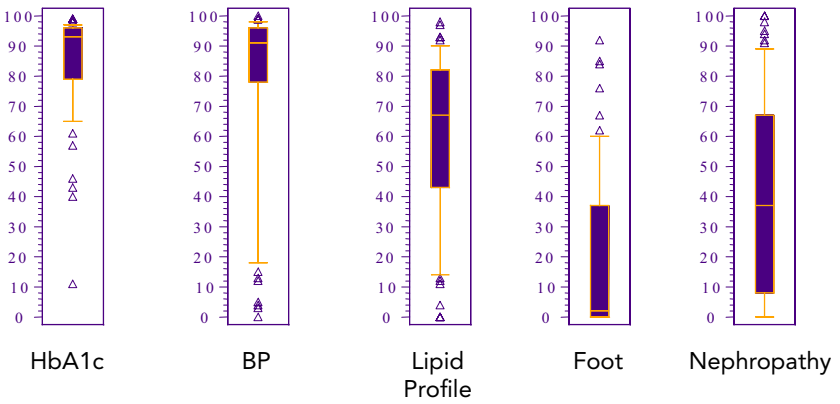
Boxplot of Centers Analyzed by Type of Diabetes

Process Indicators Analyzed by Center and Type of Diabetes

DM1



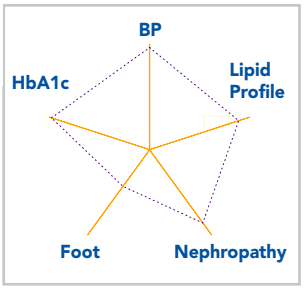
DM2



The figures show the level of variability among the centers for the process measures in question. For example, the percentage of DM1patients for which at least one value of HbA1c was available during 2004 was generally high (about 90%) in most centers; however, this measure was missing in others (a minimum of 25%). Variability was more marked for the other process measures, as shown by box height, and was particularly evident for renal function assessment.

A similar picture emerged for DM2. Noteworthy was that for all indicators some centers reported renal function assessment of nearly all patients, while in other centers this item was completely missing. Except for extreme cases, the variability among the centers was fairly limited for HbA1c and blood pressure monitoring and much wider for other parameters.

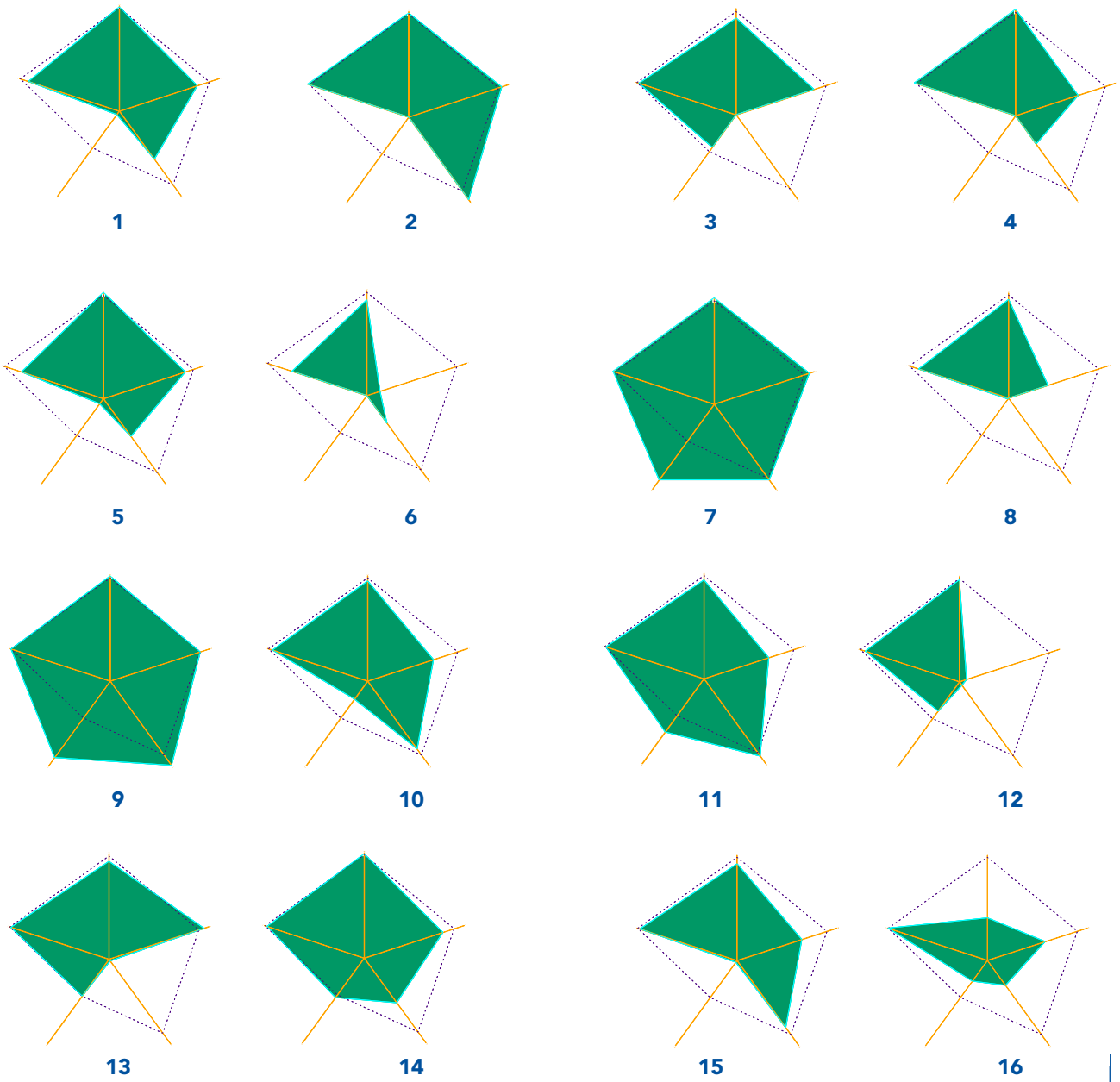
Starplots of Single Centers Analyzed by Type of Diabetes



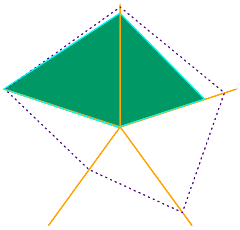
Sample of Each Center

The two sets of figures for each center show the extreme range in the availability of information about the process measures in question. It is not currently possible to establish whether and to what extent these differences are to be imputed to a fairly consistent use of the electronic medical record rather than to any real differences in the quality of care. Increasing attention to compilation of the electronic medical record will permit a more reliable evaluation of trends in quality of care in Italy.

DM1



DM1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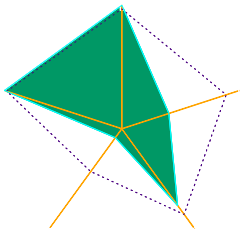
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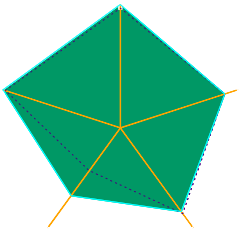
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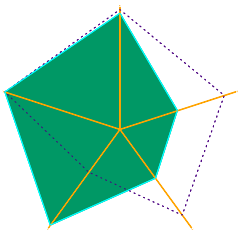
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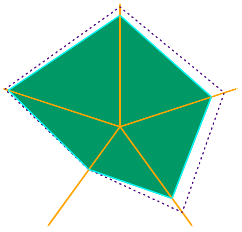
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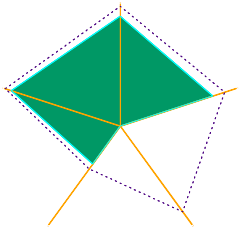
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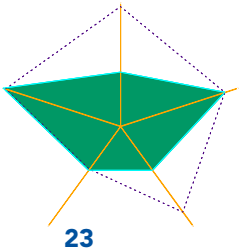
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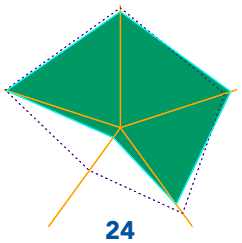
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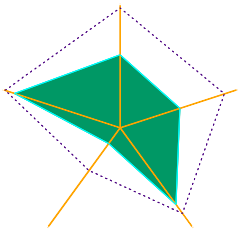
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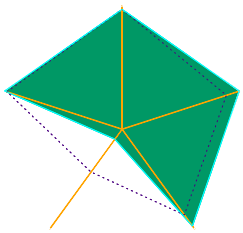
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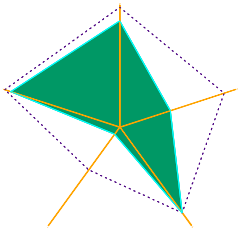
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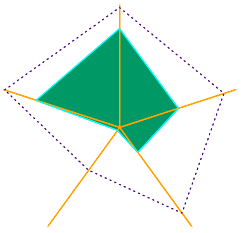
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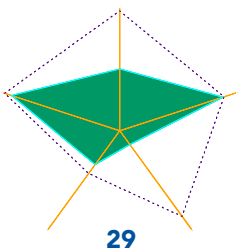
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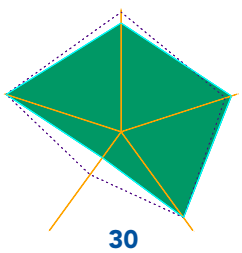
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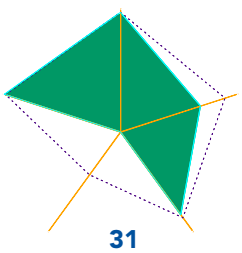
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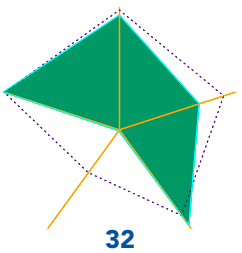
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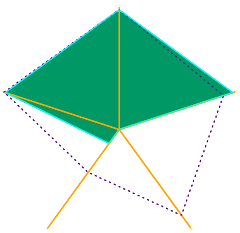
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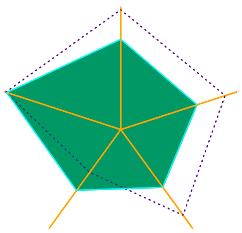
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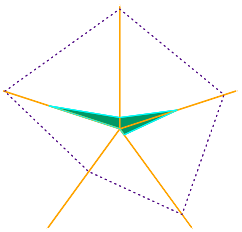
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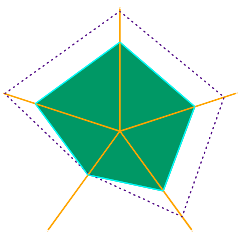
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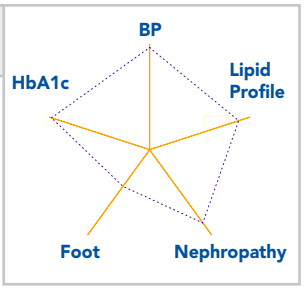
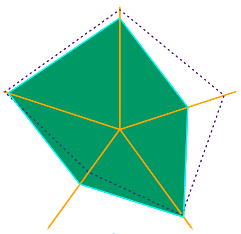
Starplots of Single Centers Analyzed by Type of Diabetes



DM1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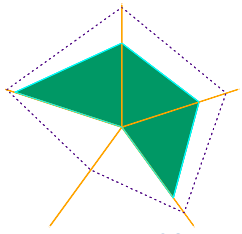
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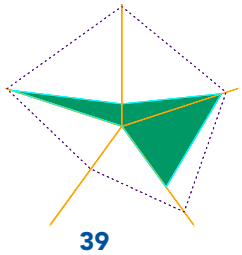
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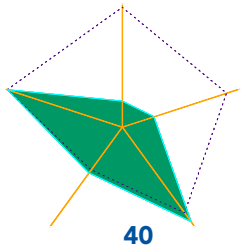
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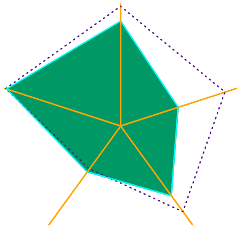
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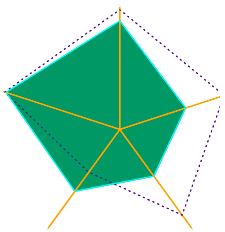
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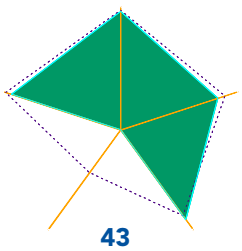
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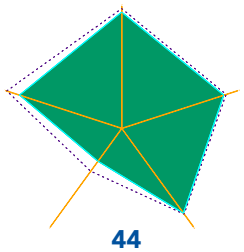
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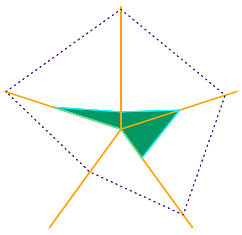
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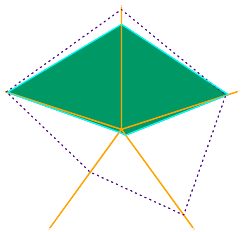
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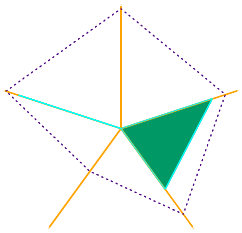
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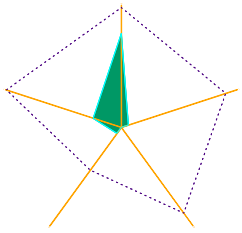
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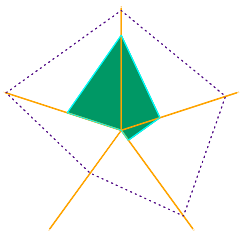
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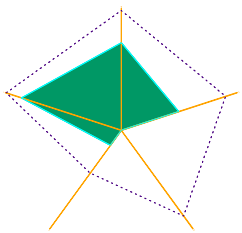
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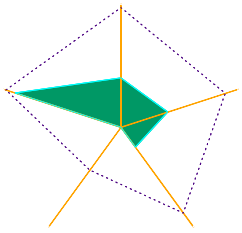
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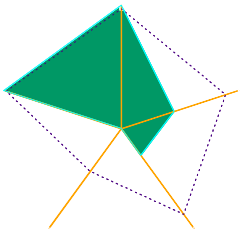
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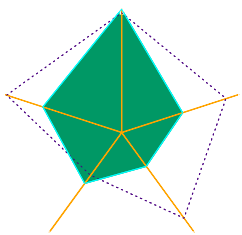
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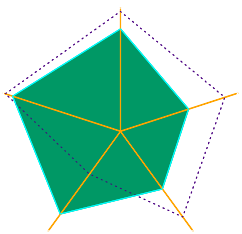
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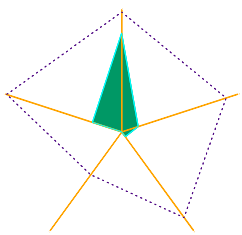
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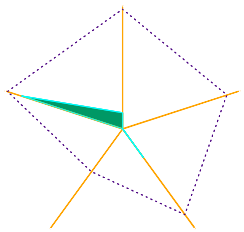
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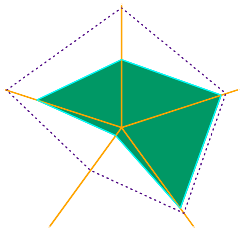
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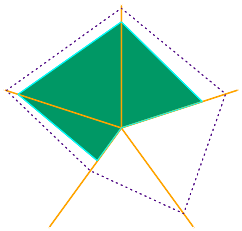
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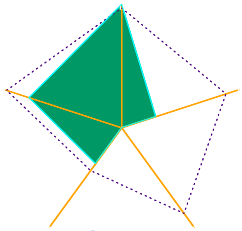
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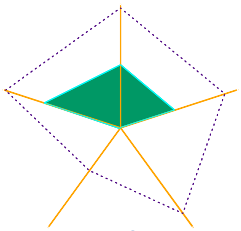
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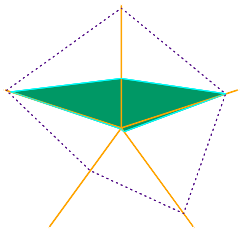
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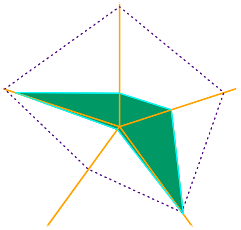
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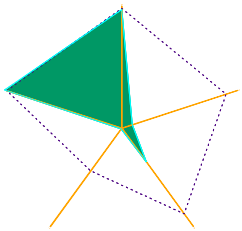
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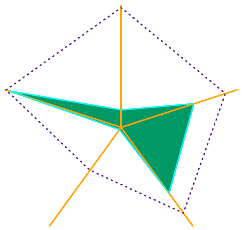
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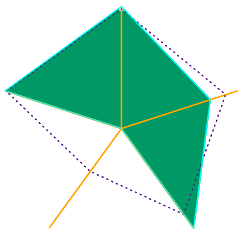
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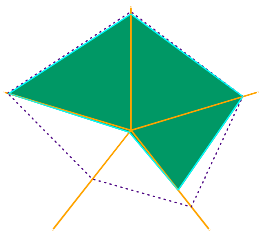
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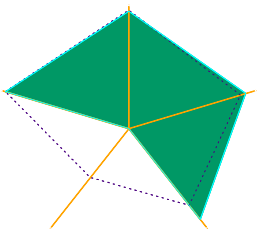
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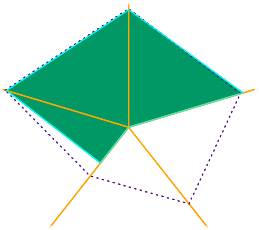
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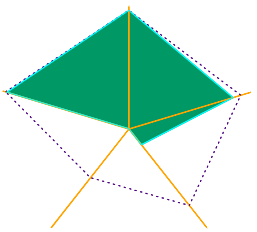
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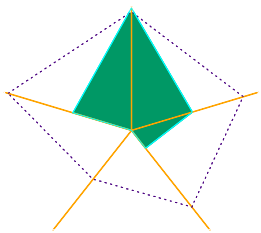
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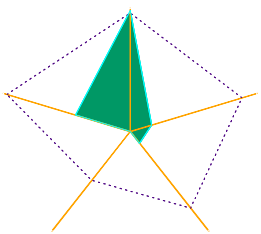
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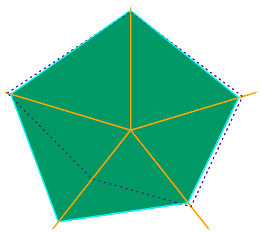
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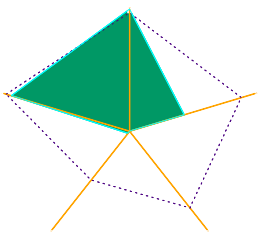
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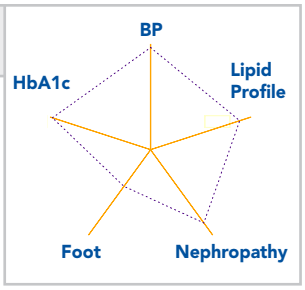
Starplots of Single Centers Analyzed by Type of Diabetes



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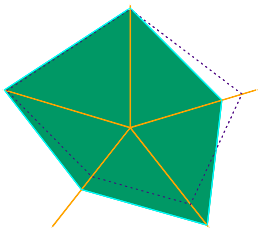
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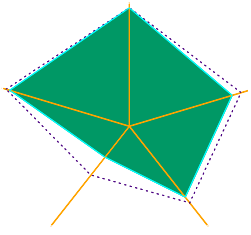
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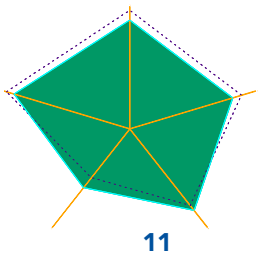
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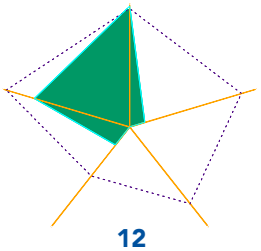
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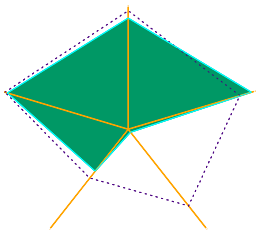
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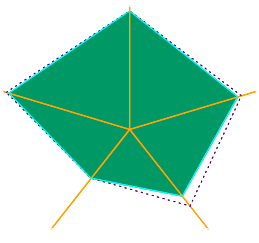
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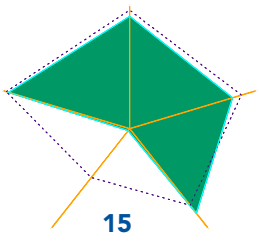
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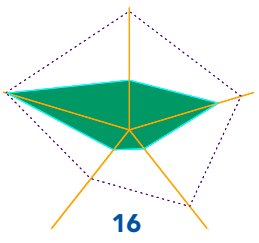
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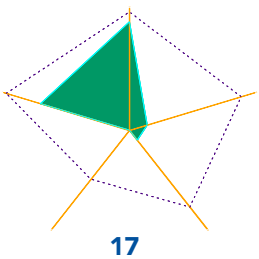
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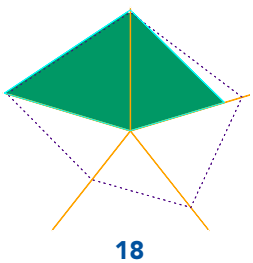
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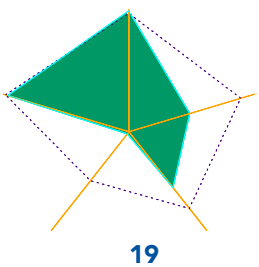
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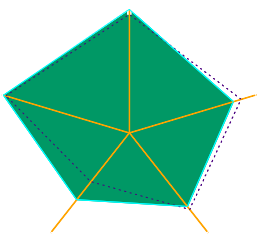
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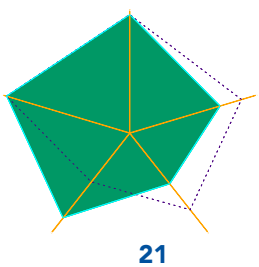
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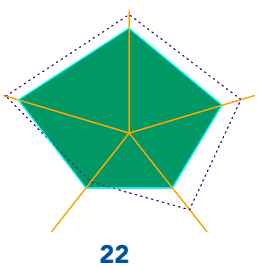
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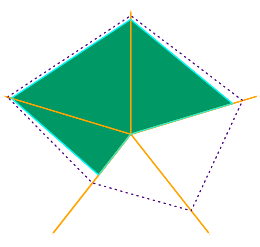
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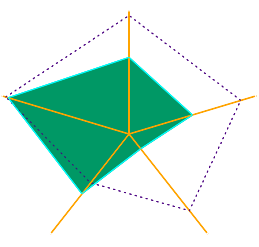
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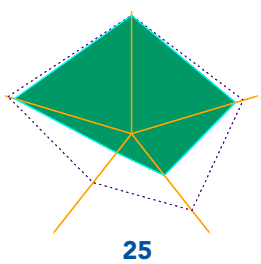
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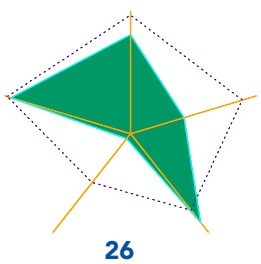
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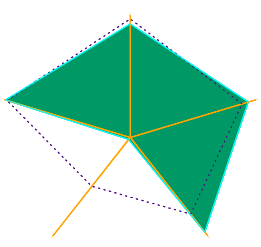
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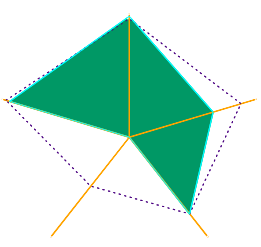
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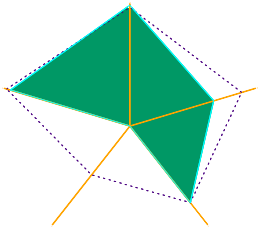
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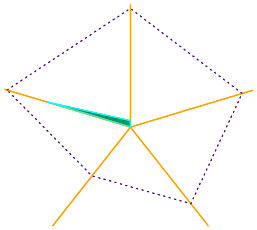
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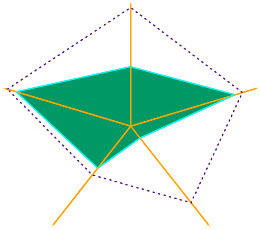
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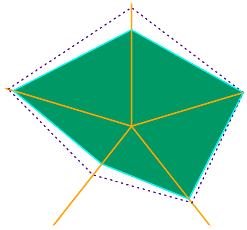
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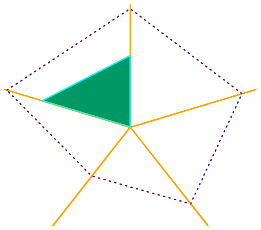
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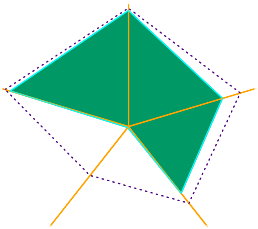
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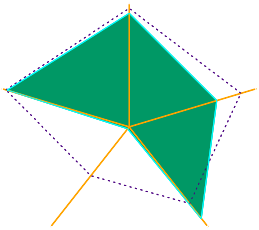
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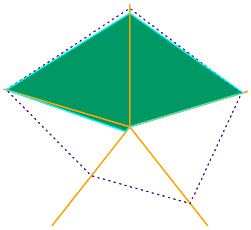
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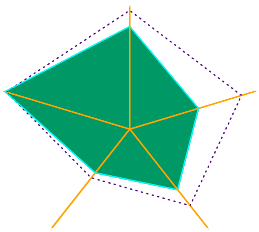
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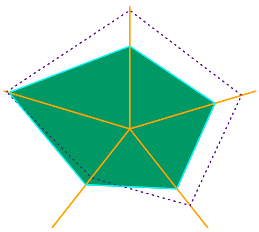
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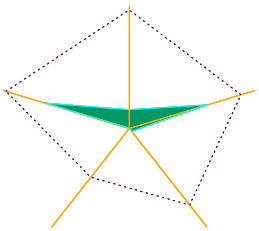
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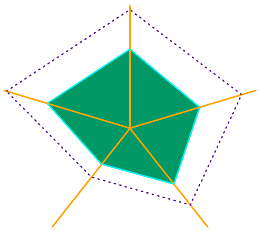
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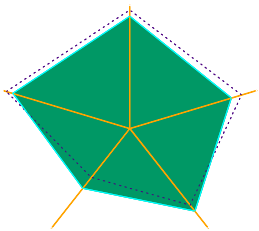
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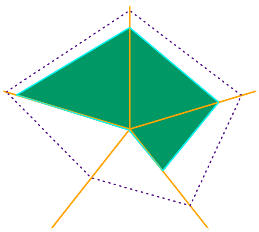
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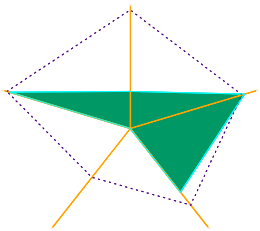
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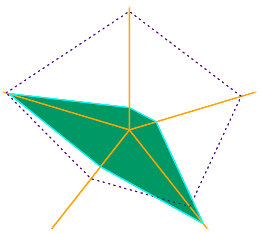
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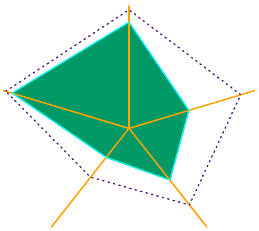
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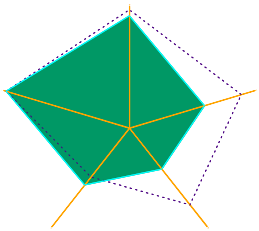
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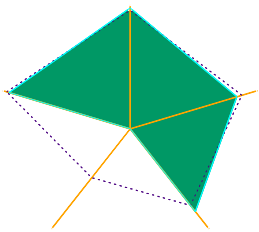
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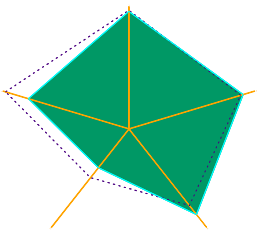
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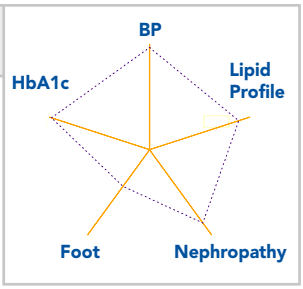
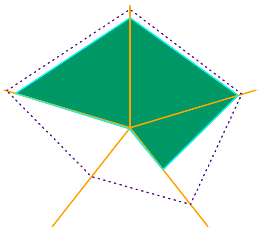
Starplots of Single Centers Analyzed by Type of Diabetes



DM2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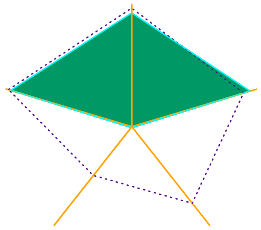
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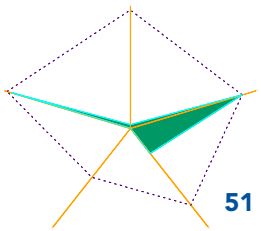
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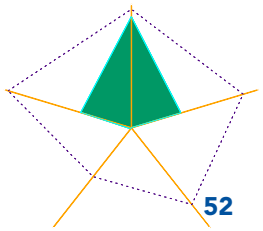
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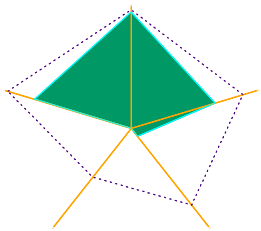
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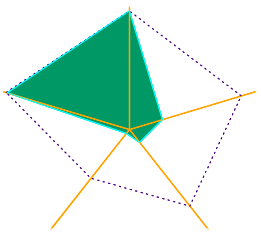
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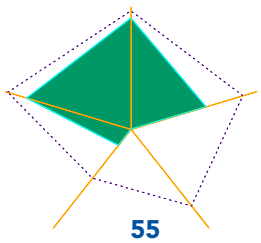
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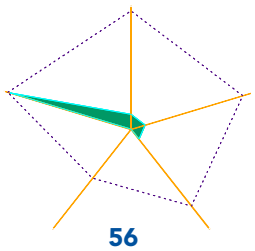
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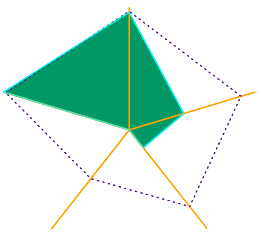
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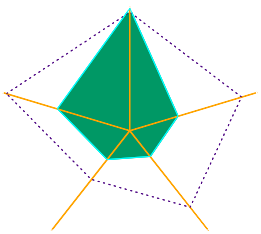
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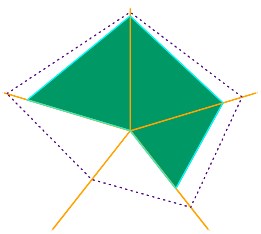
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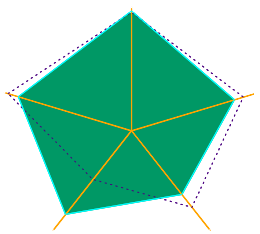
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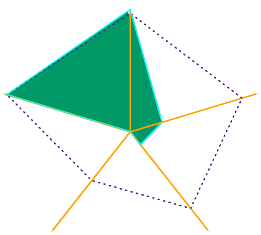
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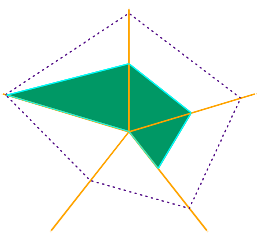
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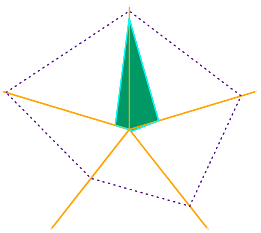
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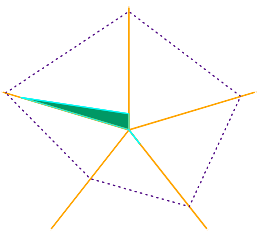
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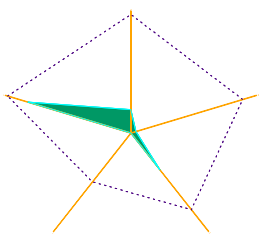
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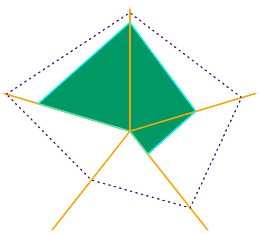
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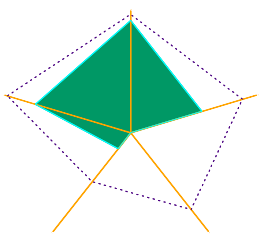
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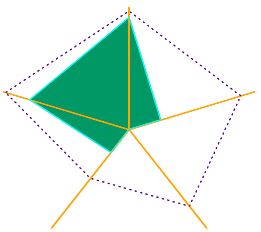
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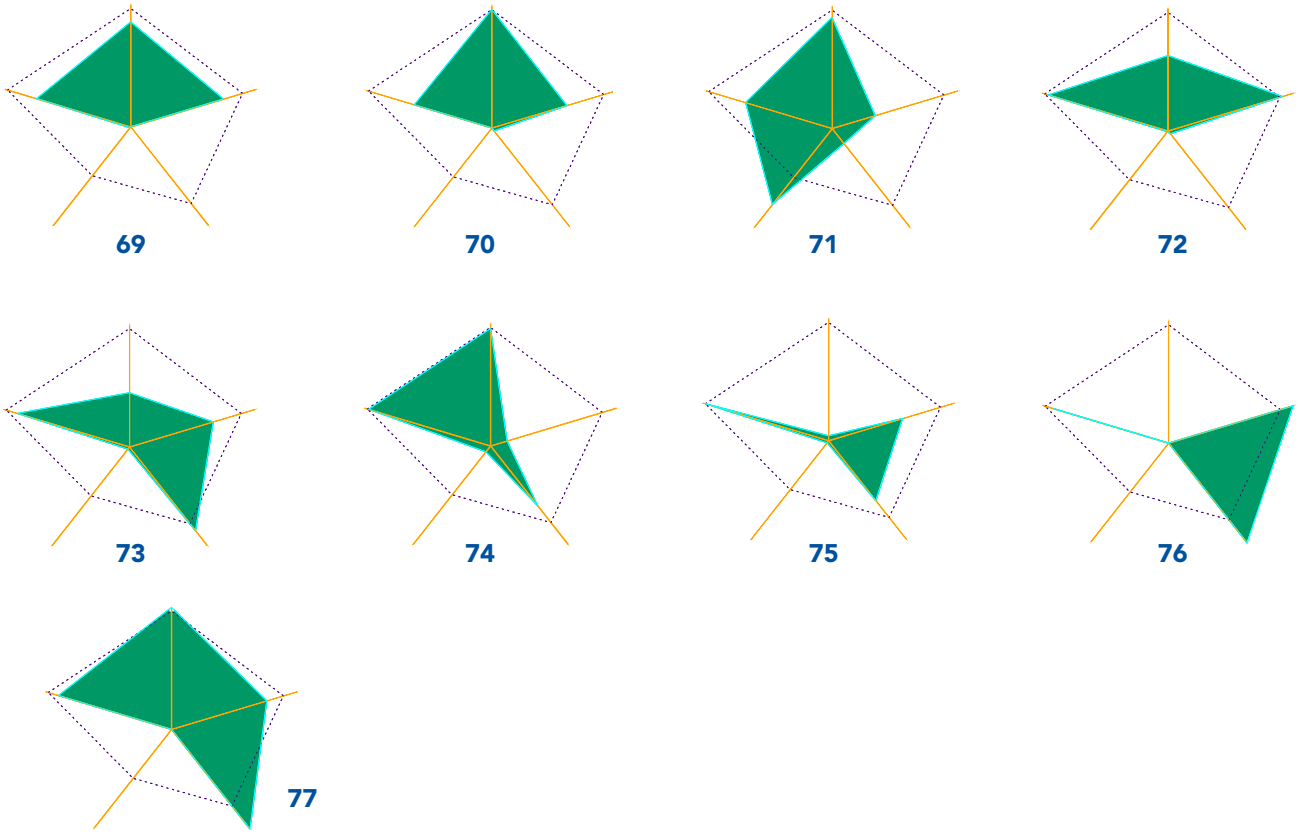
DM2



Comment

The number of diabetic patients who underwent HbA1c monitoring at least once during 2004 was extremely high (around 90%). In the hypothesis that the remaining 10% derived from a failure to enter the data, it was decided not to quantify the number of subjects who underwent glycosylated hemoglobulin testing 2 to 3 times during 2004. This analysis will be done after courses on correct data entry in the electronic medical record have been conducted.

The starplots show that the performance of the best centers was insufficient as regards foot examination and assessment of renal function. The data on fundus inspection are not reported here because they were not considered reliable enough.

An analysis of the process indicators in the starplot in relation to age shows a gradually better trend up to 65 years of age, where after it drops off.

This finding is quite understandable given the greater attention to younger diabetic patients. However, no difference emerged between the quality of indicators in DM1 and DM2 in relation to age, indicating that there were no preferential clinical pathways for DM1 patients.

The subdivision by area of the country shows a stark difference between optimal outcomes in the north and suboptimal results in the south. One hypothesis to explain this difference is the presence of larger autonomously operated diabetes centers in the north, where data can be more easily entered, while in the south the facilities are smaller (AMD survey), often with only one diabetologist and one nurse, where recording data on an electronic medical record is often impossible.

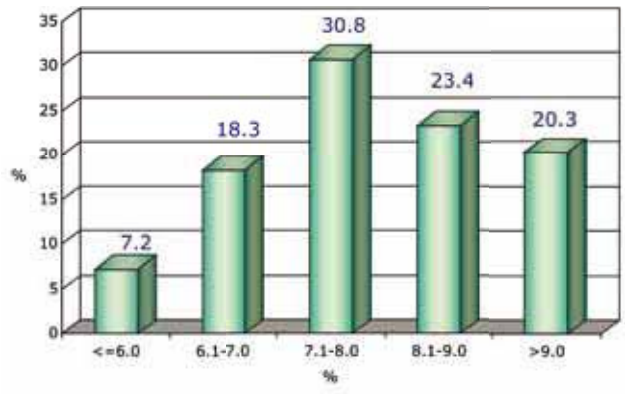
Giacomo Vespasiani

Intermediate Outcome Indicators

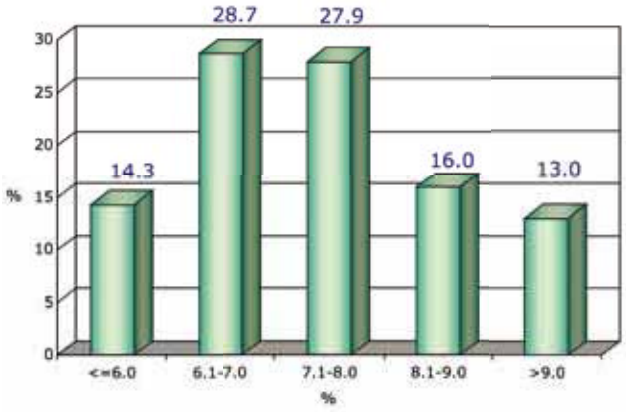
AMD Intermediate Outcome Indicators Analyzed by Type of Diabetes

Trend of Five Classes of HbA1c (normalized to 6.0%)

DM1



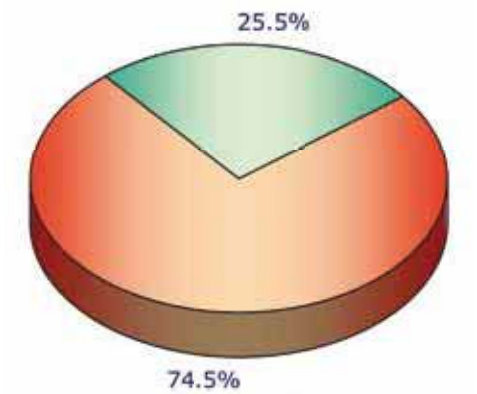
DM2



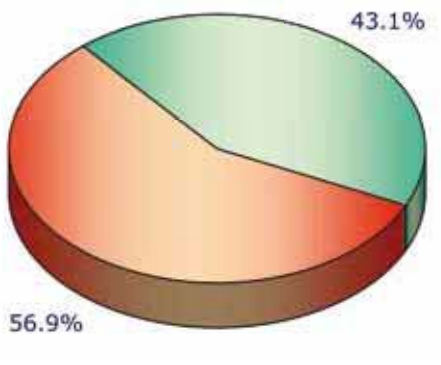
These figures illustrate how difficult it is to obtain adequate glycemic control in DM1 patients: 43% had HbA1c >8.0% and 20% >9.0; while only 7% had HbA1c ≤6.0%. The situation appears somewhat better in DM2 patients: less than 30% had HbA1c >8.0% and 14% had HbA1c ≤6.0%.

Subjects with HbA1c ≤7.0%

DM1



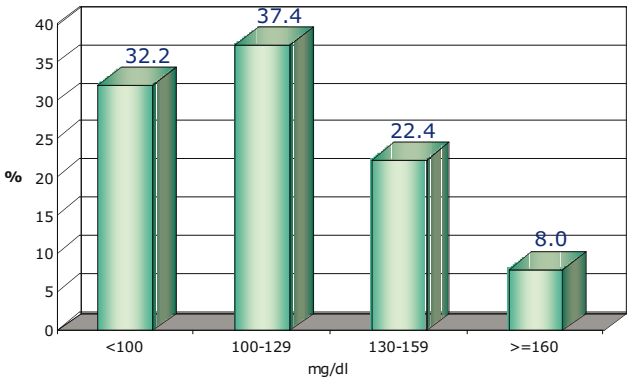
DM2



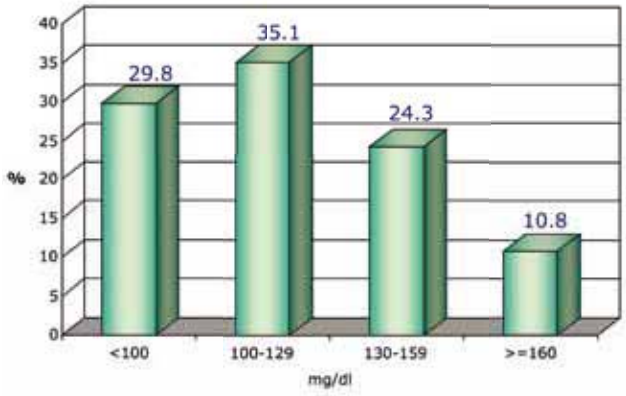
The difficulty in attaining adequate glycemic control, especially in DM1 patients, is further underlined in this set of figures which shows that one fourth of DM1 patients and over 40% of DM2 patients had HbA1c ≤7.0%.

Trend by Class of LDL Cholesterol

DM1



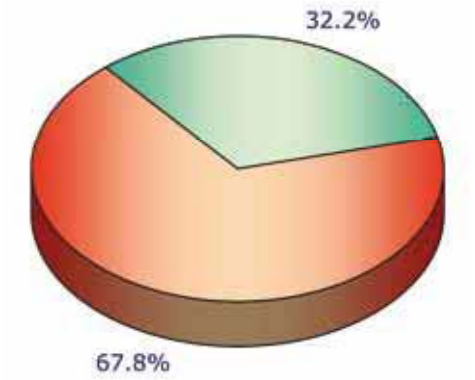
DM2



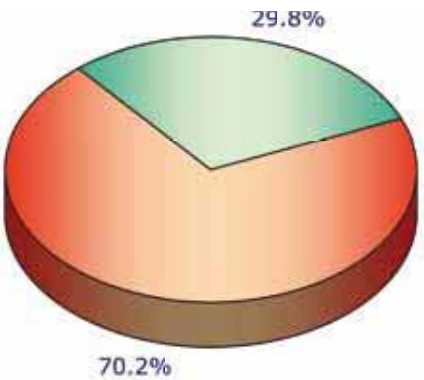
The figures show that one third of DM2 patients and 30% of DM1 patients had particularly elevated LDL levels (≥130 mg/dl). These data underline that DM1 and DM2 patients are at similar risk for cardiovascular events linked to dislipidemia.

Subjects with LDL Cholesterol <100 mg/dl

DM1



DM2

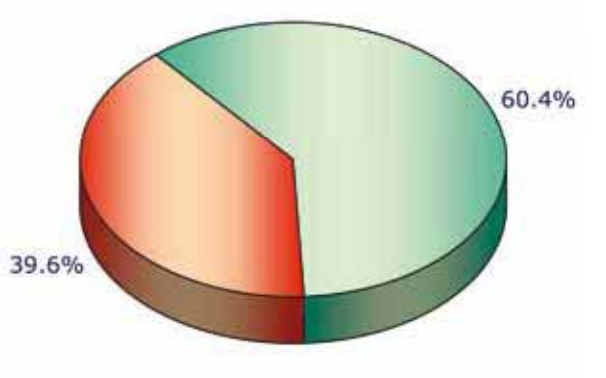


Yes No

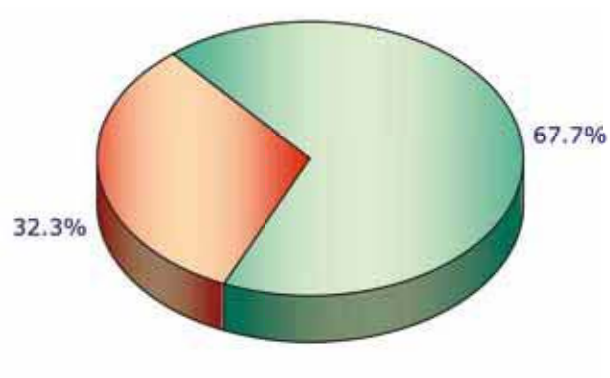
The elevated cardiovascular risk is further documented in this set of figures which show that less than one third of patients, both DM1 and DM2, had LDL cholesterol levels <100 mg/dl.

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

DM1



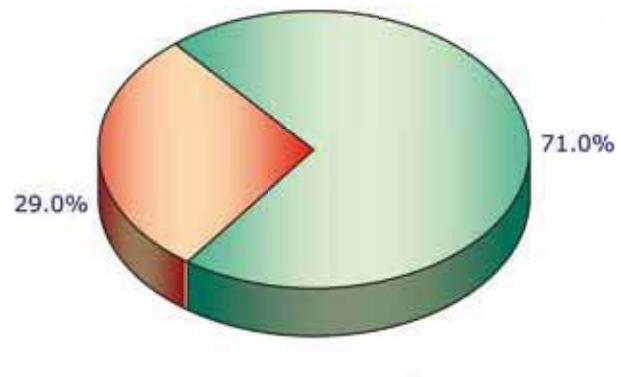
DM2



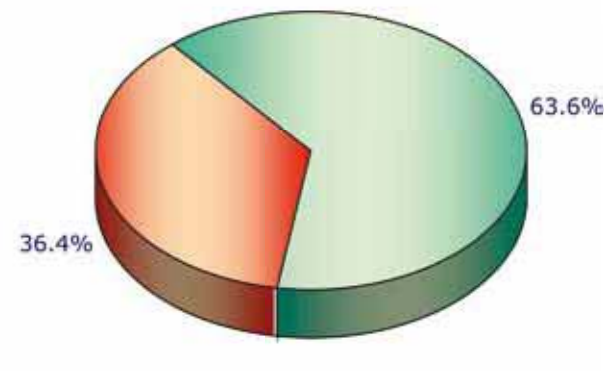
Of the subjects receiving lipid-lowering therapy (16.9% of DM1 and 33.8% of DM2 patients), two thirds of DM2 patients and less than two thirds of DM1 patients had LDL cholesterol <130 mg/dl, demonstrating the efficacy of therapy in achieving adequate treatment targets. This evidence highlights the need for more aggressive intervention in the remaining subjects with elevated LDL.

Subjects with LDL Cholesterol ≥130 mg/dl not Receiving Lipid-lowering Therapy

DM1



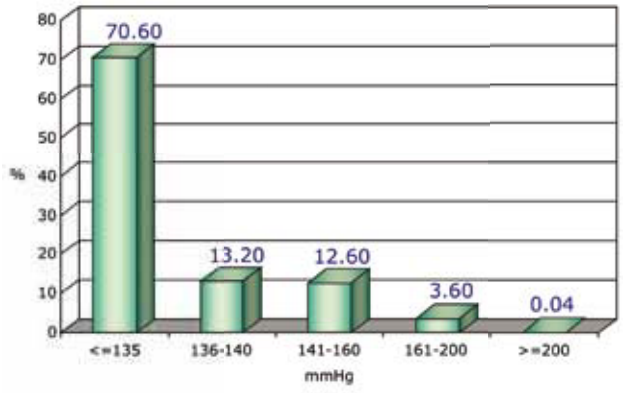
DM2



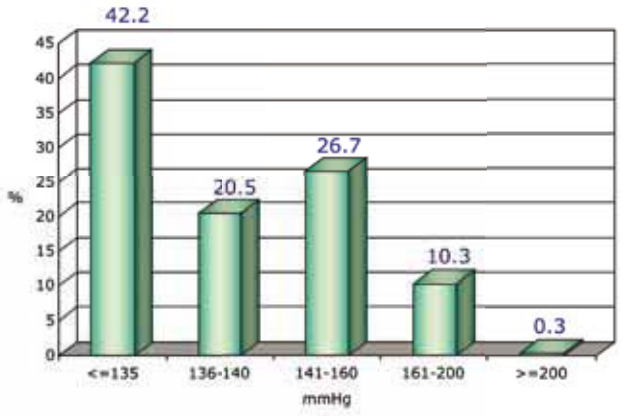
Of the subjects not receiving lipid-lowering therapy, about one third had LDL cholesterol ≥130 mg/dl and could therefore benefit from therapy. These data demonstrate a considerable margin for improvement in controlling the lipid profile.

Trend by Class of Systolic Blood Pressure

DM1



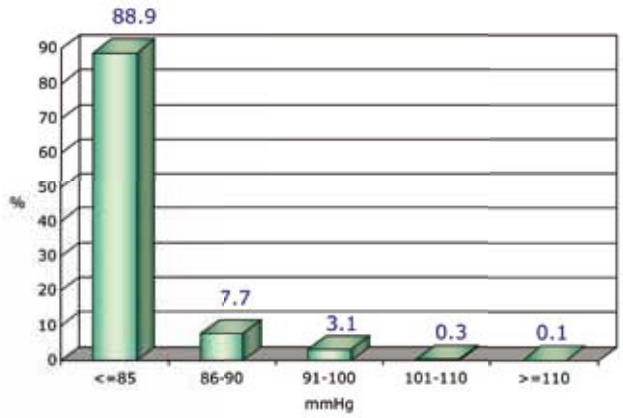
DM2



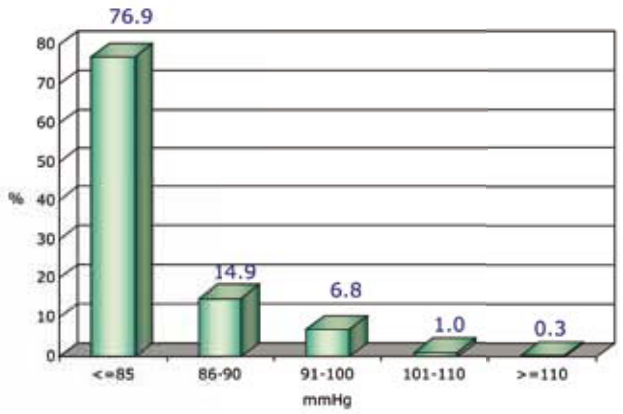
The trend for the class of systolic blood pressure shows extremely high values in 10% of DM2 patients and a small proportion of DM1 patients.

Trend by Class of Diastolic Blood Pressure

DM1

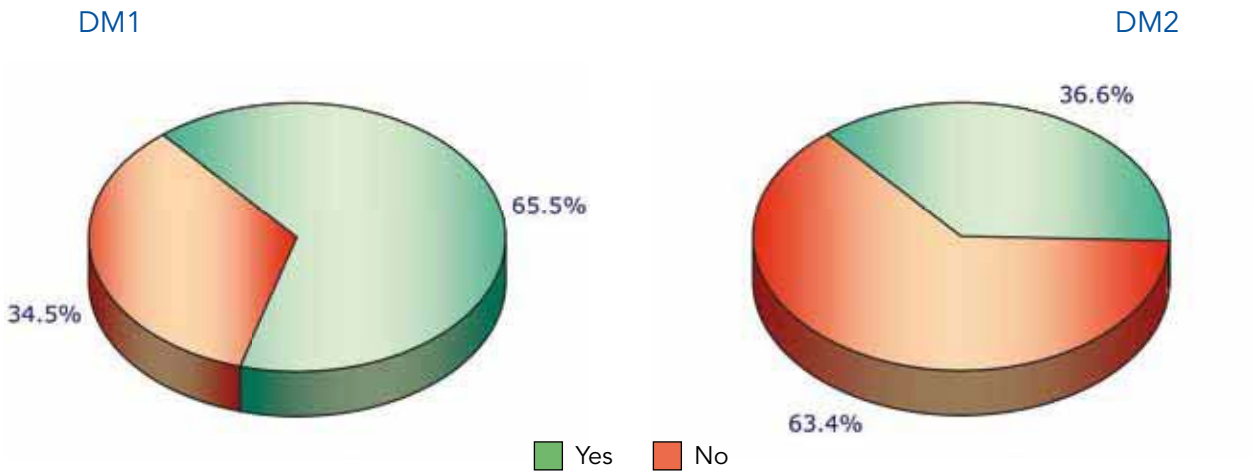


DM2



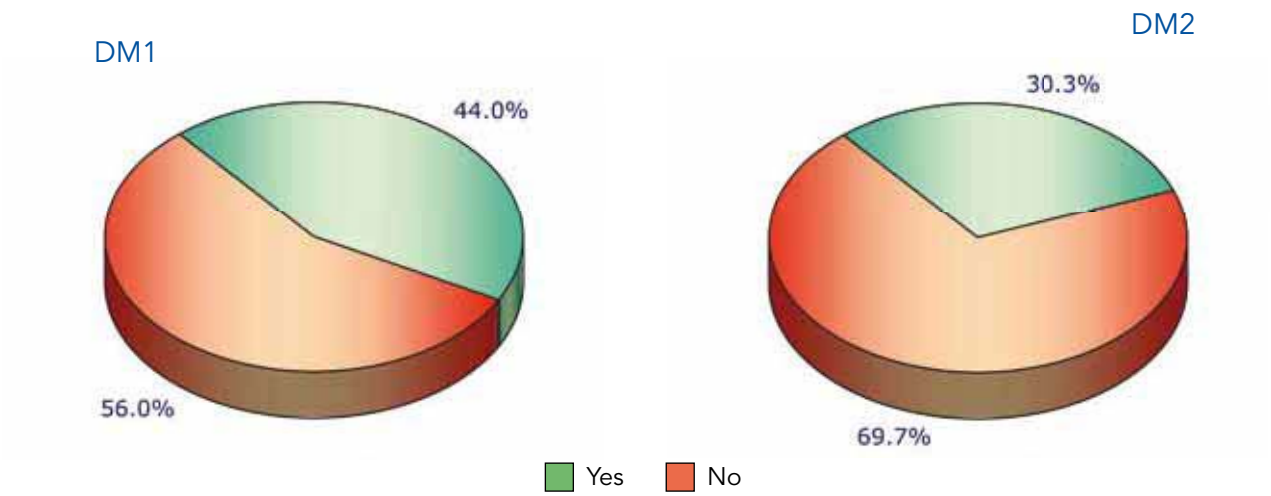
Good diastolic blood pressure values (≤85 mm Hg) were present in most DM1 patients and in 77% of DM2 patients, indicating that the unsatisfactory blood pressure levels in a high percentage of cases is chiefly attributable to elevated systolic pressure.

Subjects with Blood Pressure ≤130/85 mm Hg



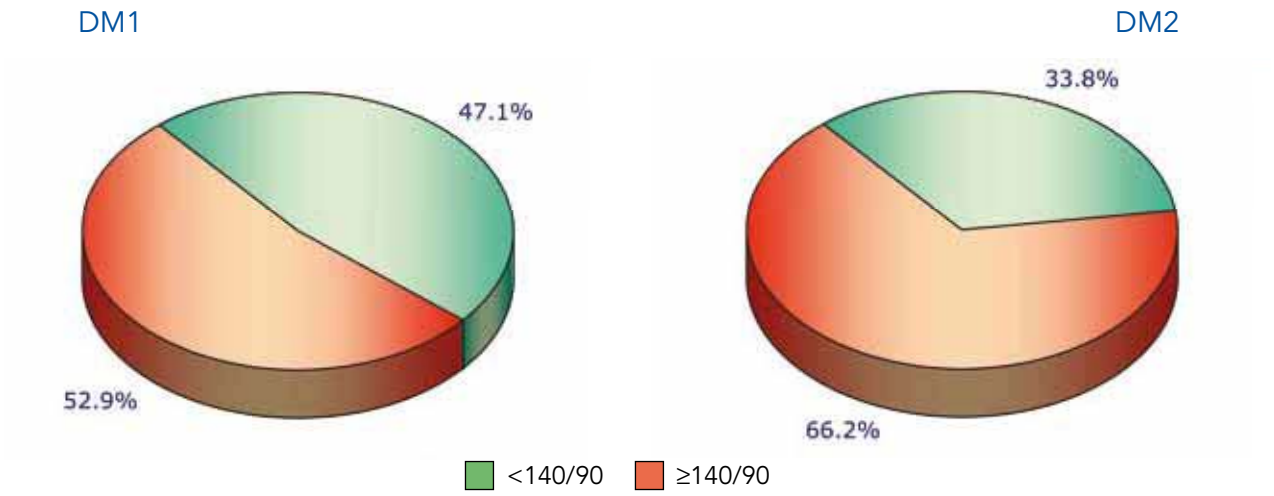
The figures show that two thirds of DM1 patients and only one third of DM2 patients had acceptable blood pressure levels.

Hypertensive Subjects with Blood Pressure ≤130/85 mm Hg



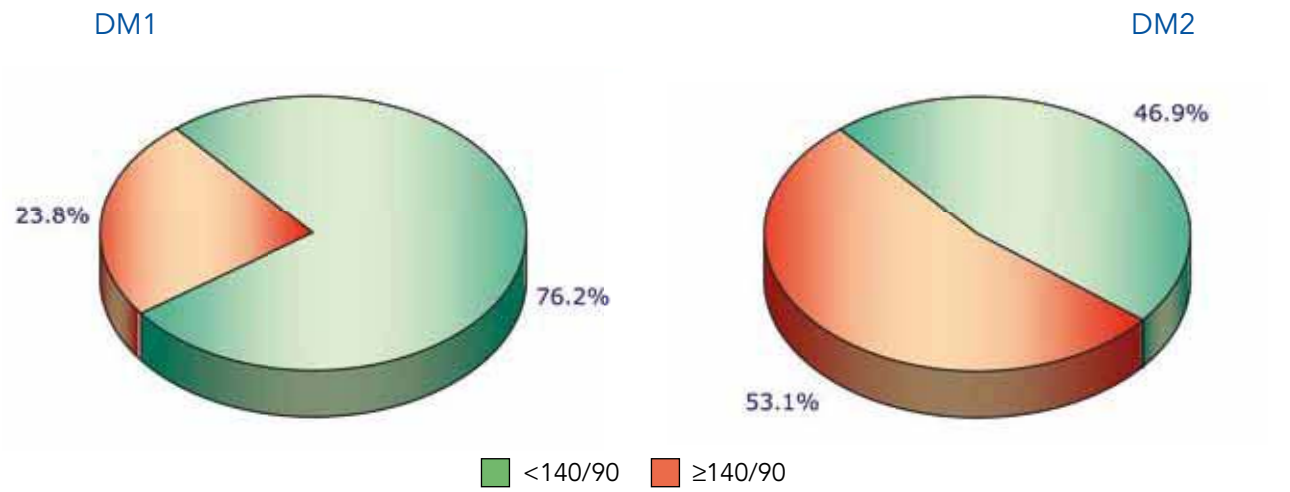
Of the hypertensive subjects in antihypertensive treatment, 27.6% were DM1 patients and 52.8% DM2 patients; 56% of DM1 patients and two thirds of DM2 patients did not achieve adequate blood pressure control. These data suggest the need for more aggressive pharmacological management to reach the recommended therapeutic targets in these patient groups.

Subjects with Blood Pressure ≥140/90 mm Hg Receiving Antihypertensive Treatment



As confirmation of the previous finding, over half of DM1 patients and two thirds of DM2 patients had blood pressure ≥140/90 mm Hg, despite antihypertensive therapy.

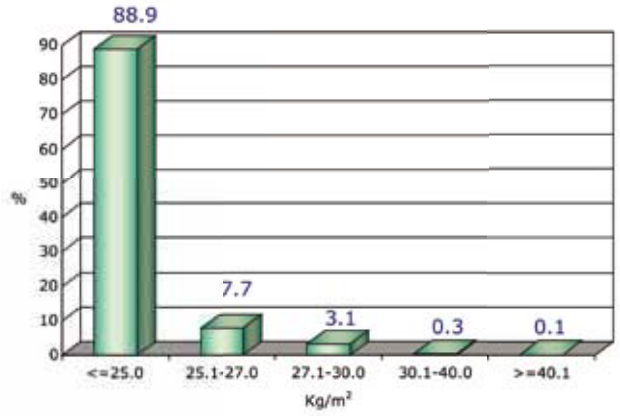
Subjects with Blood Pressure ≥140/90 mm Hg not Receiving Antihypertensive Treatment



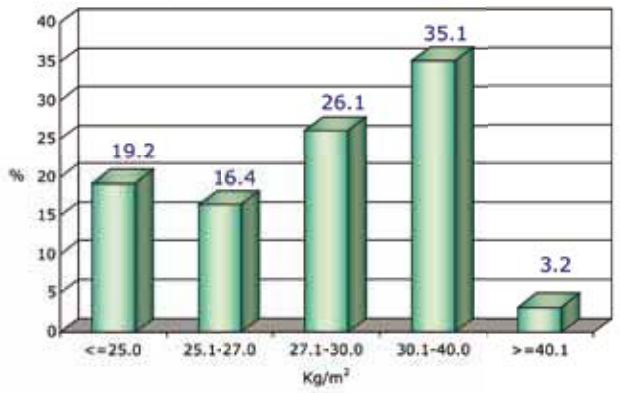
Reluctance toward instituting an sufficiently aggressive approach to this important risk factor is further documented by the high percentage of subjects not receiving antihypertensive treatment despite their elevated blood pressure values. Half of DM2 patients and one fourth of DM1 patients not receiving specific therapy had blood pressure ≥140/90 mm Hg.

Trend by Class of Body-mass Index

DM1



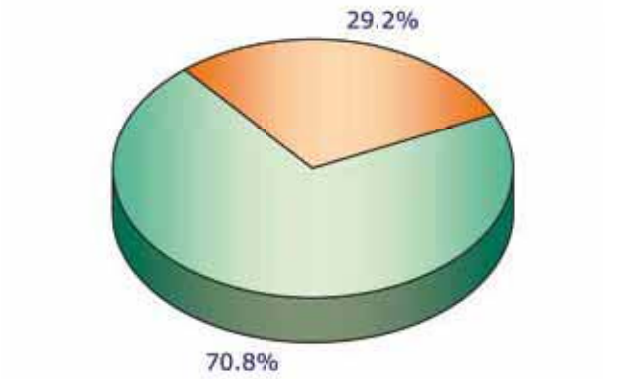
DM2



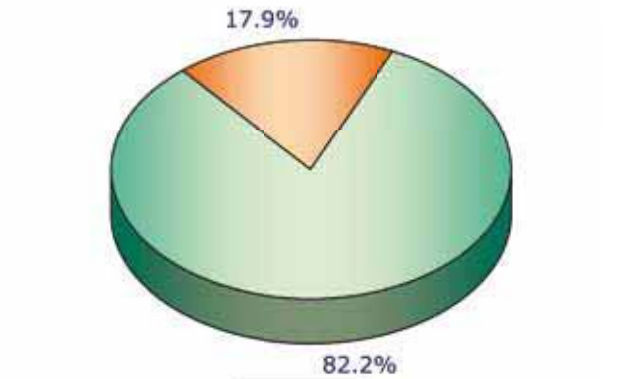
A moderate proportion of DM1 patients was overweight or frankly obese, whereas over one third of DM2 patients was frankly obese (BMI >30) and less than 20% had normal body weight.

Smokers

DM1

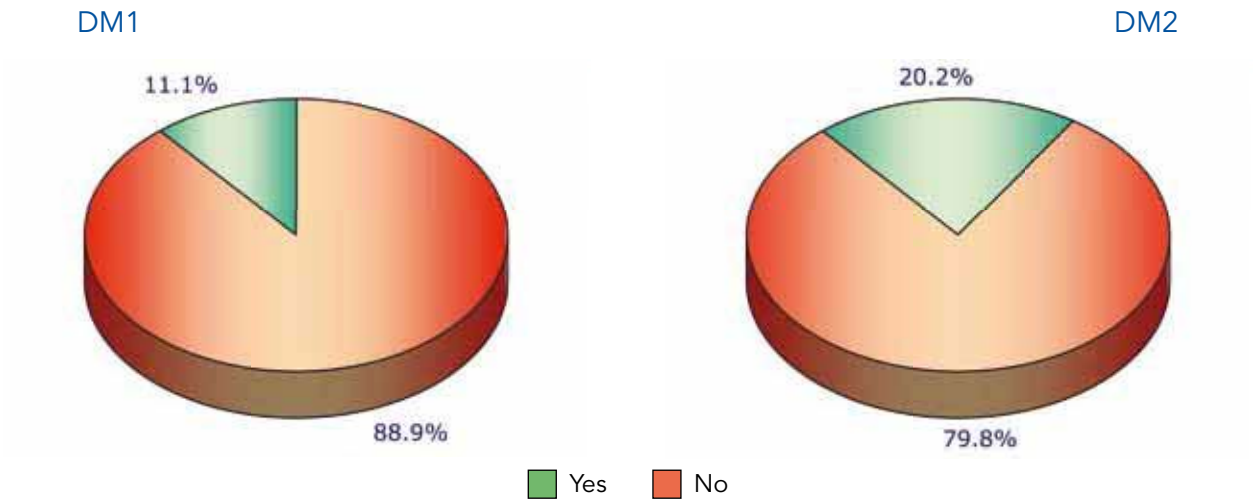


DM2



Less than one third of DM1 patients and 18% of DM2 patients were smokers. That smoking is still prevalent among DM1 patients is reason for alarm, given the high risk of microvascular complications associated with smoking.

Heavy Smokers (>20 cigarettes/day)



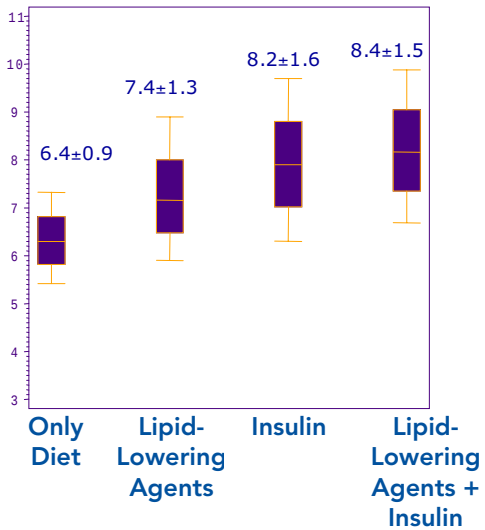
While proportionately more DM1 patients were smokers, the proportion of heavy smokers (>20 cigarettes/day) among DM2 patients is twice that of DM1 patients.

Boxplot Analyzed by Type of Diabetes, Patient Sex and Age

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

The mean HbA1c values were 8.0±1.5 for DM1 patients and 7.4±1.5 for DM2 patients. These data show a considerable range within each type of diabetes and a marked difference between DM1 and DM2 patients.

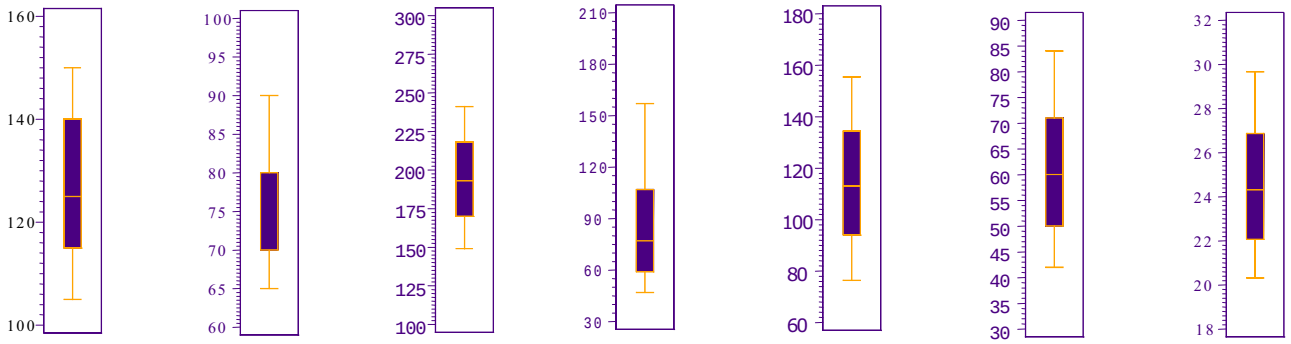
Mean HbA1C and Standard Deviation (SD) (Last Value Normalized to 6.0) Analyzed by Type of Treatment in DM2 Patients



As expected, HbA1c values in the DM2 patients were associated with treatment type. The lowest values were found among subjects on a controlled diet, while the highest were found among those taking insulin, particularly when associated with oral lipid-lowering agents.

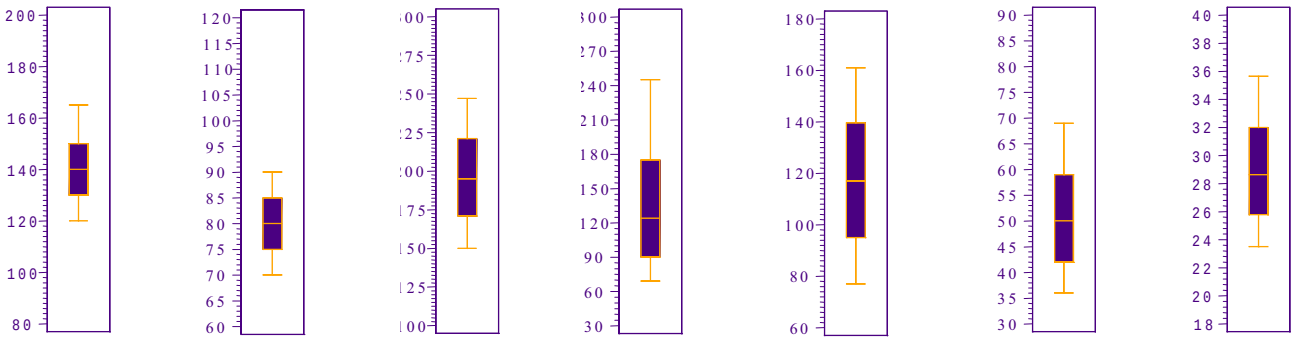
Mean Values of Principal Clinical Parameters Analyzed by Type of Diabetes

DM1



Systolic BP | Diastolic BP | Total Cholesterol | Triglycerides | LDL Cholesterol | HDL Cholesterol | BMI

DM2

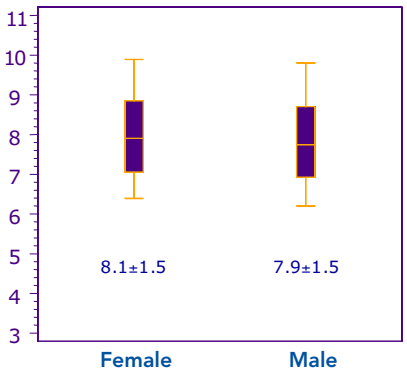


Systolic BP | Diastolic BP | Total Cholesterol | Triglycerides | LDL Cholesterol | HDL Cholesterol | BMI

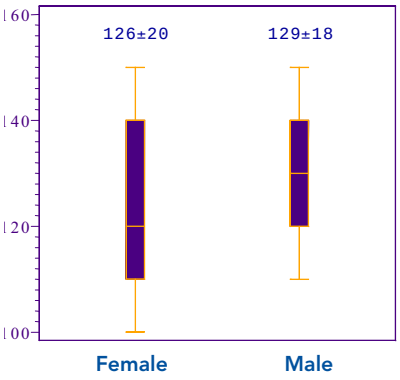
In DM1 patients, the mean values of clinical parameters were: systolic blood pressure 127±19 mm Hg; diastolic blood pressure 77±9 mm Hg; total cholesterol 194±38 mg/dl; triglycerides 94±69 mg/dl; LDL cholesterol 115±31; HDL cholesterol 61±16 mg/dl; BMI 25±4.
In DM2 patients, the mean values of clinical parameters were: systolic blood pressure 141±19 mm Hg; diastolic blood pressure 81±10 mm Hg; total cholesterol 197±39 mg/dl; triglycerides 148±106 mg/dl; LDL cholesterol 118±33.3; HDL cholesterol 51±14 mg/dl; BMI 29.2±5.0.
These data indicate that DM1 patients tended to have a lower risk profile of blood pressure than DM2 patients and a similar profile of lipid levels, especially with respect to total and LDL cholesterol.

Mean Values of Principal Clinical Parameters Analyzed by Type of Diabetes and Patient Sex

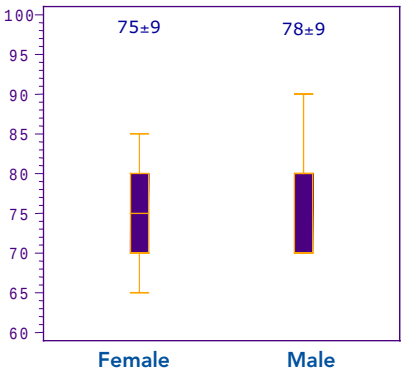
DM1



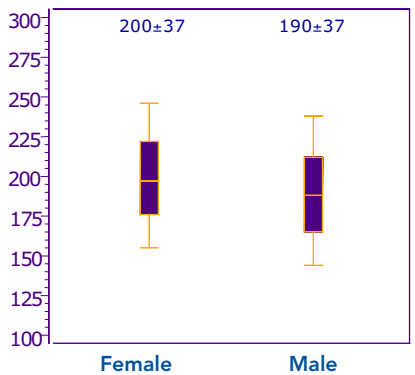
HbA1c



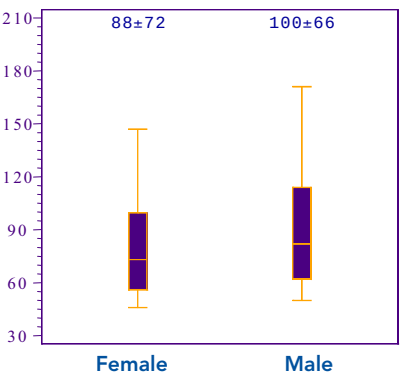
Systolic BP



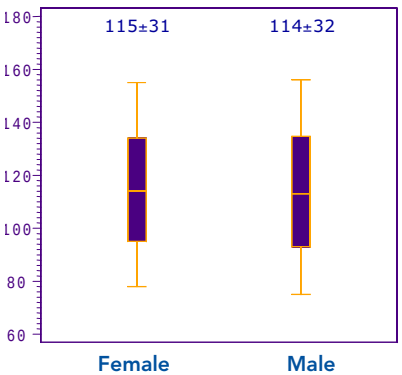
Diastolic BP



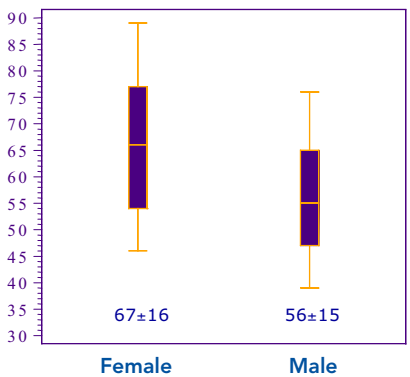
Total Cholesterol



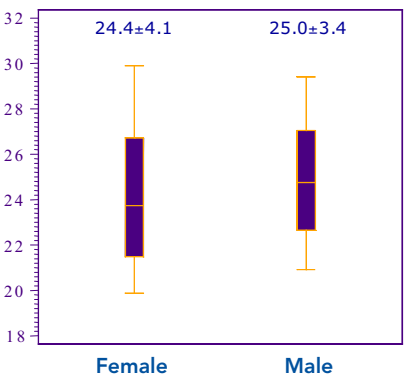
Triglycerides



LDL Cholesterol



HDL Cholesterol

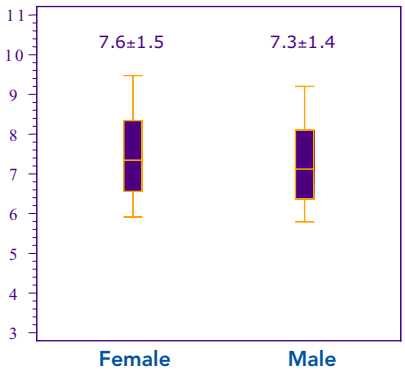


BMI

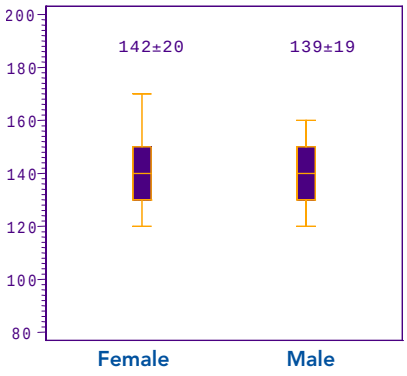
Of the DM1 patients, females tended to have higher HbA1c, total and HDL cholesterol levels than males but lower blood pressure, triglycerides and BMI.
The gender-specific differences in the lipid profile parameters were similar for mean LDL cholesterol.

Mean Values of Principal Clinical Parameters Analyzed by Type of Diabetes and Patient Sex

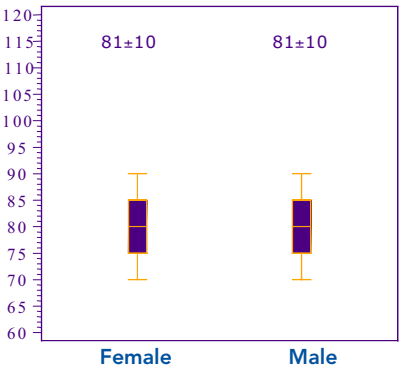
DM2



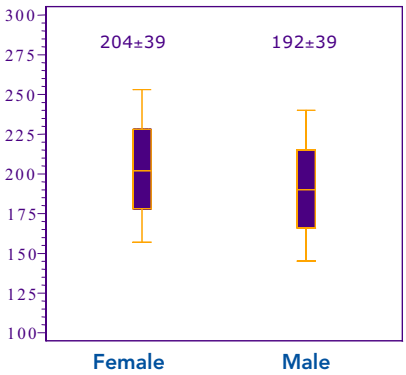
HbA1c



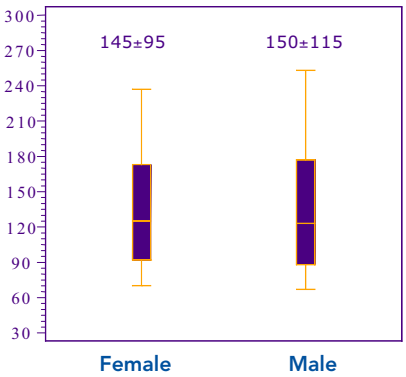
Systolic BP



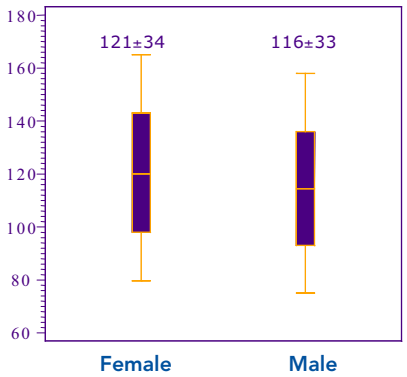
Diastolic BP



Total Cholesterol

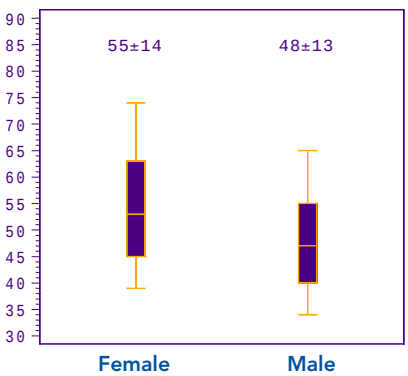


Triglycerides

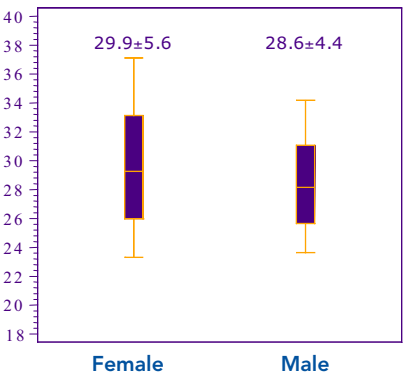


LDL Cholesterol

Of the DM2 patients, females tended to have not only higher HbA1c and total cholesterol levels but lower systolic blood pressure, LDL cholesterol and BMI than males, while the mean values of triglycerides and diastolic blood pressure were minimally different.
These data indicate a poorer control of the more relevant cardiovascular risk factors among women DM2 patients.



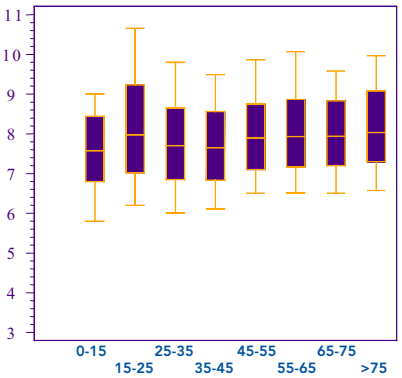
HDL Cholesterol



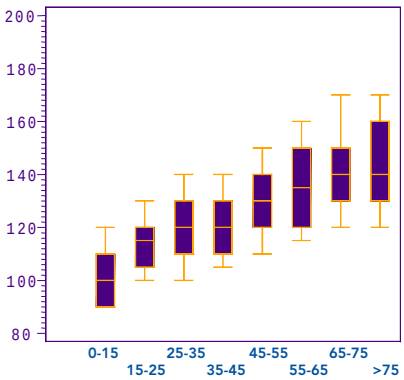
BMI

Mean Values of Principal Clinical Parameters Analyzed by Type of Diabetes and Age Group

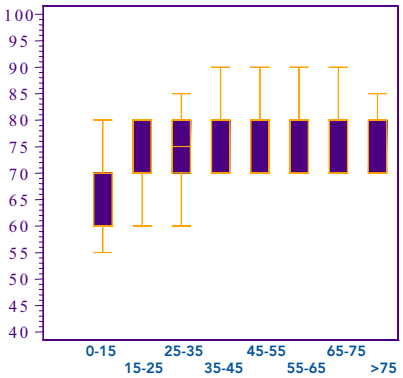
DM1



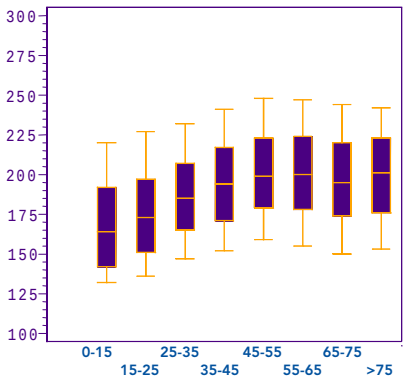
HbA1c



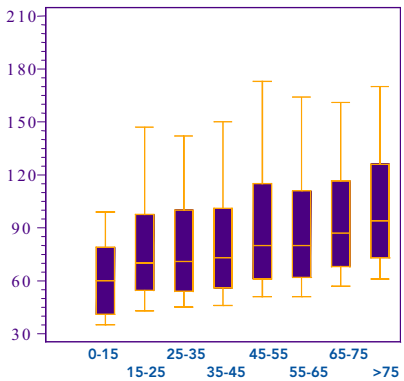
Systolic BP



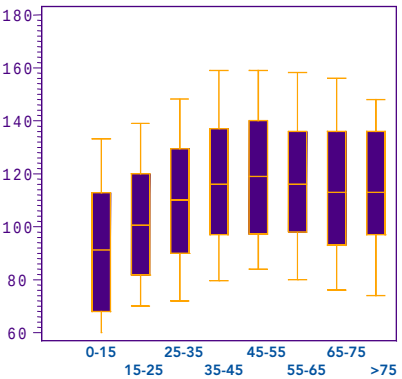
Diastolic BP



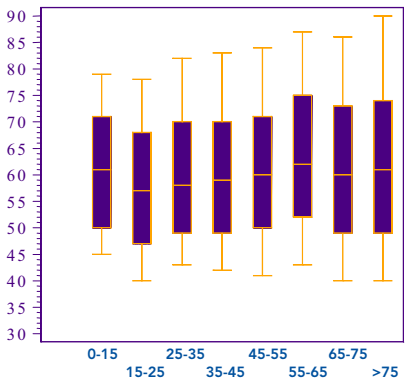
Total Cholesterol



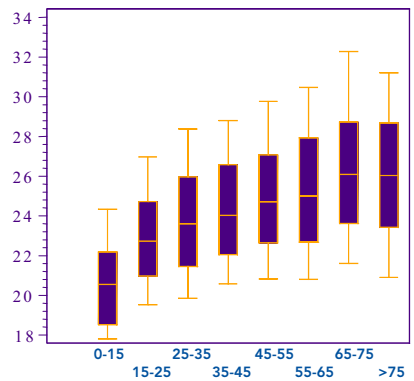
Triglycerides



LDL Cholesterol



HDL Cholesterol

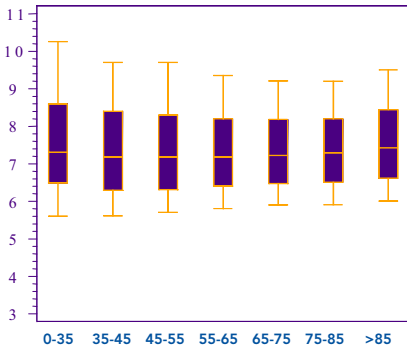


BMI

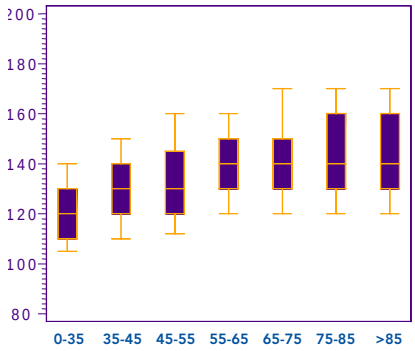
In DM1 patients, the mean HbA1c levels showed minimal variation, with a slight rise and major variability between 15 and 25 years of age. There was also a gradual rise in systolic, but not diastolic blood pressure, and BMI.
Total and LDL cholesterol levels tended to increase up to age 45 and then plateau.

Mean Values of Principal Clinical Parameters Analyzed by Type of Diabetes and Age Group

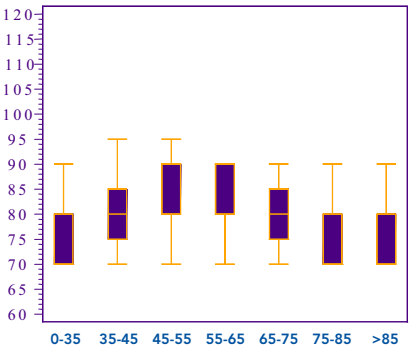
DM2



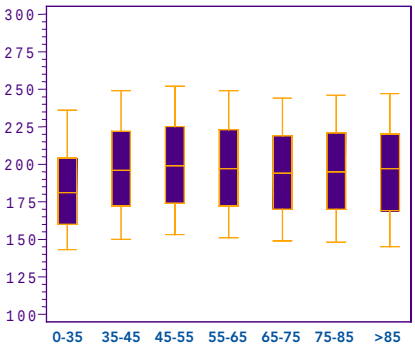
HbA1c



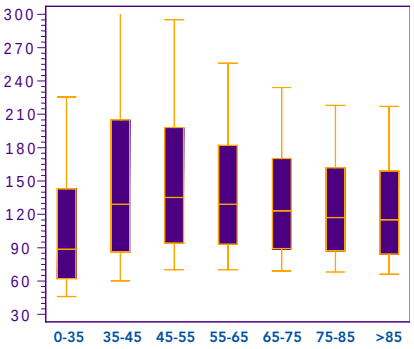
Systolic BP



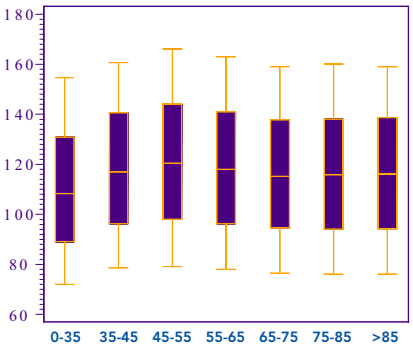
Diastolic BP



Total Cholesterol

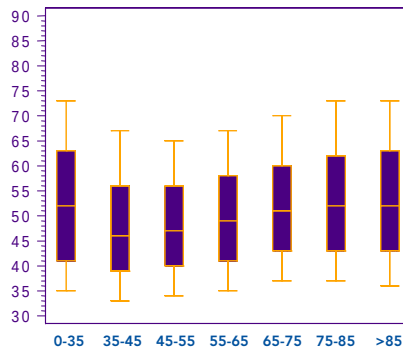


Triglycerides

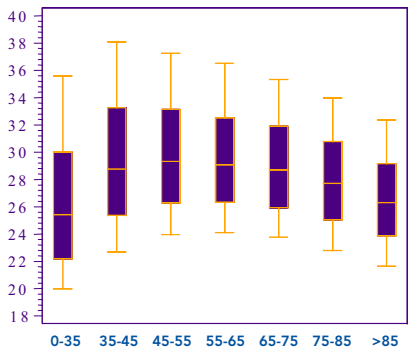


LDL Cholesterol

DM2 patients had minimal variations in mean HbA1c levels. Systolic blood pressure tended to gradually increase up to age 55 years and then plateau, while diastolic blood pressure tended to diminish with age. The lipid profile was substantially stable, although variability appeared to increase with age. The highest BMI was found in the 35 to 55 year age group.

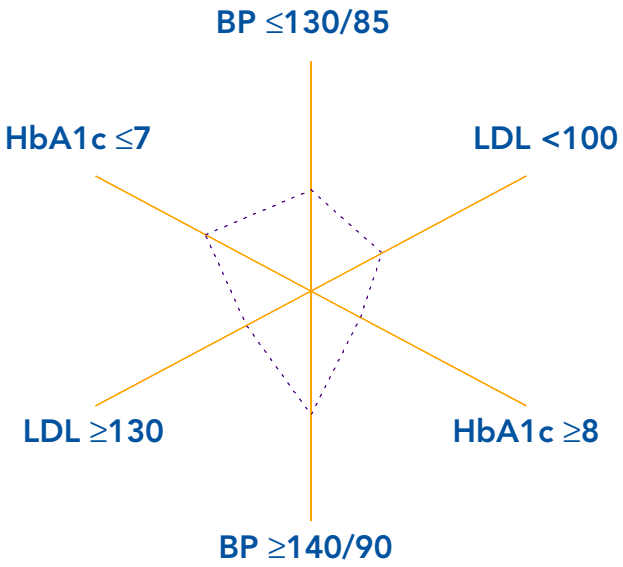


HDL Cholesterol



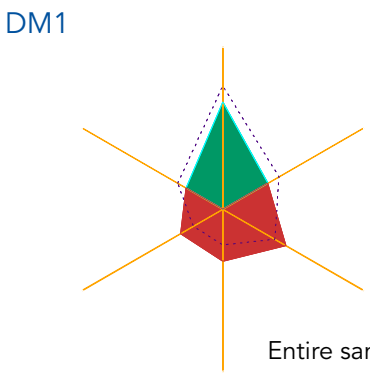
BMI

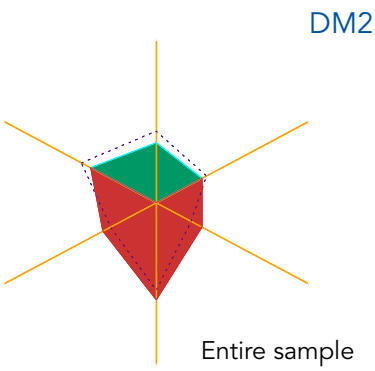
Starplots Summarizing Type of Disease, Patient Sex and Age, and Region of Country



These starplots summarize the intermediate outcome measures. Each starplot is divided into two parts. The three radii in the upper half show the percentage of patients with a favorable outcome for HbA1c, blood pressure and LDL cholesterol; the three lower 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 represents the patient group in question. The area in green indicates favorable outcomes, the area in red indicates unfavorable outcomes.

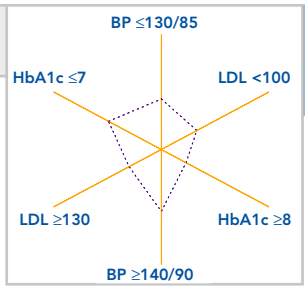
Total Sample Analyzed by Type of Diabetes



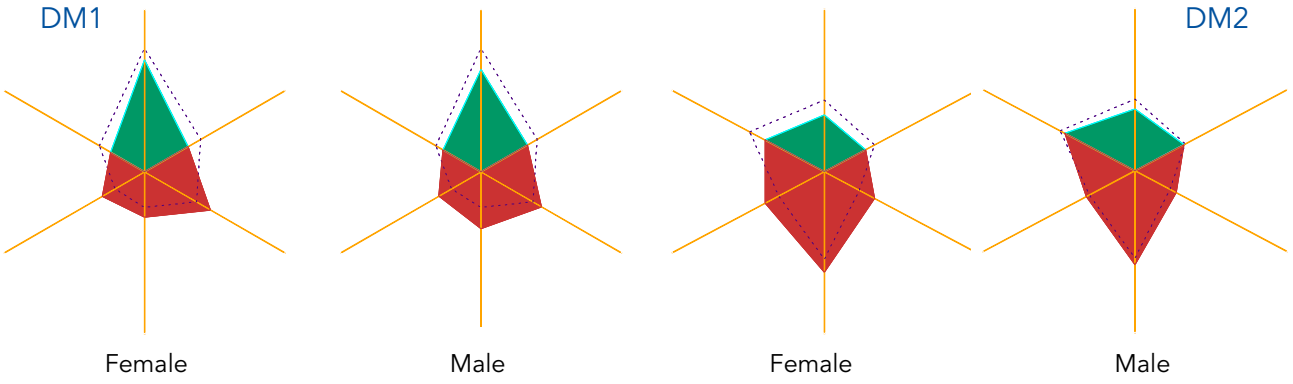


In both types of diabetes, the dashed line starplot indicates that also in those centers that contributed to defining the gold standard only a moderate proportion of patients had adequate HbA1c, blood pressure and LDL cholesterol levels, while the proportion of those with particularly elevated parameters is considerably high. Unlike process measures, there was no large gap between the total sample and the gold standard for either type of diabetes.

Starplots Summarizing Type of Disease, Patient Sex and Age, and Region of Country



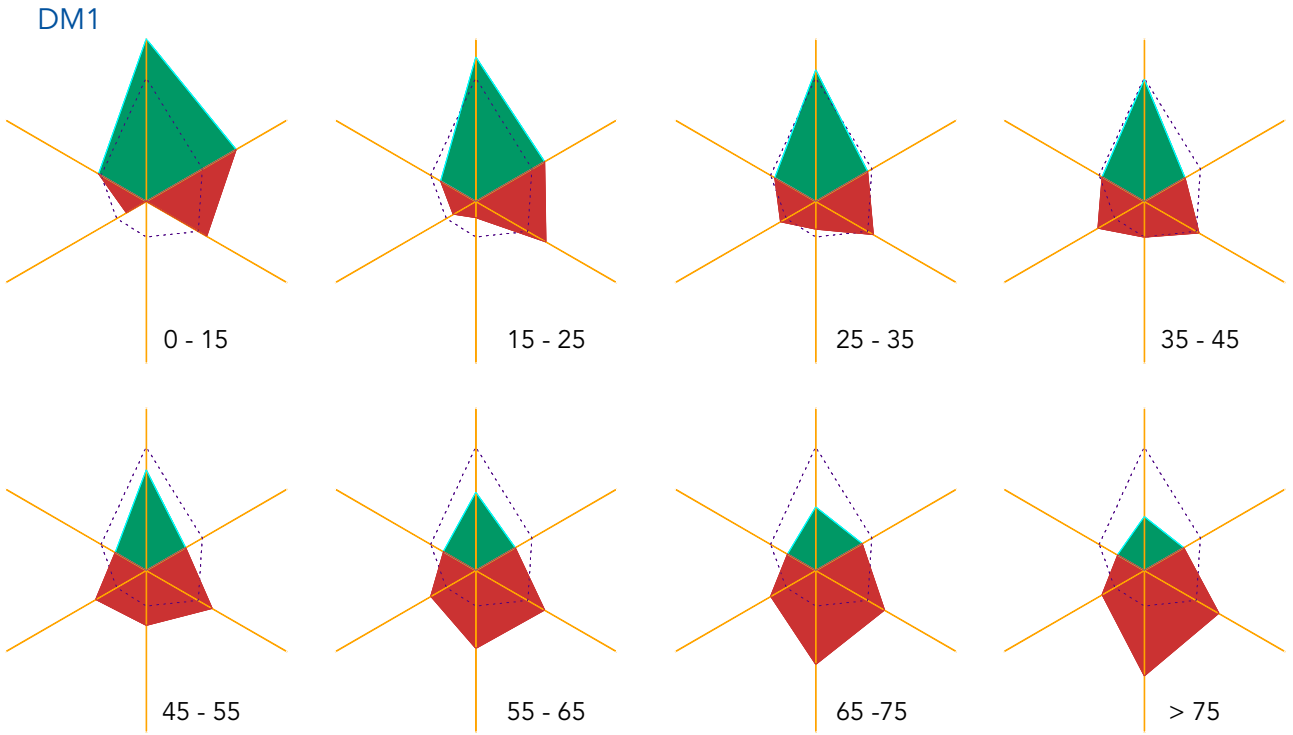
Total Sample Analyzed by Type of Diabetes and Patient Sex



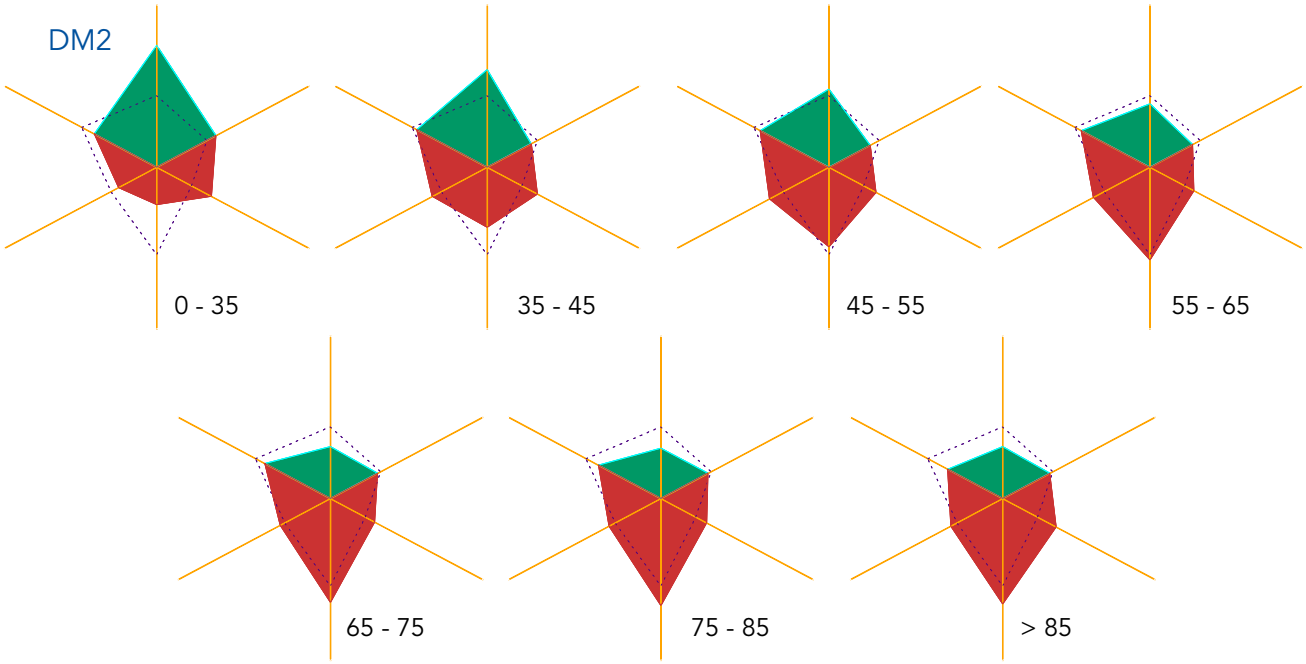
Among the DM1 patients, the percentage of those with blood pressure values ≥140/90 mm Hg (28% of females and 35% of males) differed considerably, while the other measures were similar.

Among the DM2 patients, while the males had values very close to the gold standard, a consistently small segment of the women had adequate values and a higher proportion had elevated values. On the whole, it appears that less attention is directed at achieving target values in female DM2 patients.

Sample Analyzed by Type of Diabetes and Age Group

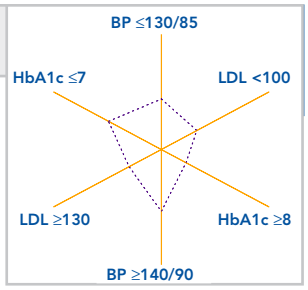


Sample Analyzed by Type of Diabetes and Age Group

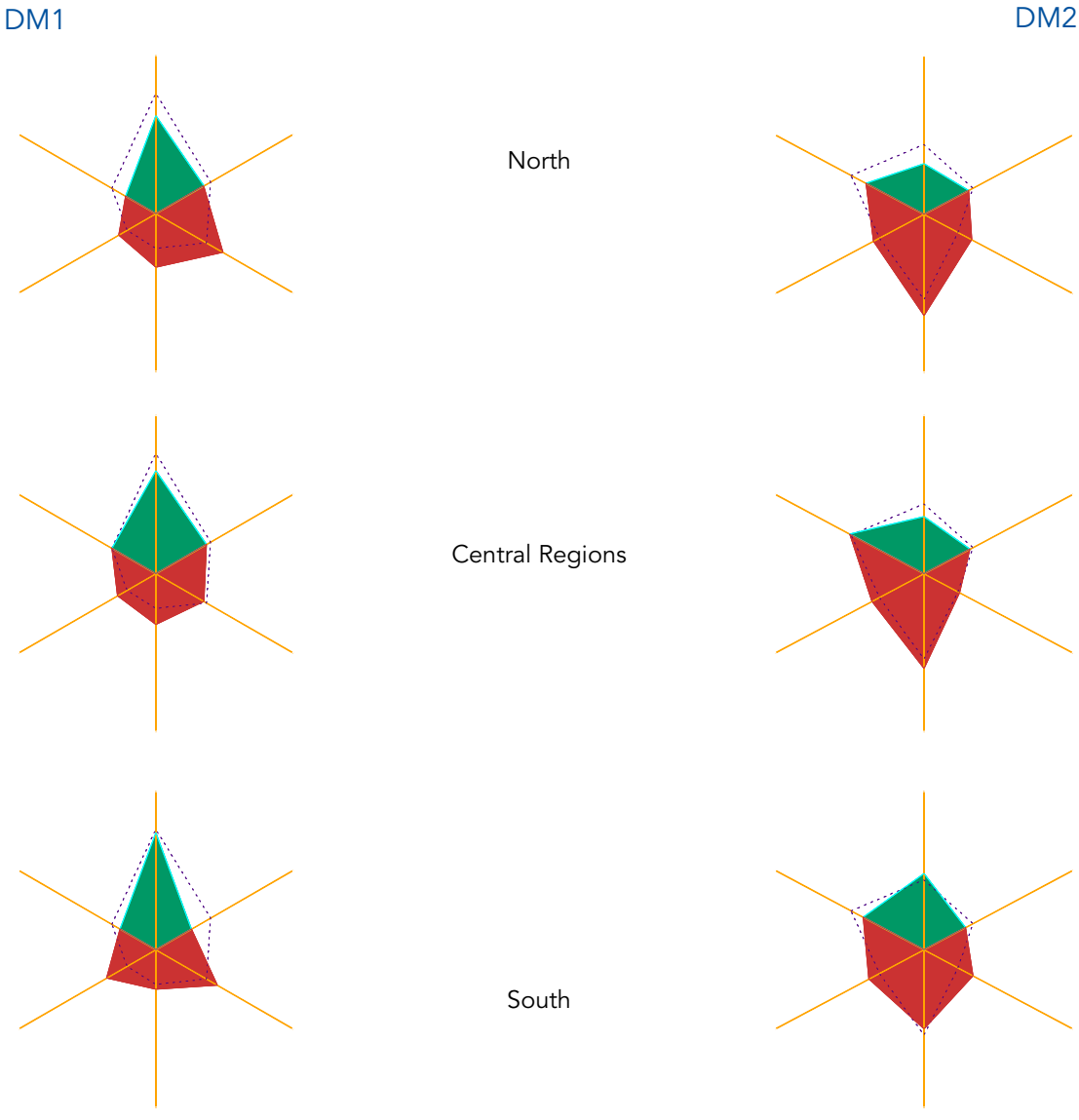


In the DM1 patients, favorable outcomes (green area) gradually decreased with advancing age, and a corresponding increase in unfavorable outcomes (red area), indicating greater difficulty in achieving adequate values. In the DM2 patients, the trend was similar but somewhat more limited.

Starplots Summarizing Type of Disease, Patient Sex and Age, and Region of Country



Intermediate Outcome Indicators: Sample Analyzed by Type of Diabetes and Region of Country



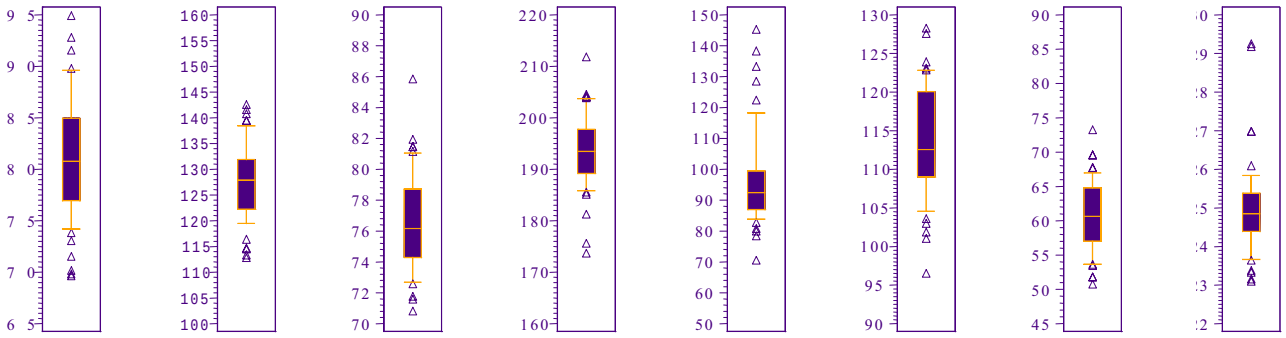
In the DM1 patients, the situation varied by area of the country. Compared against the gold standard, the north appears to have a greater percentage of patients with elevated HbA1c and blood pressure, while in the central regions the gap between the actual and the gold standard is more pronounced only for blood pressure; in the southern regions the gap is larger for LDL cholesterol and smaller for HbA1c.

In the DM2 patients, the results of the central and southern regions did not differ substantially from the gold standard, while the northern regions show a higher percentage of patients with HbA1c ≥8.0% and blood pressure ≥140/90 mm Hg.

Boxplot of Mean Values of Centers Analyzed by Type of Diabetes

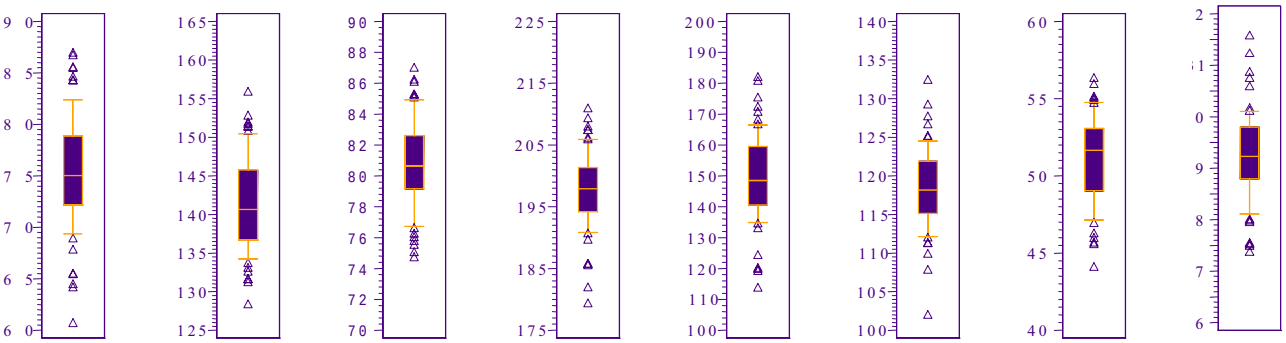
Distribution of Mean Values of Principal Parameters Analyzed by Center and Type of Diabetes

DM1



HbA1c | Systolic BP | Diastolic BP | Total Cholesterol | Triglycerides | LDL Cholesterol | HDL Cholesterol | BMI

DM2



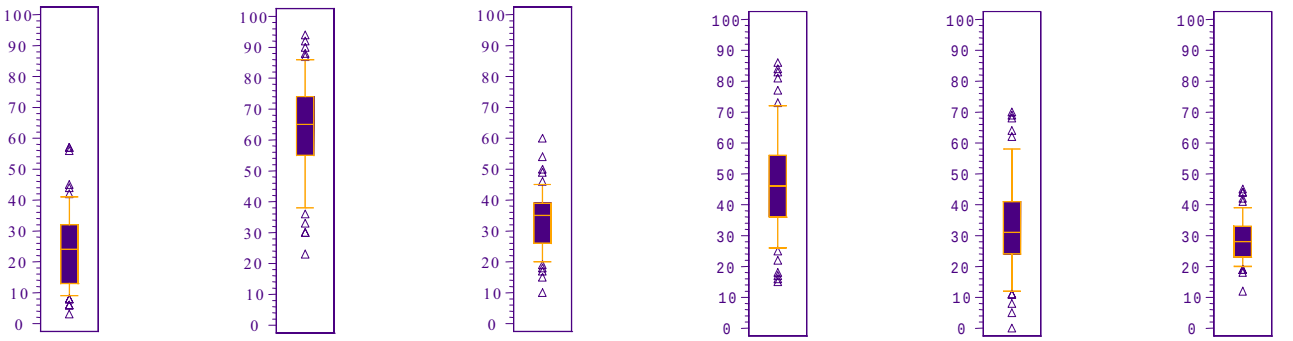
HbA1c | Systolic BP | Diastolic BP | Total Cholesterol | Triglycerides | LDL Cholesterol | HDL Cholesterol | BMI

This set of figures shows for each center the distribution of mean values of the parameters in question. In the DM1 patients there was a marked variability in all parameters. In glycemic control, for example, in 50% of the centers the range of mean HbA1c (normalized to 6.0) was from 7.7% and 8.5%. However, there were also centers with much lower (up to 7.0%) or much higher values (up to 9.9%). This spread was indicative for all parameters in question.

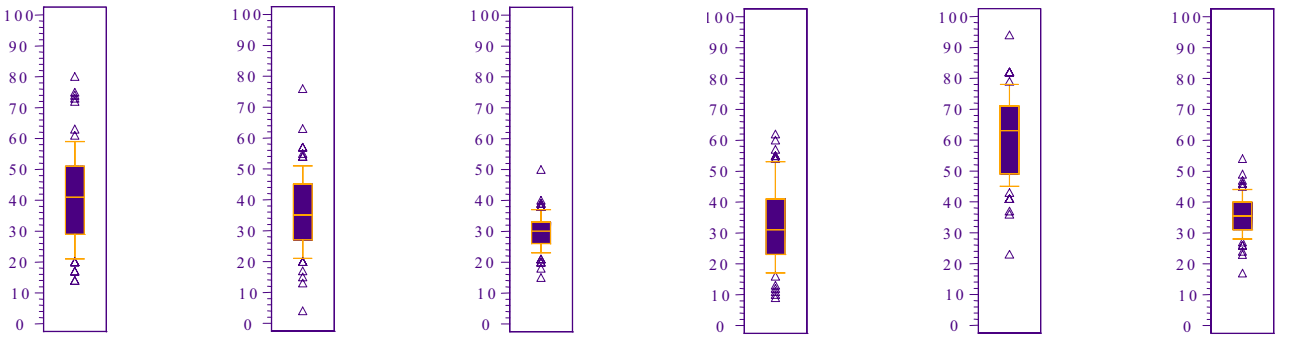
Also in the DM2 patients there was a marked variability among centers in mean values of various parameters. Noteworthy is that there was for all parameters a number of outlier centers with mean values well above or below the mean of the other centers. These data highlight a pronounced heterogeneity in the outcome of care and indicate the need to align therapeutic approaches with available scientific evidence.

Intermediate Outcome Indicators Analyzed by Center and Type of Diabetes

DM1



DM2



In the DM1 patients HbA1c levels <7.0% were reached in a relatively low percentage of patients in most centers. Few centers achieved a segment of 30% of users. Similarly, in most centers 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 glycemic control in DM1 patients is further highlighted by the percentage of patients with HbA1c ≥8.0%. This generally elevated value tended to vary considerably among centers (range, 15-85%. A similar consideration can be made for the percentage of patients with elevated blood pressure, while the outcomes in LDL cholesterol control tended to be more homogeneous among the centers.

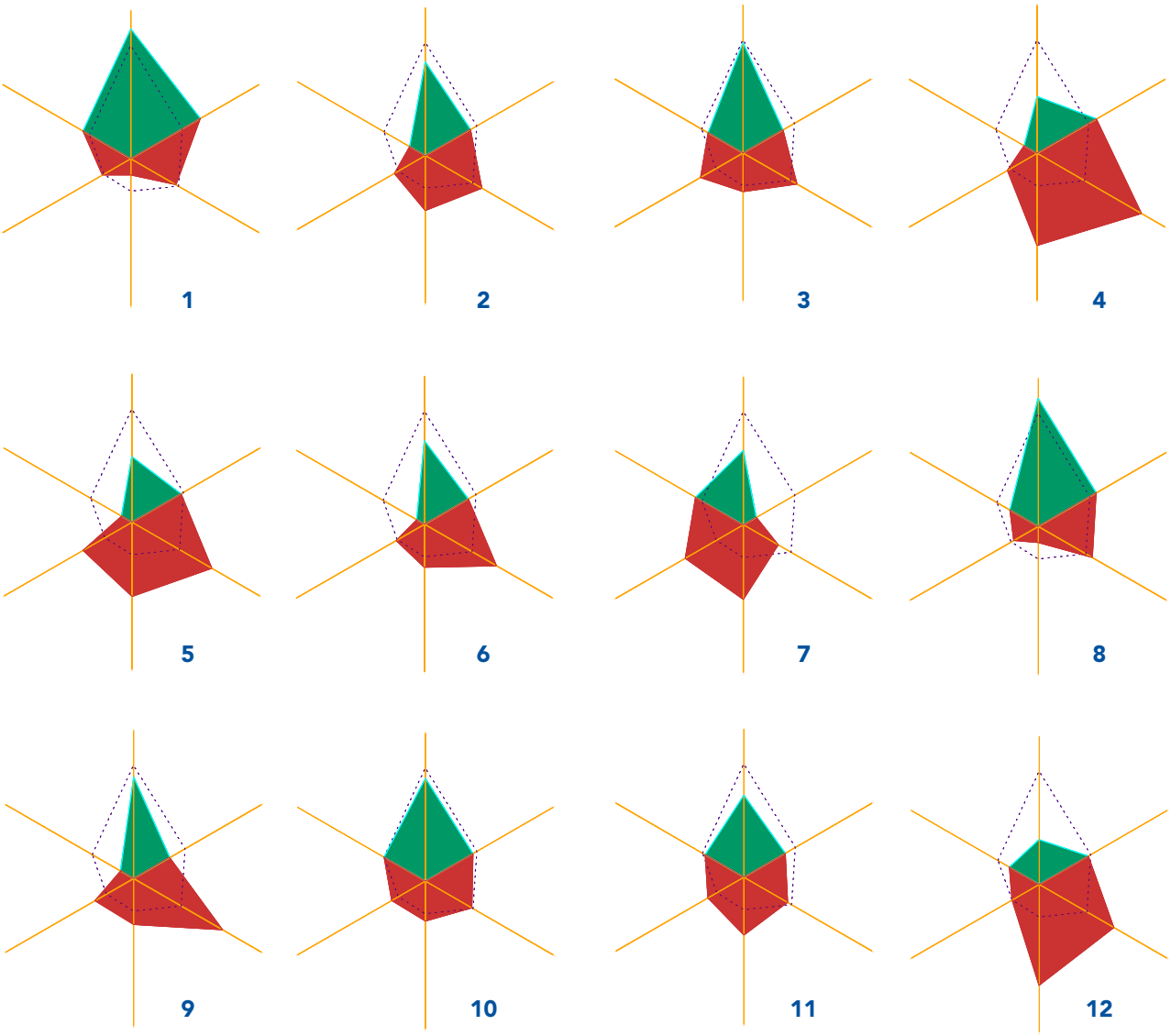
In the DM2 patients, the proportion of those with good HbA1c levels was higher, despite marked variability. In this patient group there tended to be a lower percentage of subjects with adequate blood pressure levels, which was rarely more than 45% of users in most centers. Similarly, in nearly all centers about one third of patients had adequate LDL cholesterol levels. The margin for improvement in care is further underlined by the generally high percentage, especially among patients with elevated blood pressure.

Starplot Summarizing Single Centers and Type of Diabetes

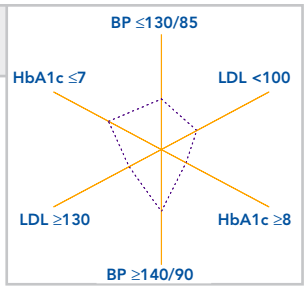
Intermediate Outcome Indicators for Each Center Analyzed by Type of Diabetes

The two sets of figures for each center show the extreme variability in the percentage of patients who within each center presented with adequate or less than adequate values of the parameters in question. The outcomes were highly variable also with respect to the outcome in question. There were centers that achieved highly positive results for all indicators, others that achieved only one or two, and yet others that showed wide gaps with respect to the gold standard for all outcome measures in question.

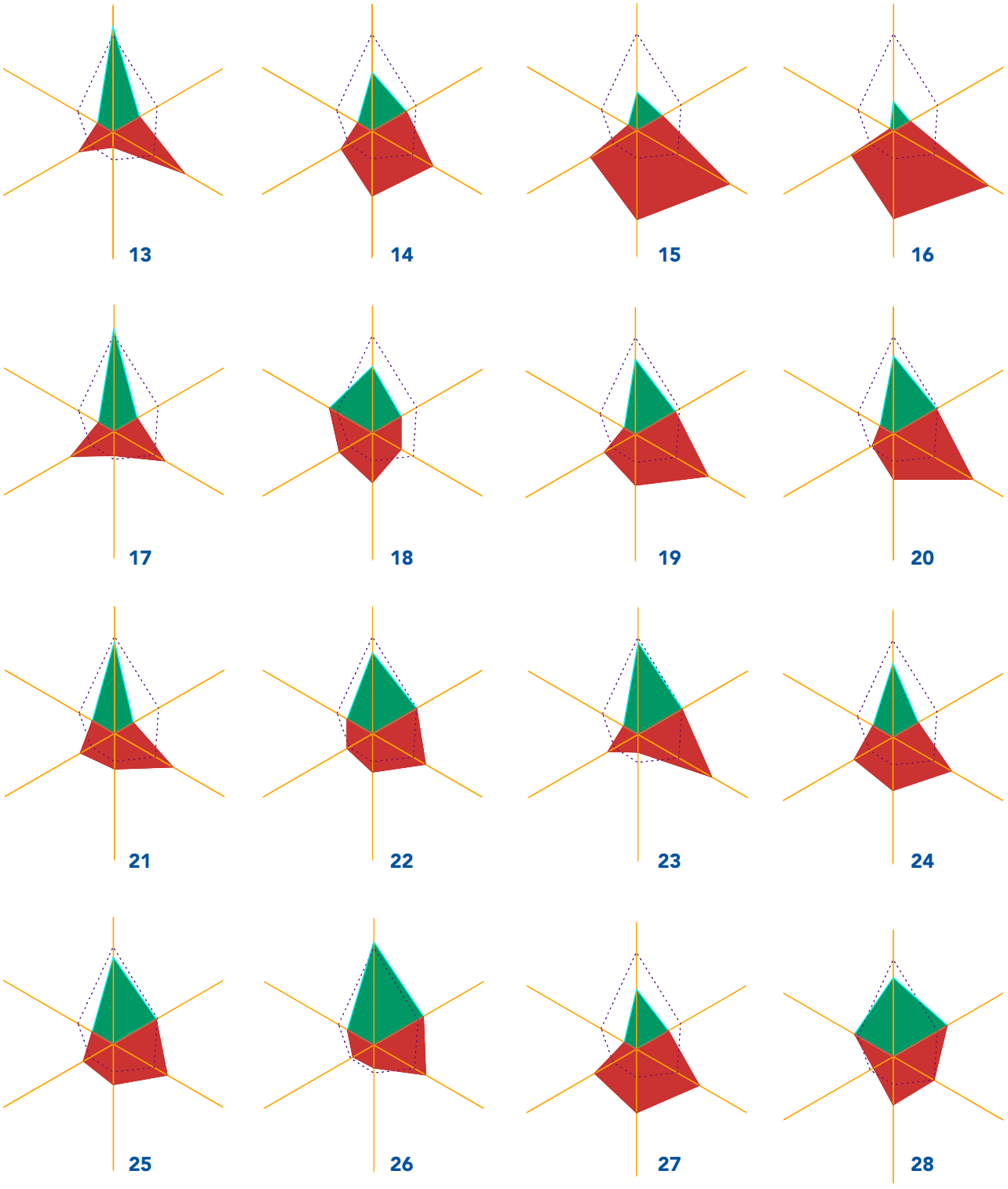
DM1



Starplot Summarizing Single Centers and Type of Diabetes



DM1



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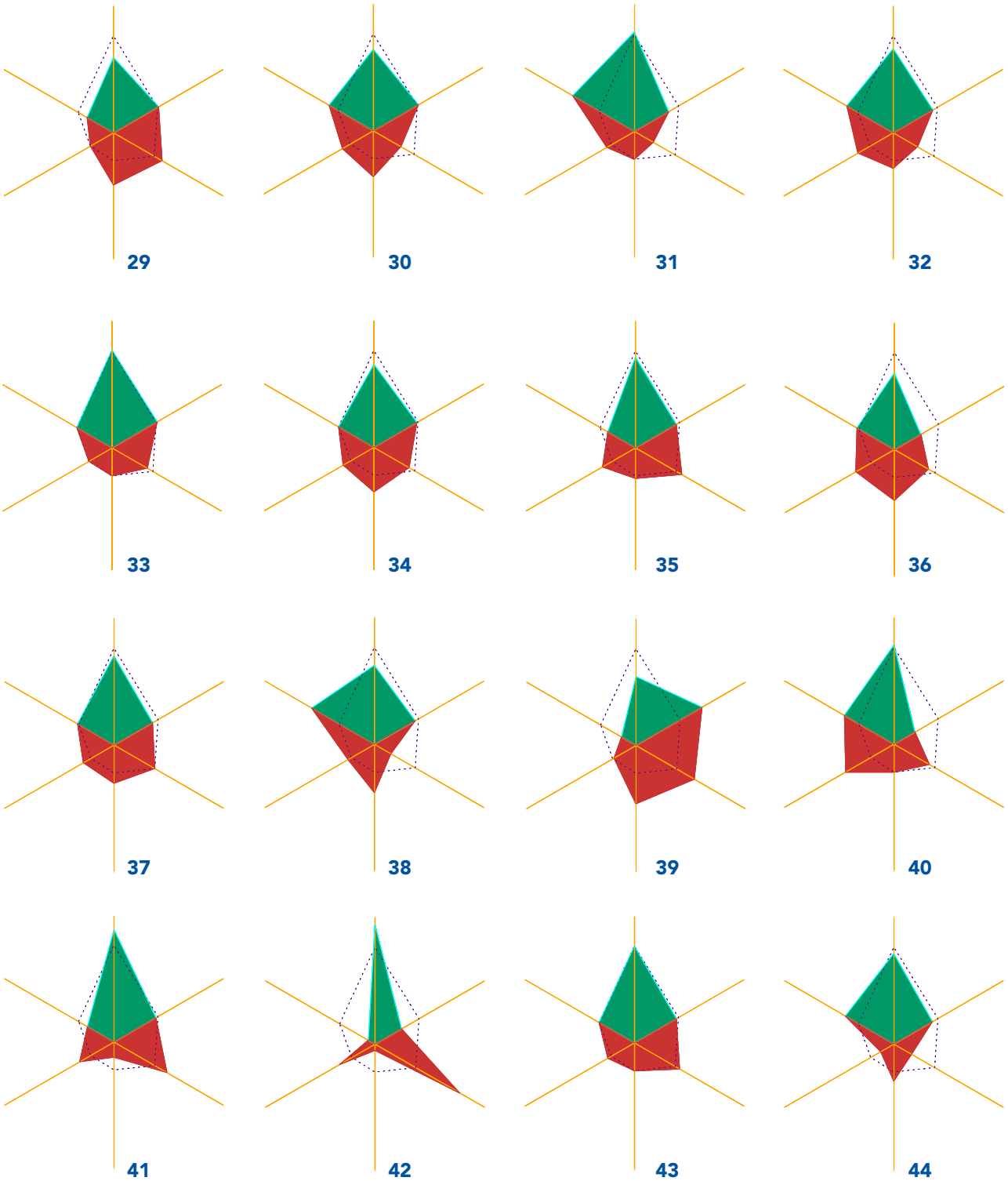
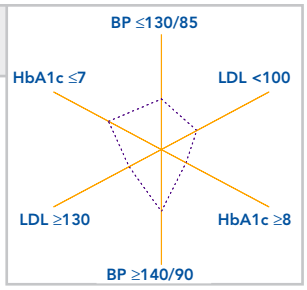
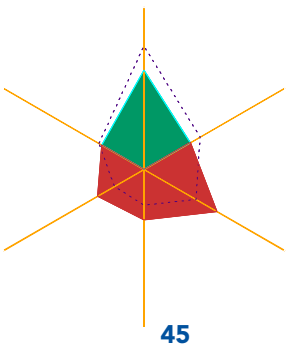


Starplot Summarizing Single Centers and Type of Diabetes



DM1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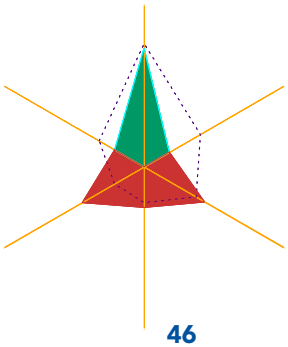
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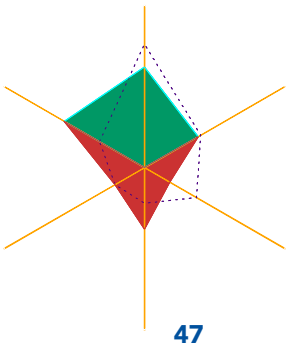
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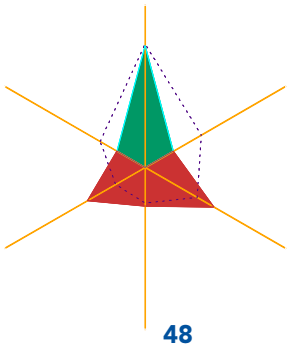
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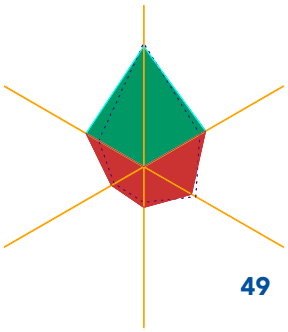
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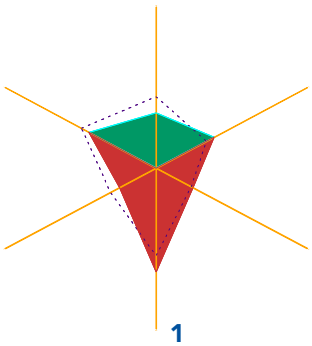
DM2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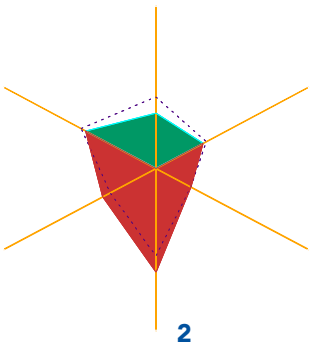
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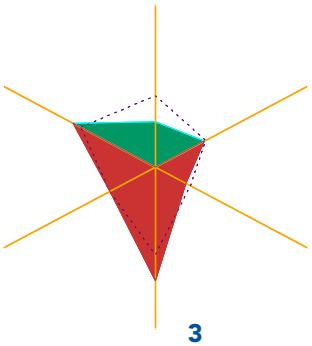
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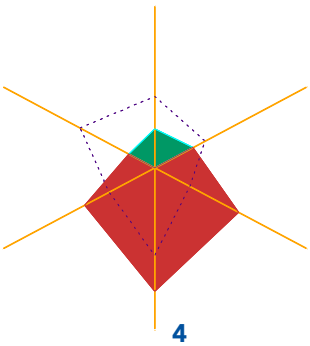
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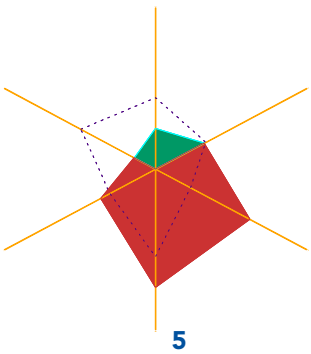
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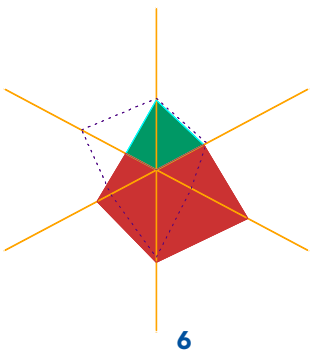
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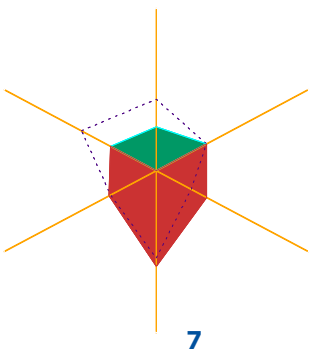
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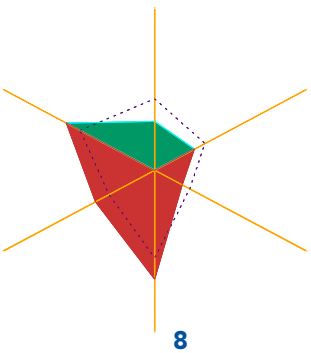
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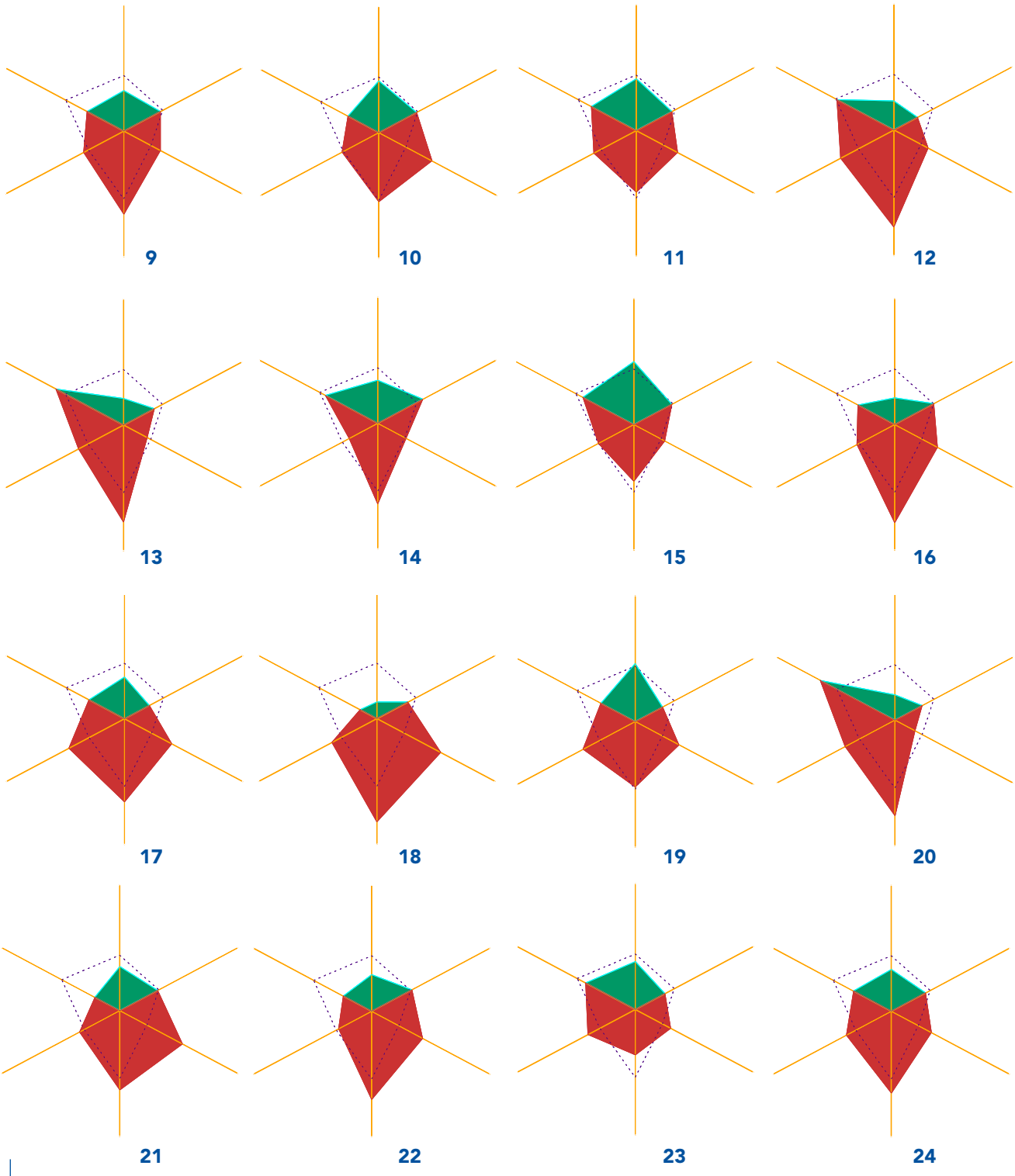

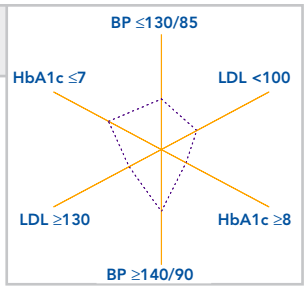

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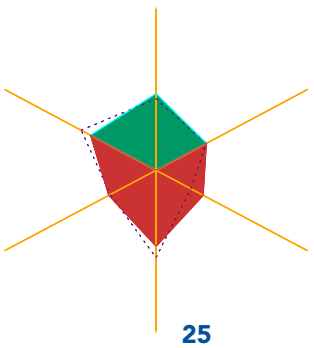
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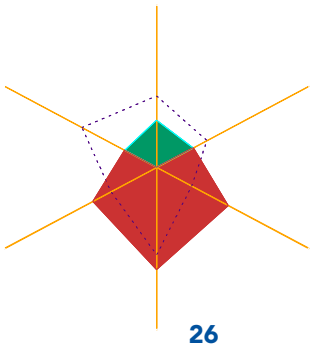
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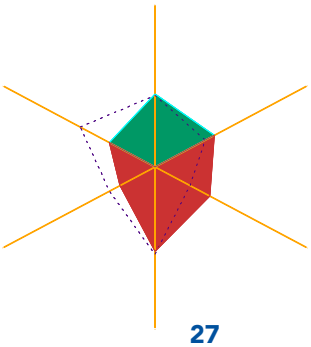
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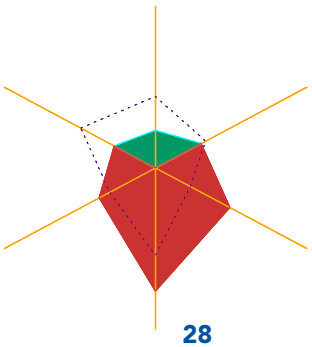
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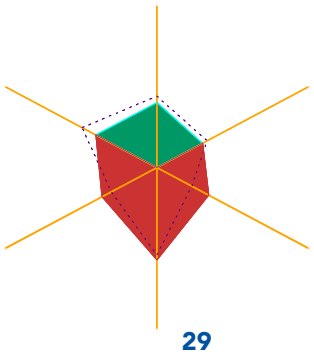
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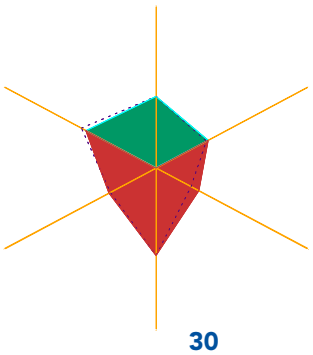
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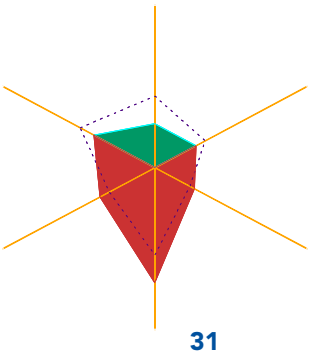
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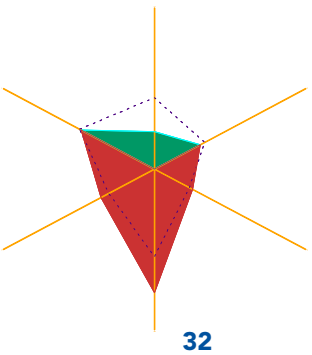
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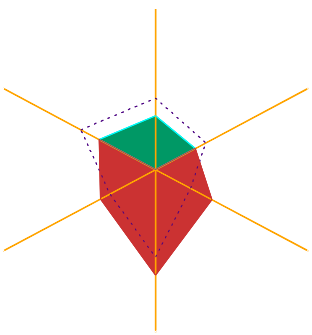
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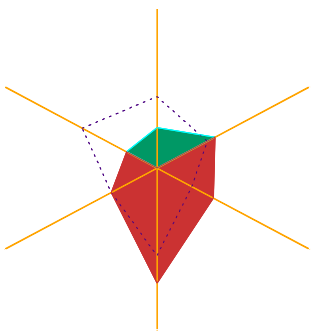
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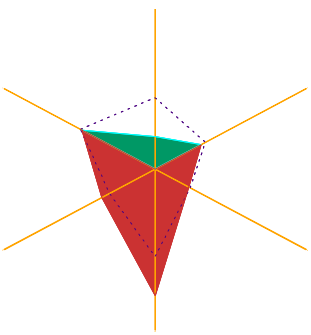
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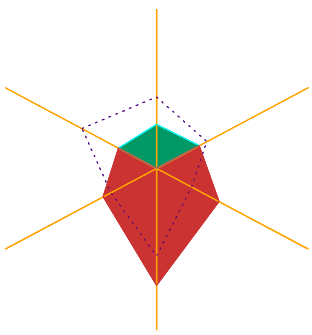
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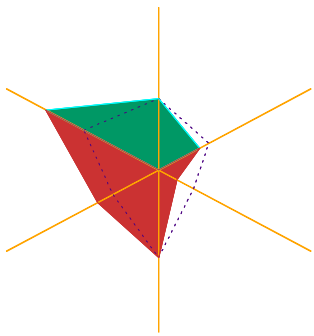
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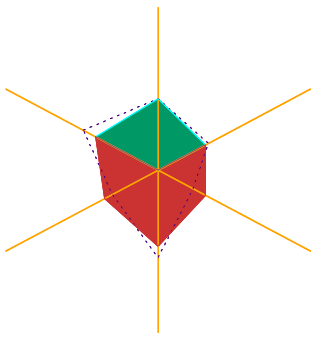
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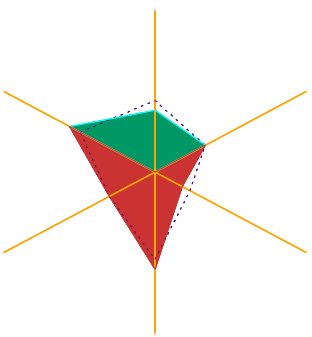
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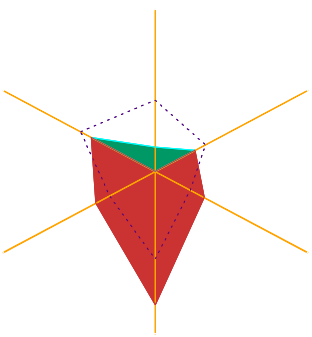
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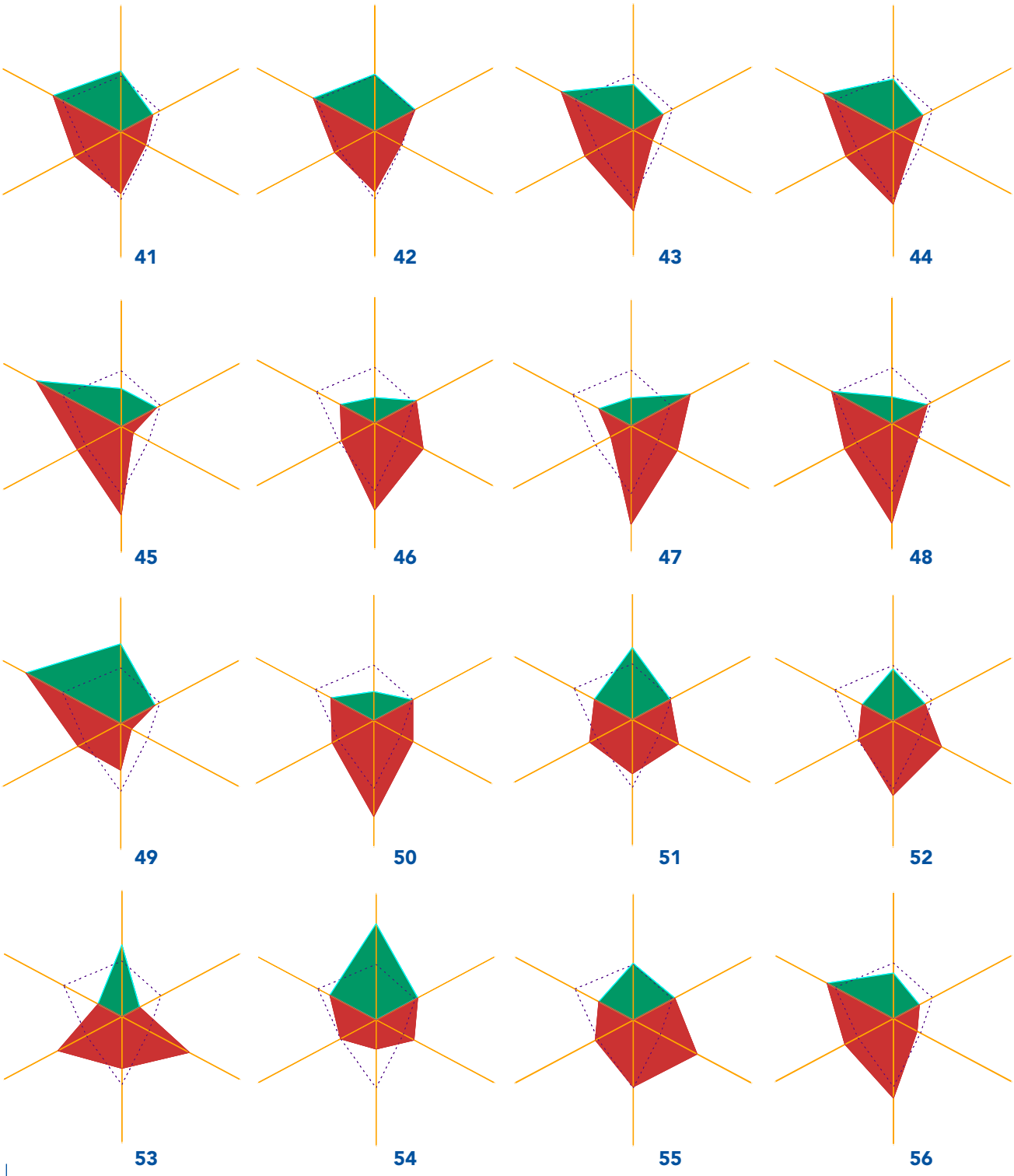
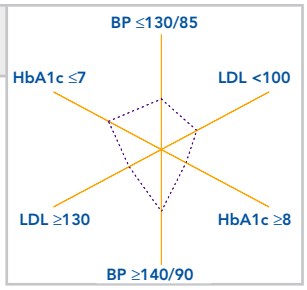


Starplot Summarizing Single Centers and Type of Diabetes



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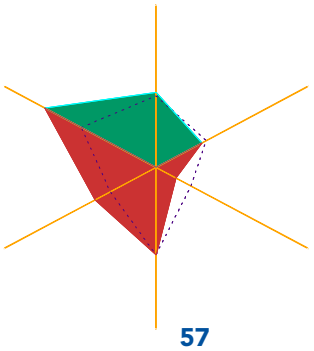
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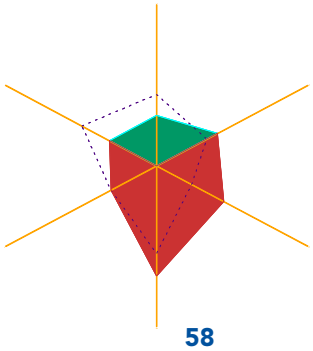
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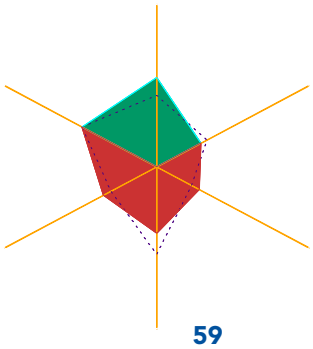
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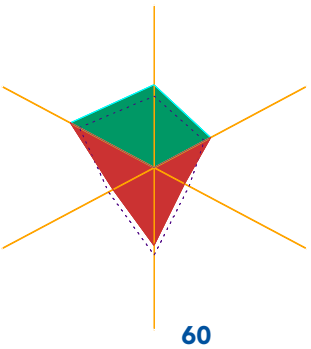
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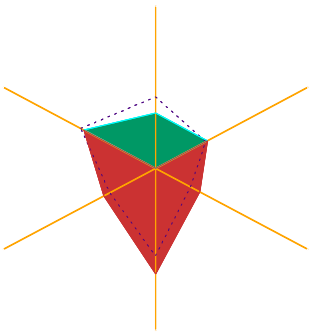
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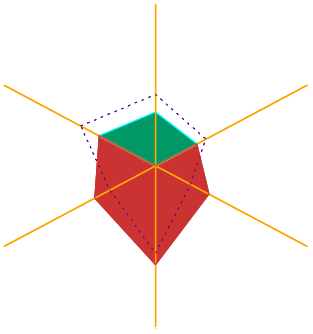
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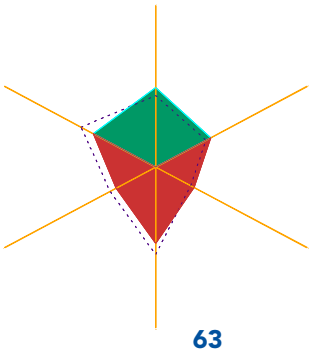
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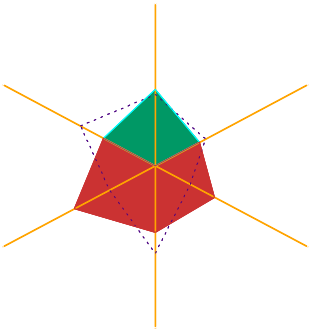
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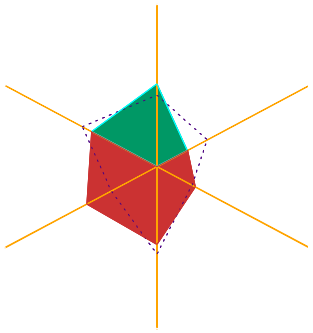
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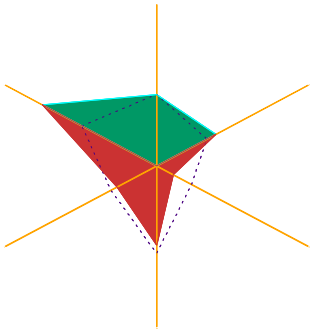
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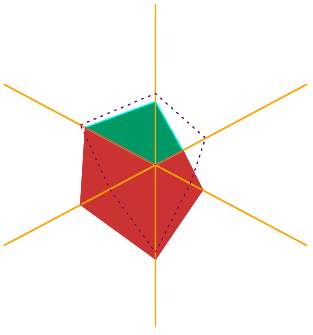
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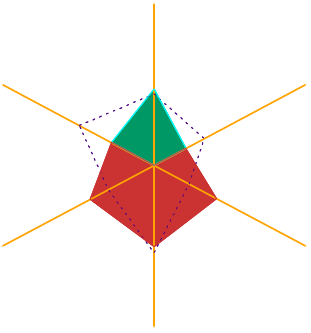
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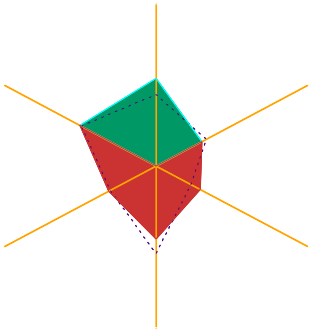
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Comment on Intermediate Outcome Indicators – 1

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

Glycometabolic Control

Glycosylated Hemoglobin

HbA1c is universally recognized as the best parameter for evaluating glycometabolic function. Prevention guidelines on microvascular complications of diabetes suggest achieving a target value of HbA1c <7% and maintaining 6.5% as the goal in the prophylaxis of macrovascular complications. The results demonstrate how difficult it is to achieve these values in daily clinical practice and with today's therapeutic means.

HbA1c was suboptimal (>7%) in many (74.5%) DM1 patients and in over half (56.9%) of DM2 patients. Slightly less than half (46.3%) of DM1 patients and slightly more than two thirds (70.9%) of DM2 patients had HbA1c <8%, which is still associated with a risk of chronic complications. Unsurprisingly, the percentage of HbA1c in DM2 patients rose as the complexity of treatment increased from controlled diet to combined insulin-oral agents. However, total glycometabolic function in the sample population was fair, even if the outcomes indicated a need for more aggressive therapeutic intervention.

Cardiovascular Risk Factors

LDL Cholesterol

LDL cholesterol levels <130 mg/dl were recorded in 69.6% of DM1 patients and 64.9% of DM2 patients. Nevertheless, it should be remembered that the guidelines recommend optimal LDL cholesterol levels <100 mg/dl. In our sample population, this target was reached in about one third of DM1 and DM2 patients (32.2% and 29.8%, respectively).

Data on pharmacological therapy indicated that many more patients require treatment (LDL >130 mg/dl) who are not currently receiving therapy (29% of DM1 and 36.4% of DM2 patients), in addition to those who, despite treatment, have not attained recommended target levels (39.6% DM1 and 32.3% DM2 patients).

Blood Pressure

Blood pressure data showed a substantial difference between the two patient groups: they were generally satisfactory for DM1 patients, 65%of which had acceptable blood pressure values, but less so for DM2 patients, of which only 36.6% had satisfactory values primarily because of problems with systolic blood pressure.

Data on pharmacological treatment indicate the need for more aggressive intervention in hypertensive patients to improve treatment outcome (52.9% of DM1 and 66.2% of DM2 patients failed to reach the goal) and to increase the number of patients receiving treatment (23.8% DM1 and 53.1% DM2 not treated but with elevated blood pressure).

Obesity

The BMI was elevated in nearly all DM2 patients; only one in five had normal body weight.

Smoking

Data on smoking indicated that far too many patients ignore the added burden of smoking to cardiovascular risk. DM1 patients require targeted education about the risk smoking carries.

Gender-specific Differences

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

Antonino Cimino, Illidio Meloncelli

Glycosylated Hemoglobin Analyzed by Type of Diabetes and Type of Treatment

The mean HbA1c in DM2 patients was 7.4%, which is in line with the results of the DAI and QuED studies on patients followed up by this service network. It can be considered a positive outcome in that similar findings on U.S. and European series often report levels of HbA1c >8%. Even so, we know that to prevent cardiovascular complications more ambitious objectives have been set: HbA1c <6.5% and fasting glycemia <100 mg/dl. This is perhaps one of the most arduous challenges in diabetes care. The Steno 2 study reported that, owing to a lack of otherwise efficacious therapies, hyperglycemia is more difficult to control than other cardiovascular risk factors.

In DM1 patients, the mean HbA1c (8.0%) was above the desired target, testifying to the major complexity of managing these patients; the lack of a portion of DM2 patients following a controlled diet, but generally with good glycemic function, tended to reduce the mean HbA1c value.

An interesting finding was the gradual increase in mean HbA1c among patients from controlled diet alone to combined insulin plus lipid-lowering agents, which depends on disease severity and perhaps also on duration of the disease. What is striking, however, is that insulin plus oral lipid-lowering reducing agents appears the less efficacious solution to the problem. This may be because of a certain reluctance to switch to multi-injection insulin therapy in patients long managed suboptimally or with an inadequate insulin dosage.

Cardiovascular Risk Factors Analyzed by Type of Diabetes and Patient Sex

Blood Pressure

The difference in blood pressure between DM1 and DM2 patients is relevant especially as concerns systolic pressure. DM2 patients were distinguished for having systolic hypertension; this distinction should be kept in mind with respect to prevention since the condition is strongly associated with the risk of cardiovascular events. While mean patient age may have an effect, this does not rule out the need for prevention.

Among the DM2 patients, women appeared clearly disadvantaged as having higher mean systolic pressure than men. Is this the result of genetic predisposition or of a different treatment approach? This finding should prompt further study into an explanation for this difference between the sexes.

Lipid Profile

The figures underscore perhaps more clearly here than in the earlier DAI and QuEd studies that while Italian diabetics may have moderately elevated total cholesterol it is still well below the levels reported in other series. However, the levels in our sample were higher than the target mean LDL of 100 mg/dl. Considerable differences existed between DM1 and DM2 as regards HDL (10 mg/dl less in DM2), confirming the insulin resistance underlying DM2.

As with blood pressure, women DM2 patients showed worse total and LDL cholesterol profiles; this difference is not negligible, difficult to explain and may have implications for cardiovascular complications.

Obesity

As expected, the body-mass index was considerably higher among women DM2 patients.

Age Effect

At first sight, age appears to have a stronger effect on DM1 patients. This is understandable in that the course of DM1 is longer than that of DM2. In DM1, age has a strong effect on systolic pressure and BMI, as occurs in the general population.

Noteworthy is that in DM2 patients lipid values and body weight peaked around age 55 and then tended to diminish, revealing an elderly diabetic with milder lipid than systolic hypertension problems.

Starplot Summarizing Type of Diabetes, Patient Sex and Age, and Region of Country

This interesting figure highlights the strengths and weaknesses of diabetes care with respect to the internal gold standard.

In DM2 patients, the obstacles to managing LDL and blood pressure adequately nearly always hinder attaining positive results. This situation generally worsens with age in general and in women in particular. The analysis by region shows that centers in the north have greater difficulty in attaining optimal targets perhaps because of a less wider use of drugs than in the south.

Boxplot of Centers Analyzed by Type of Diabetes and Starplot of Each Center Analyzed by Type of Diabetes

In Italy, a commonplace notion about collecting health care data on a specific disease is the incontrovertible variability across the country.
The spread of mean values in this analysis of diabetes centers is a typical representation of this reality. Tangent issues are problems with accurate data recording, where some centers store data that are more pertinent to diabetes (e.g. HbA1c) than other parameters.
The variability in outcomes can be accounted for by local differences in resources and organization.
There is also variability in the education of the physician, his or her conviction about pursuing objectives, as clearly emerged from an analysis of outcome research in the DAI and QuEd studies. It is also known that the type of services delivered in a diabetes clinic varies with different operator mindsets: ranging from an attitude defined as "glycemologic", i.e. meticulous attention to glycemic control, but only that, to a more specialist vision of metabolic diseases, with equal attention directed to the problems of hypertension, lipid profile and obesity.

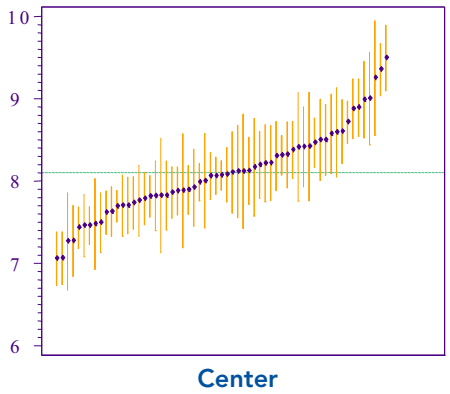
Carlo Giorda

Variability Adjusted for Case-mix and Clustering Among Centers

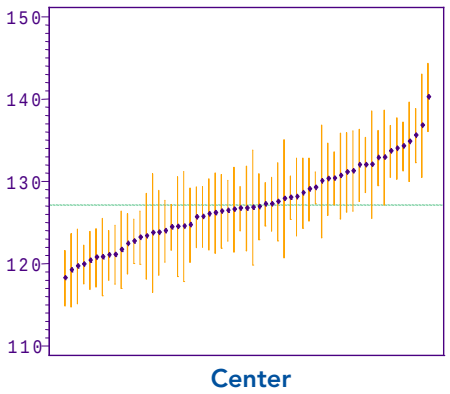
Variability Among Centers
Mean Values Adjusted for Patient Age, Sex and Clustering Effect

DM1

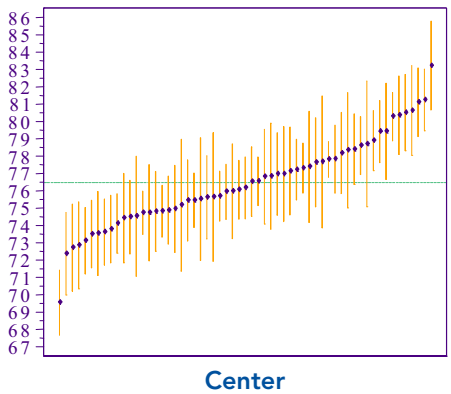
HbA1c



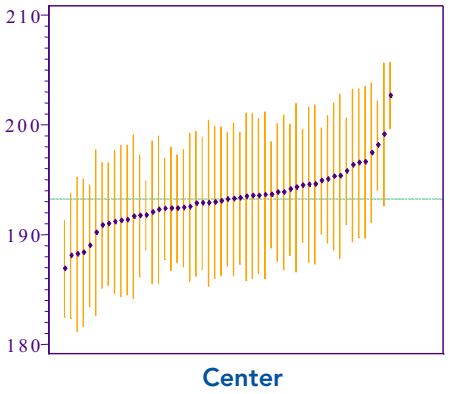
Systolic BP



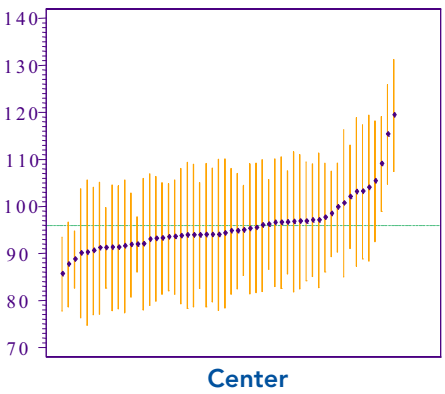
Diastolic BP



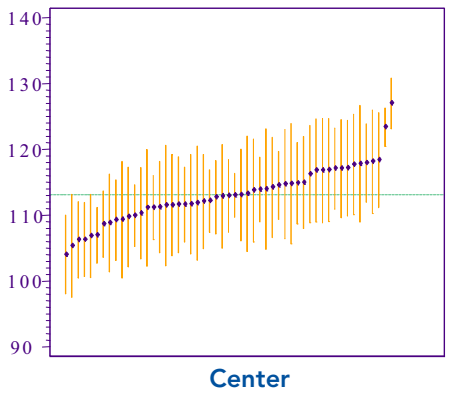
Total Cholesterol



Triglycerides

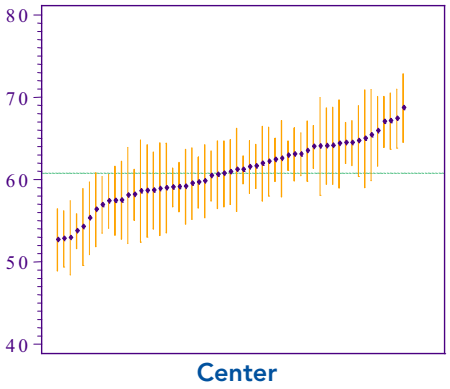


LDL Cholesterol

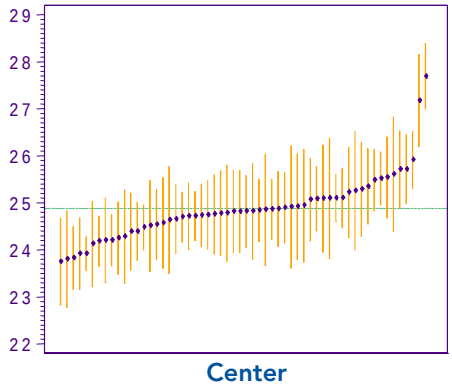


DM1

HDL Cholesterol

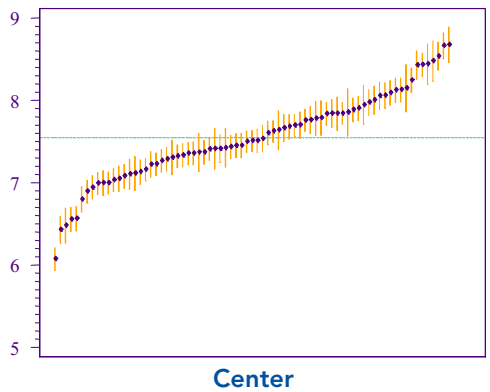


BMI

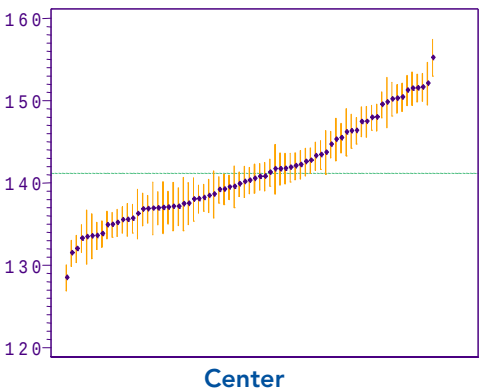


DM2

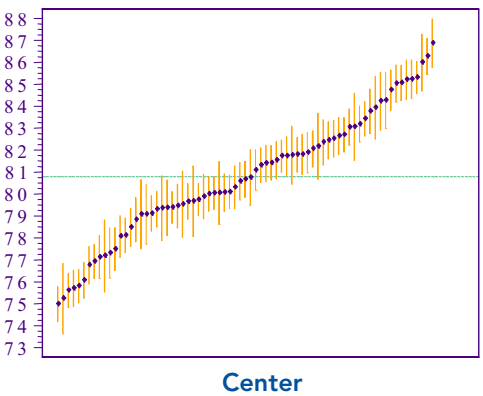
HbA1c



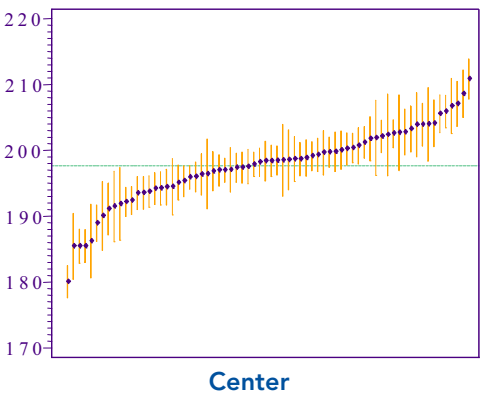
Systolic BP



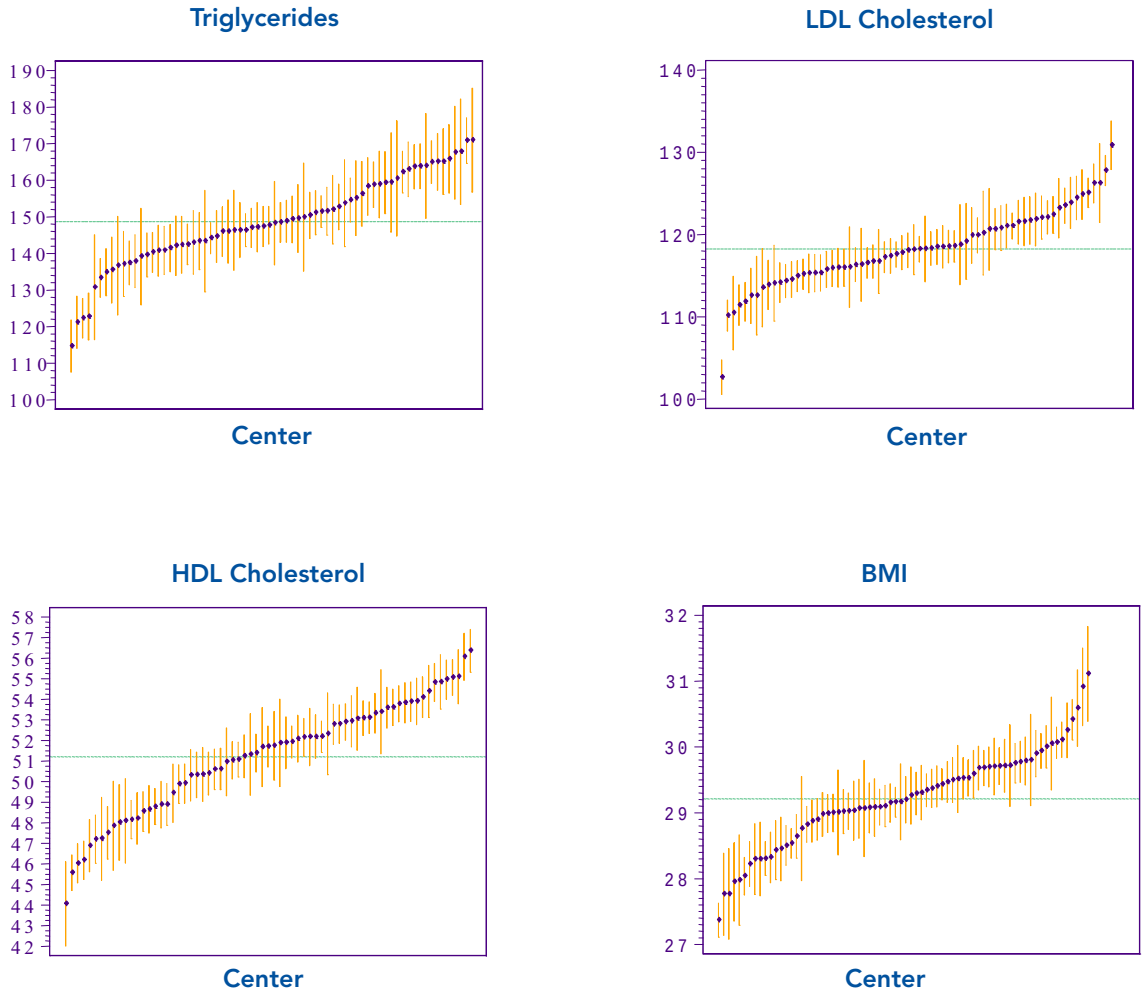
Diastolic BP



Total Cholesterol



DM2

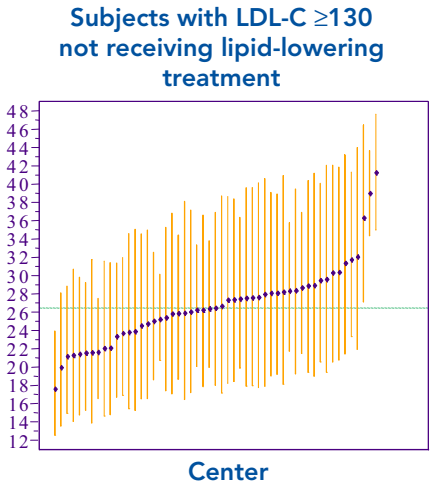


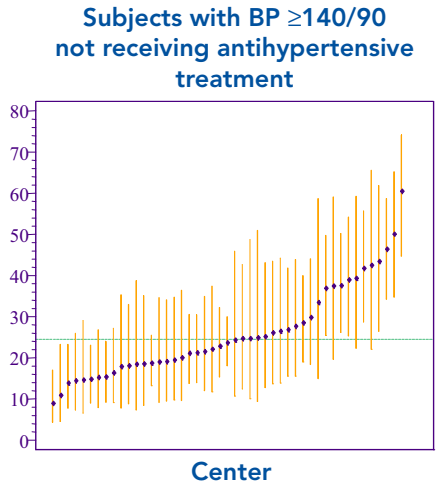
As discussed in the methods section, the variability in process measures and intermediate outcome measures among centers may partly have resulted from differences in patient population and clustering. For this reason, the intercenter variability shown in these figures was adjusted for the effect of clustering and patient age and sex. Even after these potential confounders were considered, however, the figures show that in both DM1 and DM2 a variability in mean values of the parameters in question remained, with some centers 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, owing to the few cases reported per center, the estimates have wider confidence intervals.

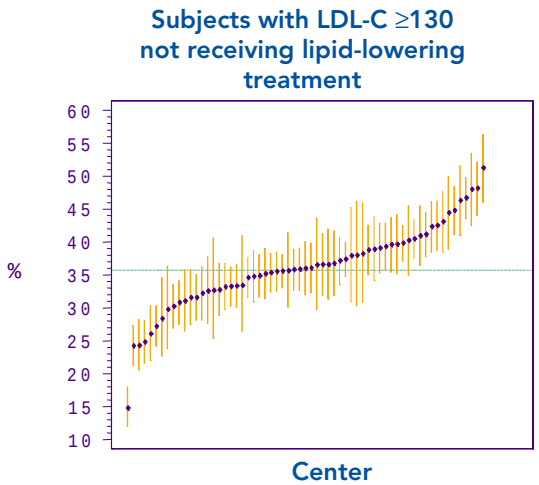
Variability in Tendency to Prescribe Lipid-lowering and Antihypertensive Treatment

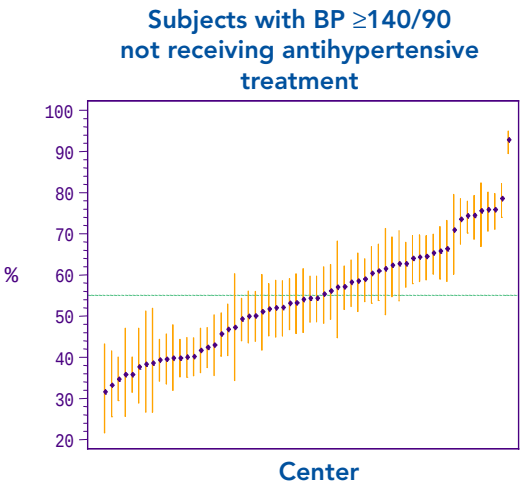
DM1





DM2



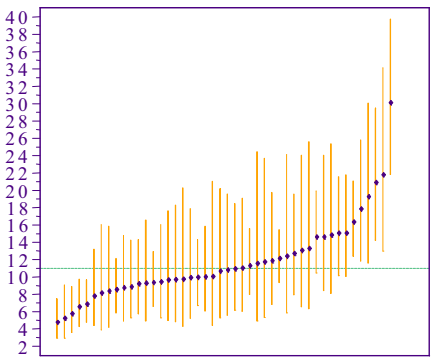


The same approach to statistical analysis was taken to evaluate the tendency of centers to treat subjects with LDL cholesterol ≥130 mg/dl or blood pressure ≥140/90 mm Hg. The figures show that the percentage of potential candidates for statin therapy, but not treated, varied among centers from 17% to 40% in DM1 patients and from 15% to 52% in DM2 patients. Similarly, the percentage of hypertensive patients not treated with antihypertensive agents ranged between 10% and 60% among DM1 patients and between 30% and 90% among DM2 patients.

Variability in the Use of Specific Drug Classes

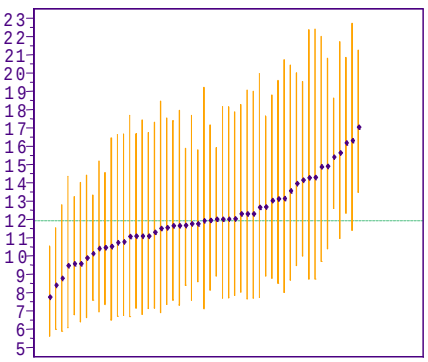
DM1

Statins



Center

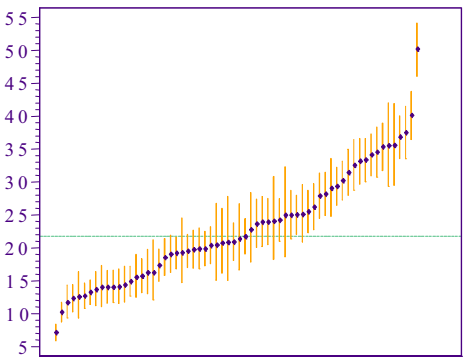
ACE Inhibitors



Center

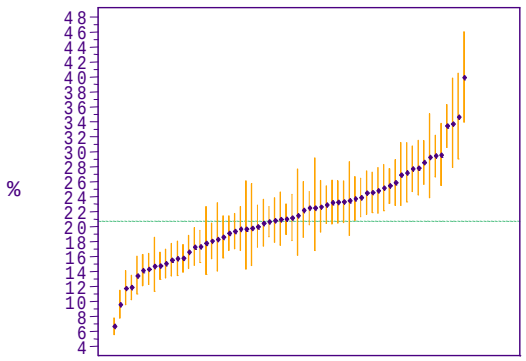
DM2

Statins



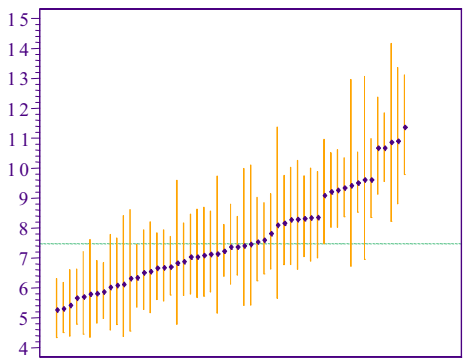
Center

ACE Inhibitors



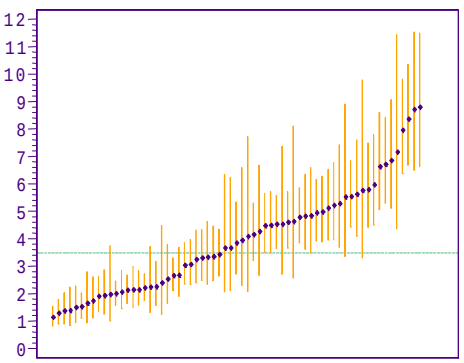
Center

Sartans

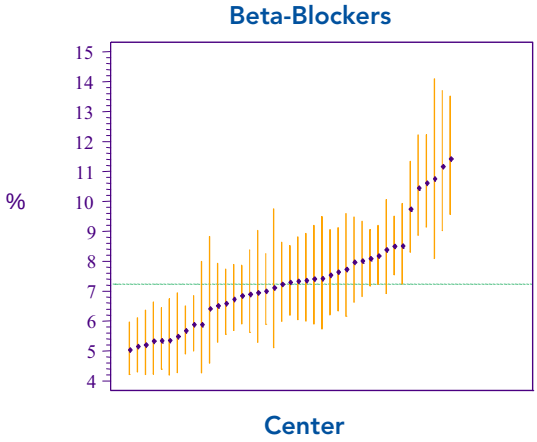


Center

Omega 3



Center



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 4% and 30%, while the percentage of those receiving ACE inhibitors ranged from 8% to 17%.

Wider variability was found in the treatment of DM2 patients. The mean percentage of those treated with statins was 22% (range, 7-50%), while the mean percentage of those treated with ACE inhibitors was 21% (range, 7-40%). Less wider variability in the use of sartans (range, 5-11%), beta-blockers (range, 5-11%), and omega-3 (range, 1-9%) was found.

Comment on Intercenter Variability

Again, this set of figures shows a certain variability in outcome. Tendency to treat merits special comment. The graphs clearly show that on finding with a certain blood pressure value or LDL concentration, not all centers respond in the same way, whether for DM1 or DM2. This phenomenon is not particular to diabetes care nor to Italian health care in general. Similar variability can be found in cardiology and internal medicine throughout Europe and in the United States and has been widely reported in the literature.

In practice, certain factors will somehow influence a correct therapeutic approach. Patient age, number of tablets to be taken, cost of medication, control of appropriateness of expenses by health care administrators, a physician's beliefs and education, and patient compliance.

Analyses published in the DAI and QuEd studies led to the conclusion that beliefs and mindset of physicians, cardiologists, and general medicine physicians, and not only diabetologists, represent a variable that may help explain these phenomena.

Educating patients about the usefulness of prevention is probably the most efficacious tool we physicians have to improve this situation.

To end on a positive note, the percentage of treated patients, specifically those treated with statins, although still unsatisfactory, is double the low percentage the DAI and QuEd studies found nearly 5 years ago.

Carlo Giorda

A scientific society needs to have a vision. For the AMD this means being able to foresee how diabetes care will be delivered over the next five years and what needs to be done to bring about the necessary changes and assemble the tools for building the future of this specialty. To attain this objective, clinical research evidence for hypothesis testing that can be applied to clinical practice is vital.
Publication of the Annals, the result of AMD research, provides the cornerstone for Italian diabetes care and forms an integral element in the AMD project for continuing improvement in diabetes care. As this volume illustrates, the data reflect the realities of diabetic care in Italy.
The Annals are based on an analysis of the Data File, a database containing clinical information collected from 87 Italian diabetes centers. The powerfulness of the system resides in the capability to extract clinical data from diverse medical records and unite them into a single shared database.
This volume is intended as a useful reference for national and international administrations, the Institute of Health and all institutions involved in promoting health care at a time when they are called to make foresighted decisions in health care policy and organization.
The Data File will not only permit publication of the Annals but create a basis for diabetes clinical research in Italy. QUASAR is the first major AMD project to use the Data File. The 6-year project will involve 10,000 patients and evaluate the organization of care and the occurrence of cardiovascular events in patients with type 2 diabetes.
But I believe that an even greater benefit of the Data File derives the ability to visualize the difficulties we encounter in daily practice and the guidance it can offer for undertaking action to improve our activities.
An accurate analysis of the AMD Annals has shed light on critical aspects of our ways of working. Much of the collected information is incomplete or formatted such that it cannot be used, indicating the need to further exploit the potential to be gained from a computerized system. But the quality of the finding sometimes reveals the difficulties behind the organization and inherent to implementing recommendations and to defining health care processes. It is here that the Database can become a powerful tool for improving the quality of care and a means for diabetes centers to compare their methods against the yardstick a only shared database can provide.
Both showcase to the outside world and framework for diabetes research, the AMD Annals constitutes a major step toward improving the delivery of diabetes care and our personal skills as well.

Umberto Valentini
AMD National President

Mission Statement of the Italian Association of Clinical Diabetologist (AMD) 2005-2007

To contribute to the development of the Italian system of diabetes care by improving the quality of care of persons with metabolic disorders and diabetes.
AMD recognizes the need for a systematic approach to raising the quality of care and to actively involving all members in this effort.
AMD has set cultural and policy priorities for working toward better quality, continuing education, communication, and clinical research.
AMD has identified areas of development, treatment pathways for diabetes and metabolic diseases, patient education, clinical and health care research.